

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2017

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 001-38241



**OPTINOSE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State of other jurisdiction of  
incorporation or organization)

**42-1771610**

(I.R.S. Employer Identification Number)

**1020 Stony Hill Road, Suite 300  
Yardley, Pennsylvania 19067**

(Address of principal executive offices, including zip code)

**(267) 364-3500**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| <b>Title of Each Class</b>      | <b>Name of each exchange on which registered</b> |
|---------------------------------|--|
| Common Stock, \$0.001 par value | The Nasdaq Global Select Market                  |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of June 30, 2017 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant's common stock was not listed on any exchange or over-the-counter market. The registrant's common stock began trading on the Nasdaq Global Select Market on October 13, 2017. As of March 12, 2017, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$70.7 million based on the number of shares held by non-affiliates as of March 12, 2017 and the last reported sale price of the registrant's common stock on March 12, 2017.

The number of shares of common stock outstanding at March 1, 2018 was 37,865,740 shares.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for its 2018 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K where indicated. Such definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the year ended December 31, 2017.

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Unless the context otherwise requires, all references in this Form 10-K to "Optinose," "Company," "we," "us," and "our" refer to OptiNose, Inc. and its subsidiaries.

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[Trademark Notice](#)

OPTINOSE® and XHANCE™ are trademarks or registered trademarks of ours in the United States. This 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names. All other trademarks, trade names and service marks appearing in this 10-K are the property of their respective owners. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, among others, statements relating to:

- the potential advantages of XHANCE™ and our product candidates;
- the planned launch of XHANCE in retail pharmacies in the United States in early April 2018;
- our expectation to achieve 65% coverage of commercial lives during launch;
- our ability to secure broad market access in the commercial segment for XHANCE by targeting Tier 3 payor coverage, single step edit with no prior authorization;
- planned product development activities, studies and clinical trials, including our plans to initiate additional clinical trials of XHANCE in the fourth quarter of 2018 in pursuit of a follow-on indication for chronic sinusitis;
- our expectation that our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations through the end of 2019;
- our plans to commercial plans and objectives for XHANCE and our product candidates;
- the size and growth potential of the markets for XHANCE and our product candidates, and our ability to service those markets;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of XHANCE and our product candidates;
- our ability to maintain regulatory approval of XHANCE and our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- regulatory developments in the United States and foreign countries;
- our ability to operate our business without infringing the intellectual property rights of others;
- the scope and duration of patent protection and other barriers to entry that we expect to benefit XHANCE and our product candidates;
- the performance of our third-party suppliers, manufacturers and contract sales organizations;
- the success of competing products that are or become available;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for XHANCE and our other product candidates and to avoid claims of infringement;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-K entitled "Item 1 - Business," "Item 1A - Risk Factors," "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Item 7 - Quantitative and Qualitative Disclosures About Market Risk." In some cases, you can identify forward-looking statements by words such as "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "target," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing," "scheduled" and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon our current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under section "Item 1A - Risk Factors" of this Form 10-K. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-K represent our views only as of the date of this Form 10-K (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the reports that we file with the SEC.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-K. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

This Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

## PART I

### ITEM 1. BUSINESS

#### Overview

##### *Our Company*

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat, or ENT, and allergy specialists. Our lead product, XHANCE™ (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System, or EDS, that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids, or INS, that have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS. We also believe that payors will respond favorably to XHANCE's clinical, cost, and quality-of-care profile, as compared to current and potential future costly drug therapy and surgical treatment options.

On September 18, 2017, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, for XHANCE for the treatment of nasal polyps in patients 18 years of age or older. Based upon our research of over 300 launches between 2010 and 2016, we believe the evidence suggests that the success of a launch is highly dependent upon four critical factors: level of unmet need that exists within the market, level of clinical differentiation of a brand, market access and brand awareness. Therefore, rather than rushing our product to the market immediately following approval, our Company employed a different, purposeful launch model that would enable our commercial team to build market access for XHANCE and achieve critical levels of customer awareness to facilitate adoption upon making XHANCE available in the market.

Since the FDA approved of our NDA for XHANCE, we have been focused on executing our integrated launch plan with the objective of making XHANCE widely available through retail pharmacies in the second quarter of 2018; we now believe XHANCE will be available in retail pharmacies in early April 2018. The key strategies in our integrated launch plan include: (i) build a robust supply chain network and quality management system, (ii) drive awareness and appreciation of the clinical differentiation of XHANCE, (iii) design and deploy our customer facing model, (iv) engage commercial payors with the objective of securing tier 3 coverage, and (v) develop our internal capabilities (Finance, HR, IT, Data Analytics and Compliance) to support a commercial stage company. We have made progress in each of these key strategic areas:

- Commercial Supply Chain. We have entered into commercial supply agreements with our key suppliers, spent significant time with our suppliers to oversee product production and quality management, and manufactured our initial commercial supply of XHANCE. We have contracted with a third-party logistics partner and are in the process of finalizing agreements with our distribution partners.
- Brand Awareness. We have executed a broad, multi-channel awareness campaign leveraging digital, non-personal promotion and journal advertising and have already reached over 10,000 ENT physicians and allergists with disease state and branded messages. In November 2017, we launched a nurse educator team of approximately 85 nurse professionals who have since called on approximately 5,000 ENT physicians and allergists and delivered over 10,000 presentations. The focus of their interactions with healthcare professionals include: (i) introducing Optinose and highlighting the unmet medical need and limitations of current treatments, (ii) increasing awareness about XHANCE along with differentiating the Optinose EDS, and (iii) familiarizing healthcare professionals with the proper administration of XHANCE. Initial reaction to core brand messages among target physicians has been positive.
- Customer Model. We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENT physicians, allergists and "specialty like" primary care physicians and are deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target customer universe. We have prioritized approximately 80 territories within our sales force footprint to deploy at launch based upon an expectation that we will achieve an estimated 65% commercial market access within each of those territories during launch. Most of the initial

80 territory managers have completed training and are already engaging approximately 8,000 ENTs, allergists and primary care physician targets to promote XHANCE for the treatment of nasal polyps. Additionally, in March 2018, we introduced the XHANCE Xperience program to offer select physicians and their patients an opportunity to gain initial experience with XHANCE. Physicians can enroll a limited number of eligible patients in this program. Patients will receive up to two XHANCE prescriptions at no cost to them (\$0 co-pay), and physicians will receive an opportunity for feedback on patient experience. We believe the positive experience that physicians and patients have with XHANCE in this program will help drive demand for XHANCE during the retail launch, starting in early April 2018.

- **Market Access.** We have been engaging payors with the goal of securing tier 3 commercial coverage, primarily with a single step edit and no prior authorization. We have engaged with approximately 40 plans representing approximately 85% of commercial lives. In meeting with potential payors, we have shared what we believe is our compelling economic value proposition. Our analyses show that XHANCE will have a comparatively low pharmacy budget impact and our clinical trial data suggest that XHANCE may produce an offsetting benefit by helping reduce the rate of surgery with its related costs. For an insurance plan, this could represent a potential overall cost reduction for the population of patients with nasal polyps, as the overall cost of XHANCE could be less than the offsetting costs related to the reduction in surgeries. During clinical studies, XHANCE was also associated with an improvement in reported work productivity in treated patients, which should be valued by employers and patients. Further, we believe the cost of XHANCE to insurance plans will likely be significantly less than the projected costs of monoclonal antibodies that are currently in development for the treatment of nasal polyps. We expect to achieve approximately 65% coverage of commercial lives during the retail launch of XHANCE, and will seek to increase the number of covered lives during the first year. We have contracted with the Centers for Medicare and Medicaid Services regarding certain government covered lives. Further, we plan to introduce a co-pay assistance program and other patient affordability programs to appropriately support patient access to XHANCE.
- **Infrastructure.** We continue to develop our internal capabilities and grew from 21 employees as of January 1, 2017 to 82 employees as of March 1, 2018 to support a commercial stage company. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have implemented a robust healthcare compliance program to guide our staff's and our partners' compliance with rules and regulations regarding pharmaceutical sales. In managing our growth, we have remained focused on fostering our One Mission culture.

In addition to XHANCE's existing indication for nasal polyps, we plan to initiate additional clinical trials in the fourth quarter of 2018 to seek a follow-on indication for the treatment of chronic sinusitis in order to broaden our market opportunity. XHANCE is the second commercial product that we have developed utilizing an Optinose EDS. Our first commercial product, indicated for the acute treatment of migraines in adults, was licensed in 2013 to Avanir Pharmaceuticals, Inc., or Avanir, and was approved by the FDA in January 2016.

### ***The Unmet Need***

Chronic rhinosinusitis is a serious nasal inflammatory disease characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain. This disease significantly impacts the quality of life and daily functioning of an estimated 30 million adults in the United States. The U.S. healthcare system spends approximately \$60 billion annually in direct costs treating patients with chronic rhinosinusitis and its associated symptoms, including an estimated \$5 billion on sinus surgeries. In the United States, physicians perform over 500,000 sinus surgeries each year, and we estimate that over seven million adults have undergone sinus surgery to treat chronic rhinosinusitis with and without nasal polyps.

In medical literature and medical practice, chronic rhinosinusitis is commonly divided into two subgroups: chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with chronic rhinosinusitis with nasal polyps also develop non-cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the United States have chronic rhinosinusitis with nasal polyps.

Both subgroups of chronic rhinosinusitis share the same four defining diagnostic symptoms: nasal congestion/obstruction; facial pain and pressure; purulent runny nose and postnasal drip; and loss of sense of smell and taste. Additional symptoms may include headaches, chronic sleep problems, fatigue, frequent episodes of acute

rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer's quality of life from chronic rhinosinusitis, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief.

Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA does not recognize chronic rhinosinusitis as a single indication for drug development purposes. Instead, the FDA recognizes chronic sinusitis, defined as inflammation of the sinuses with a duration longer than eight weeks, and nasal polyps, defined as non-cancerous polyps on the inflamed tissue of the nasal passages and sinuses, as separate indications for drug development purposes. For purposes of this 10-K, we use the terms chronic sinusitis and nasal polyps when referring to FDA treatment indications and our clinical trials, and use the term chronic rhinosinusitis with and without nasal polyps when referring to disease and economic data reported in the medical literature, medical practice and our estimates of XHANCE's market opportunity.

### **Current Treatment Limitations**

Multiple current clinical practice guidelines specify the use of INS early in the treatment algorithm for chronic rhinosinusitis with and without nasal polyps. Steroids are generally pharmacologically effective at treating inflammation. However, conventional INS, including nasal sprays and nasal aerosols, are topically-acting and unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages. These products deposit a majority of the drug in the front of the nose or on the floor of the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief. These recognized limitations cause some physicians to seek out alternative treatment regimens such as high-volume steroid nasal rinses. This approach, however, has not been well studied, is difficult to administer, can be costly and may risk systemic side effects. Physicians may also prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids, which are often effective in reducing inflammation and nasal polyps, offer only temporary benefit and are limited by the risk of significant systemic side effects associated with both short- and long-term use.

In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation or drainage. The effectiveness of sinus surgery can vary significantly and many patients experience persistent or recurrent symptoms and surgery may not address the underlying cause of inflammation. In patients with nasal polyps, regrowth of the nasal polyps has been reported in as high as 60% of cases within four years. In addition, it has been reported that 80% of patients who had surgery within the past two years continued to have symptoms. Because sinus surgery is often not curative and may not address the underlying cause of the inflammation, many patients continue to receive short- and long-term courses of INS after surgery.

### **Our Solution**

XHANCE combines an Optinose EDS with a liquid formulation of fluticasone propionate, a well-characterized, second-generation corticosteroid. XHANCE is designed to deliver medication into the high and deep regions of the nasal passages where both nasal polyps and inflamed and swollen membranes can obstruct normal sinus ventilation and drainage. In multiple studies utilizing advanced imaging, an Optinose EDS produced a differentiated pattern of drug delivery in healthy subjects with significant drug deposited in the high and deep regions of the nasal passages, areas not well accessed by conventional INS delivery mechanisms. We believe XHANCE has the potential to become part of the standard of care for the treatment of patients with chronic rhinosinusitis before they progress to more costly treatment alternatives. We also believe that the current treatment practice of postoperative INS use could support XHANCE's adoption as a maintenance therapy to improve outcomes following sinus surgery.

We conducted five clinical trials evaluating over 1,500 adult patients, including two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials in adults with nasal polyps and two supportive open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. In both Phase 3 pivotal clinical trials, patients treated with XHANCE experienced statistically significant reductions of both nasal congestion/obstruction symptoms and total polyp grade, which were the co-primary endpoints. Treatment benefits were also observed in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination, quality of life measures, need for sinus surgery and patient global impression of change. In addition, the magnitude of improvement for patients treated by XHANCE in our Phase 3 pivotal clinical trials, as measured by the Sinonasal Outcome Test-22, a validated clinical outcome assessment, was comparable to the reported benefits in third-party studies of endoscopic sinus surgery, or ESS, and balloon sinus dilation. XHANCE had an adverse event profile generally comparable to the profile reported in similarly designed studies with conventional INS. In our supportive



open-label Phase 3 clinical trials, which evaluated approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, XHANCE was generally well tolerated and produced results on efficacy endpoints similar to those observed in our Phase 3 pivotal clinical trials. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months.

We believe XHANCE will offer a cost-effective treatment solution to payors who are increasingly being asked to pay for multiple high-cost therapies for a variety of diseases priced at tens of thousands of dollars per year. We priced XHANCE comparably to the only other branded INS that is currently approved to treat nasal polyps, but at a price higher than generic INS products. We expect XHANCE to be adopted by physicians at a natural point in the care pathway for use in patients with chronic rhinosinusitis with or without nasal polyps before they progress to costly surgical interventions or biologic monoclonal antibodies in development for nasal polyps. Sinus surgery costs between \$8,500 and \$16,000 per procedure, and we expect that biologic monoclonal antibodies for the treatment of nasal polyps will cost approximately \$35,000 per year based on the doses being studied in nasal polyps and the current costs per dose in other indications. We believe XHANCE will offer a cost-effective clinical benefit to payors that will reduce the perceived need for multiple step-edits and prior authorizations, which we believe will increase the likelihood of successful commercial adoption of XHANCE.

### ***U.S. Market Opportunity***

Our initial target market for XHANCE will consist of ENT physicians, allergists and primary care physicians in the United States that most frequently prescribe INS. This group of approximately 5,000 primary care physicians, which we refer to as high-decile INS-prescribing primary care physicians, account for approximately 25% of all INS prescriptions written by primary care physicians. We refer to these ENT physicians, allergists and high-decile INS-prescribing primary care physicians collectively as the specialty segment of our target market. We believe the approximately 15,000 physicians in this specialty segment together treat an estimated 3.5 million U.S. patients with chronic rhinosinusitis, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. We believe the total annual U.S. market opportunity for XHANCE in this specialty segment is over \$3.4 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. If we are able to obtain approval for the follow-on indication of chronic sinusitis, we intend to broaden our commercialization efforts to target additional primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We refer to these additional primary care physicians as the primary care segment of our target market. We believe the total additional annual U.S. market opportunity for XHANCE in this primary care segment is over \$6.0 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Therefore, we estimate the total annual U.S. market opportunity for the combined specialty and primary care segments is over \$9.5 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps.

### ***Intellectual Property and Barriers to Entry***

XHANCE benefits from substantial intellectual property and other technical barriers to entry, including regulatory and drug delivery complexities. Our XHANCE U.S. patent portfolio consists of 9 issued device and method of use patents expiring through 2030, three issued design patents expiring through 2030 and 12 patent applications that, if granted, would expire through 2034. The 9 issued device and method of use patents are published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

We believe the unique features of an Optinose EDS, as well as its delivery of a topically-acting drug, will present generic and 505(b)(2) NDA competitors of XHANCE with human factors engineering challenges specific to drug-device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. We also believe that any future substitutable generic competitors would be required to conduct, among other things, non-inferiority clinical trials demonstrating equivalent efficacy and safety outcomes to establish clinical bioequivalence to XHANCE. We believe these clinical trials would require a significant amount of time and capital investment and present clinical development uncertainties.

### ***Our Management Team***

We are led by a management team with an average of over 20 years of experience developing and commercializing products at large, multinational pharmaceutical and medical device companies, such as Johnson & Johnson, Sanofi-Aventis, Bristol Myers-Squibb, Takeda and Novartis. Our management team's experience is complemented by its expertise at growing emerging healthcare companies, such as Cephalon, NuPathe and Take Care Health System. Our team previously developed our first product using an exhalation delivery system, Onzetra Xsail. We

believe the experience of our management team and our broad network of relationships with leaders within the industry and the medical community provide us with insight into product development and identification of product opportunities that benefit patients and physicians in the ENT and allergy specialty segments.

## Our Growth Strategy

Our goal is to become a leading specialty pharmaceutical company dedicated to developing proprietary products that become a part of the standard of care for diseases in the ENT and allergy segments. We also plan to expand the use of the Optinose EDS into additional indications with significant unmet needs, including potential nose-to-brain drug delivery for central nervous system disorders. The key elements of our strategy are to:

- **Commercialize XHANCE in the ENT and allergy specialty segments in the United States.** We plan to deploy an efficient, go-to-market commercialization model and have completed the build out of our commercial team and organization. Our fully dedicated specialty sales force of approximately 80 territory managers completed training and initiated promotion of XHANCE in early March 2018 to a defined prescriber base of approximately 6,000 ENT and allergy specialists, as well as approximately 2,000 high-decile INS-prescribing primary care physicians. Because we expect to secure broader market access over the next 12 to 18 months, we intend to increase the size of our sales force to approximately 120 territory managers based upon an expanded target audience of approximately 14,000 specialists or specialty-like primary care physicians. Additionally, we expect to target an additional approximately 1,000 physicians through digital and non-personal promotion in areas where we do not have territory managers. We believe these approximately 15,000 physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps.
- **Pursue pipeline development of XHANCE for chronic sinusitis to broaden our market opportunity.** We plan to seek a follow-on indication for XHANCE for the treatment of chronic sinusitis. We believe XHANCE would be the first drug therapy product approved for the treatment of chronic sinusitis. In the future, as appropriate, we plan to broaden our marketing to additional primary care physicians that we believe treat an additional estimated 6.25 million patients in the U.S. with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. In addition, at some point in the future, we intend to consider directing promotional resources to an additional estimated 20 million adult chronic rhinosinusitis sufferers who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.
- **Develop a pipeline of additional products focused on the ENT and allergy specialty segments.** We are evaluating the use of the Optinose EDS to deliver other drugs or drug combinations, including antibiotics, anticholinergics, antihistamines, mucolytics, leukotriene inhibitors and other medication classes, to treat diseases primarily managed by ENT and allergy specialists. We also intend to explore complementary drug, diagnostic or device technologies or products to make effective use of our commercial infrastructure. We also plan to evaluate strategic licensing, acquisition, development and commercial partnerships that could increase our commercial efficiencies.
- **Explore business development activities for Optinose EDS outside of the ENT and allergy segments.** We are exploring the possibility of using an Optinose EDS to support development of central nervous system treatments, particularly those enabled by nose-to-brain drug delivery. We are in the early stages of clinical development of OPN-300, which combines an Optinose EDS with oxytocin for the treatment of Prader-Willi syndrome and autism spectrum disorder. We are in preclinical development of OPN-021, which combines an Optinose EDS with orexin-A, for the treatment of narcolepsy or symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease. We intend to evaluate business development activities to capture value through the continued development of these assets.
- **Expand XHANCE into international markets.** We have begun an initial assessment of the development and commercialization of XHANCE for markets outside the United States and plan to conduct further strategic evaluation of such markets now that XHANCE has been approved in the United States. We also intend to explore strategic collaboration opportunities in Europe and the rest of the world in order to maximize the commercial potential and the availability of XHANCE to patients.

## **Chronic Rhinosinusitis and Market Opportunity**

### ***Chronic Rhinosinusitis***

Chronic rhinosinusitis is a serious nasal inflammatory disease significantly impacting patients' quality of life and daily functioning. Chronic rhinosinusitis, unlike allergic rhinitis, is characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain, causing symptoms that persist for a period of 8 to 12 weeks or longer. Chronic rhinosinusitis patients typically suffer from these symptoms four to six months a year, with symptoms often persisting for many years.

In medical literature and medical practice, chronic rhinosinusitis is commonly divided into two subgroups: chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with chronic rhinosinusitis with nasal polyps also develop non-cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the United States have chronic rhinosinusitis with nasal polyps. Both subgroups of chronic rhinosinusitis share the same four defining diagnostic symptoms: nasal congestion/obstruction; facial pain and pressure; purulent runny nose, and postnasal drip; and loss of sense of smell and taste. Additional symptoms may include headaches, chronic sleep problems, fatigue, frequent episodes of acute rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer's quality of life from chronic rhinosinusitis, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief.

Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA does not recognize chronic rhinosinusitis as a single indication for drug development purposes. Instead, the FDA recognizes chronic sinusitis, defined as inflammation of the sinuses with a duration longer than eight weeks, and nasal polyps defined as non-cancerous polyps on the inflamed tissue of the nasal passages and sinuses, as separate indications for drug development purposes.

The American Academy of Otolaryngology-Head and Neck Surgery estimates that approximately 30 million adults in the United States have chronic rhinosinusitis, and it is estimated that up to 10 million adults have chronic rhinosinusitis with nasal polyps. Chronic rhinosinusitis imposes a significant healthcare burden on insurers and employers. The U.S. healthcare system spends approximately \$60 billion annually in direct costs treating patients with chronic rhinosinusitis and its associated symptoms, including an estimated \$5 billion on sinus surgeries. In the United States, physicians perform over 500,000 sinus surgeries each year, and we estimate that over seven million adults have undergone sinus surgery to treat chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis has been reported to account for an aggregate of 73 million restricted activity days per year. Additionally, people with chronic rhinosinusitis have been reported to be absent from work because of this disease 6.5% of the time and to suffer a 38% loss of productivity.

### ***U.S. Market Opportunity***

We estimate that approximately 9.75 million chronic rhinosinusitis patients are currently being treated in physician offices in the United States. We derived this estimate from a large patient claims database that reflects actual treatment patterns of chronic rhinosinusitis over a two-year period from 2010 to 2012. We also estimate that approximately 10,000 ENT and allergy specialists, as well as approximately 5,000 high-decile INS-prescribing primary care physicians, treat approximately 36% of all chronic rhinosinusitis patients in the United States, or approximately 3.5 million patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. In accordance with multiple published clinical practice guidelines, physicians typically medically manage chronic rhinosinusitis patients by prescribing INS despite the fact that there are no FDA-approved products for the treatment of chronic sinusitis without nasal polyps. We initially intend to target approximately 15,000 physicians in the specialty segment. If we obtain the follow-on indication for chronic sinusitis, we intend to broaden our marketing outreach to additional primary care physicians that treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We may also direct promotional resources to an additional estimated 20 million chronic rhinosinusitis sufferers who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

Based on internal estimates, we believe the total annual U.S. market opportunity for XHANCE in the specialty segment is over \$3.4 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Based on these same estimates, we believe the total additional annual U.S. market opportunity for XHANCE in the primary care segment is over \$6.0 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Therefore, we estimate the total annual U.S. market opportunity for the combined specialty and primary care segments is over \$9.5 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps.

### **Treatment Landscape**

The treatment of chronic rhinosinusitis with and without nasal polyps typically begins with medical management. In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation and drainage. The following is a brief description of the current and potential future treatment landscape for chronic rhinosinusitis with and without nasal polyps:

#### *Current Therapies*

- **Intranasal Steroids.** Multiple published clinical practice guidelines generally recommend topically-acting INS as the first line of prescription therapy for the treatment of chronic rhinosinusitis with and without polyps. As a result, physicians typically prescribe INS nasal sprays or nasal aerosols despite the fact that there are no FDA-approved products for the treatment of chronic sinusitis without nasal polyps. Therefore, the majority of chronic rhinosinusitis sufferers being treated have tried INS. We estimate that physicians in the United States prescribe approximately 17 million INS prescriptions each year for the treatment of chronic rhinosinusitis, which includes, among other INS products, a generic fluticasone propionate nasal spray. Nasonex, or mometasone furoate nasal spray, is currently the only other branded INS approved by the FDA for the treatment of nasal polyps. A generic version of Nasonex, mometasone furoate monohydrate, was approved by the FDA for, among other indications, the treatment of nasal polyps and launched in 2016. Physicians not only prescribe INS as a standalone therapy, but also typically prescribe INS following sinus surgery as some third-party clinical trials suggest that INS treatment can improve symptoms and delay symptom recurrence.
- **Oral steroids.** Physicians may prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids are often effective at treating the underlying inflammation associated with the disease and reducing postoperative scarring, but the benefit is temporary. As inflammation returns, many patients resume INS therapy.
- **Other medical management.** Physicians commonly employ a variety of other non-surgical treatments in the medical management of chronic rhinosinusitis, including nasal saline rinses, multi-week courses of antibiotics, leukotriene antagonists, decongestants, aspirin desensitization and antifungals. The recognized limitations of drug deposition with current INS cause some physicians to seek out alternative treatment regimens, such as high doses of locally compounded liquid budesonide in high-volume nasal rinses. Chronic rhinosinusitis is one of the most common reasons for adult outpatient antibiotic use in the United States, comprised of approximately 37 million prescriptions per year.
- **Sinus surgery and other procedures.** Physicians generally recommend surgical treatment of chronic rhinosinusitis with and without nasal polyps only after patients fail medical management. The primary surgical alternative is ESS, which attempts to open the sinus drainage pathways while preserving as much bone and sinus tissue lining as possible. The physician typically uses rigid steel instruments and powered cutting tools to remove inflamed tissue, including any nasal polyps, and underlying bone to create a larger passage through the nasal anatomy to the sinuses. At the conclusion of the procedure, patients often have their nasal passages packed with a material that acts as a spacer to prevent surgical adhesions and control bleeding. Patients typically require one or more follow-up debridement treatments in which the physician may remove more tissue, crusting, scabs or scar tissue at the area of surgery in order to keep the sinus drainage pathway open and promote proper healing.

Several companies have developed less invasive technologies for the treatment of chronic rhinosinusitis since the introduction of ESS, such as balloon sinus dilation devices and steroid-releasing sinus implants. Balloon sinus dilation employs a high pressure inflated balloon to open blocked sinus pathways to increase ventilation and mucus drainage. Steroid-releasing sinus implants are used to hold open the surgically enlarged sinus, while releasing a steroid over a period of time in order to reduce postoperative sinus inflammation and scarring.

### *Potential Future Therapies*

Several biologic monoclonal antibodies, some of which are already approved for other indications, are being developed for the treatment of nasal polyps, and are believed to inhibit specific pathways of inflammation present in nasal polyps. These biologic monoclonal antibodies include omalizumab, reslizumab, mepolizumab and dupilumab.

### **Limitations of Therapies**

The current and potential future therapies to treat patients suffering from chronic rhinosinusitis with and without nasal polyps have a number of limitations, including:

- **Limited efficacy of INS treatments using traditional nasal sprays and nasal aerosols.** Although steroids are generally pharmacologically effective, conventional INS, including nasal sprays and nasal aerosols, are unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages. These products deposit a majority of the drug in the front of the nose or on the floor of the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief.
- **Short-term benefits of oral steroids outweighed by significant side effects.** Oral steroids offer only temporary benefit and are limited by the risk of significant systemic side effects associated with both short- and long-term use. These side effects include, among others, weight gain; increased risk of infections; loss of bone mineral density; death of bone tissue; cataract formation; glaucoma; adrenal suppression; and psychiatric complications, including mania, depression, and psychosis.
- **Varying degrees of efficacy with other medical management.** Other non-surgical treatments have varying degrees of supporting data and efficacy. In addition, high-volume steroid nasal rinses are difficult to administer, can be costly, may risk systemic side effects due to the absorption of the steroid into the body, can be associated with fluid draining from the nose after the procedure and are difficult for patients to comply with over prolonged courses of outpatient therapy.
- **Sinus surgery and other procedures are costly and may not be a complete solution.** The effectiveness of sinus surgery varies significantly and many patients experience persistent or recurrent symptoms. Reports have shown that nasal polyp regrowth following surgery occurs in as high as 60% of cases within four years. In addition, it has been reported that 80% of patients who had surgery within the past two years continued to have symptoms. Because sinus surgery is often not curative and may not address the underlying cause of the inflammation, many patients receive short- and long-term courses of INS after surgery and approximately 20% of patients elect surgical revisions. Postoperative scarring and persistent inflammation are common and can compromise symptom outcomes and also negatively impact the ability of the sinuses to heal. Sinus surgery is also a costly procedure, with estimated costs ranging from \$8,500 to \$16,000 per procedure. While balloon sinus dilation has the ability to open sinuses in a less invasive manner, it also may not address the underlying cause of the inflammation associated with chronic rhinosinusitis and is costly. Similarly, steroid-releasing sinus implants have limited duration of anti-inflammatory effect, are costly and face reimbursement challenges.
- **Potential future biologic monoclonal antibodies treatment may be costly, difficult to administer or have negative side effects.** The risks and benefits associated with the use of biologic monoclonal antibodies for the treatment of nasal polyps are not yet fully established. We expect the use of biologic monoclonal antibodies for the treatment of nasal polyps to be costly, with estimated costs of approximately \$35,000 per year based on the doses being studied in nasal polyps and the current costs per dose in other indications. These drugs also require subcutaneous injections or intravenous administration that require frequent physician office visits. We believe the systemic nature of these treatments, which target components of the immune response, may result in more adverse side effects than treatments with topically-acting steroids.

### **Our Solution**

#### **XHANCE**

XHANCE combines an Optinose EDS with a liquid formulation of fluticasone propionate, a potent, well-characterized, second-generation anti-inflammatory corticosteroid for the treatment of serious nasal diseases characterized by chronic inflammation, such as chronic rhinosinusitis. XHANCE is designed to deliver fluticasone propionate into the high and deep regions of the nasal passages where nasal polyps or inflamed and swollen



membranes can obstruct normal sinus ventilation and drainage. On September 18, 2017, the FDA approved our NDA for XHANCE for the treatment of nasal polyps in patients 18 years of age or older. We also plan to initiate additional clinical trials of XHANCE in the fourth quarter of 2018 to seek a follow-on indication for the treatment of chronic sinusitis. Similar to our NDA for XHANCE for the treatment of nasal polyps, we believe we will be able to use the FDA's Section 505(b)(2) regulatory pathway for potential U.S. approval for XHANCE for the treatment of chronic sinusitis.

We believe XHANCE could become a part of the standard of care for the treatment of patients with chronic rhinosinusitis with and without nasal polyps before they progress to more costly treatment alternatives and could also be adopted as a maintenance therapy to improve outcomes following sinus surgery. We believe the following factors could contribute to the potential success of XHANCE:

- **High patient dissatisfaction with current INS treatments.** In a market research study that we commissioned, we surveyed 438 patients with chronic sinusitis with and without nasal polyps. In this study, approximately 80% of the patients reported being frustrated with the symptom relief offered from their current INS medication and approximately 90% of the patients reported they would be interested in using a new product if it would improve symptom relief.
- **Strong physician interest in XHANCE product profile.** We surveyed approximately 700 physicians, consisting of 400 ENT and allergy specialists and 300 primary care physicians that currently treat patients with chronic sinusitis with and without nasal polyps. Approximately 75% of these physicians, including both specialists and primary care physicians, agreed, in part, that INS medications do not work well in patients with chronic sinusitis due to their belief that conventional INS do not sufficiently reach the high and deep regions of the nasal passages where inflammation occurs. In addition, 70% to 80% of these physicians reported that they would "definitely" or "probably" prescribe their patients a product with a clinical profile similar to XHANCE.
- **Fluticasone propionate is the most widely-prescribed INS in the United States.** XHANCE contains fluticasone propionate, a potent, well-characterized, second-generation, anti-inflammatory corticosteroid with a low bioavailability, meaning that only a small percentage of the drug is absorbed into the body. Corticosteroids provide multiple anti-inflammatory mechanisms of action and are used in forms such as pills, creams, inhalers and nasal sprays, to treat many sites of inflammation.
- **XHANCE was designed to overcome the limitations of current INS therapies by delivering medication high and deep in the nasal passages.** In multiple studies utilizing advanced imaging, an Optinose EDS produced a differentiated pattern of drug delivery with significant drug deposited at the primary site of inflammation high and deep in the nasal passages where nasal polyps or inflamed and swollen membranes produce nasal symptoms and can obstruct normal sinus ventilation and drainage.
- **Strong clinical data demonstrating safety and efficacy.** In two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials evaluating adult patients with nasal polyps, we met our co-primary endpoints of statistically significant reductions of nasal congestion/obstruction symptoms and total polyp grade. XHANCE also produced treatment benefits in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination, quality of life measures, need for sinus surgery and patient global impression of change. In two supportive open-label Phase 3 clinical trials evaluating approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, XHANCE was generally well tolerated. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months.
- **XHANCE is easy to use.** In a market study that we commissioned, 98% of patients reported that XHANCE was easy to use after four weeks of use and 93% stated the ease of use was comparable to other INS.
- **Potential for broad payor access.** In a market research study that we commissioned, we surveyed 26 health insurance plans representing over 150 million covered lives. Most payors reacted positively to a profile of XHANCE with respect to its product design, mechanism of action and efficacy results based upon our clinical data. This research further suggested that market access for XHANCE will be dependent on XHANCE's pricing. A majority of payors surveyed in our study indicated that they do not intend to actively manage INS products priced below a certain dollar threshold and many surveyed payors indicated that they would provide access without prior authorization to INS products priced within a certain dollar range. The surveyed payors reported the following potential coverage based on the XHANCE profile: (i) no step edits

on plans covering approximately 27% of commercial lives, meaning that payors would not require patients to use generic INS before seeking reimbursement for XHANCE, (ii) a single step edit on plans covering approximately 48% of commercial lives, (iii) a prior authorization requirement on plans covering approximately 10% of commercial lives and (iv) no coverage by plans covering approximately 15% of commercial lives. In addition to this market research study, we obtained formulary data for INS from various sources representing approximately 159 million covered lives. These data indicate that health insurance plans covering 84% of commercial lives do not require prior authorization in the INS category for contracted products. We are actively engaging payors to secure broad market access for XHANCE in the commercial segment by targeting Tier 3 payor coverage, single step edit with no prior authorization. This level of coverage indicates that payors would require patients to use a generic INS as a first step in treating their disease prior to the payor covering XHANCE. However, such coverage would not require the prior authorization of the payor. Tier 3 payor coverage requires a patient co-pay that is higher than that required for generics or drugs within a payor's formulary. We intend to contract with Commercial and Medicare Part D plans and Medicaid to accelerate physician adoption of XHANCE.

- **Cost-Effective Solution.** We have priced XHANCE comparably to the only other branded INS that is approved to treat nasal polyps, but at a price higher than generic INS products. We believe XHANCE will offer a cost-effective, clinical benefit to payors when compared to surgery and expensive monoclonal antibodies and that this benefit will reduce the perceived need for multiple step-edits and prior authorizations, which we believe will increase the likelihood of successful commercial adoption of XHANCE.

### **Optinose EDS**

Our exhalation delivery systems enable the development of drug-device combination products intended for self-administration. We have developed both a liquid delivery system and a powder delivery system utilizing natural functional behaviors of the upper nasal airways to offer better drug deposition. These systems are designed to overcome many limitations inherent in conventional nasal spray and nasal aerosol delivery systems, most notably, enabling higher and deeper intranasal drug delivery.

#### *Liquid EDS*

The liquid EDS depicted below, which is the EDS used in XHANCE, consists of the primary drug container for the liquid drug formulation, an amber glass vial sealed by a crimp-fitted metering spray pump, enclosed within a proprietary liquid delivery subassembly. The nasal spray applicator, which is a component of the subassembly, is attached to the pump and extends to the top of the nosepiece of the liquid delivery subassembly. The EDS includes a flexible mouthpiece and an asymmetrically-shaped nosepiece as part of a mechanism that uses the patient's exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The nosepiece is designed to create a seal with the nostril and also to expand and stent the upper part of the nasal valve, which is an important anatomical structure that is the narrowest part of the entire respiratory tract and a barrier that causes most medication delivered by conventional INS to deposit in the front part of the nose.



*Powder EDS*

The powder EDS depicted below, which is the EDS used in Onzetra Xsail, consists of a reusable device body incorporating a flexible mouthpiece to adjust to individual anatomic variations, and a white button piercing assembly to pierce the medication capsule. Disposable nosepieces are provided in a foil pouch to be inserted into the drug delivery device body. Each pre-filled nosepiece section contains a medication capsule containing a dry powder formulation and a clear release tab. The capsule is pierced by pressing and releasing the white button piercing assembly. The flexible mouthpiece and an asymmetrically-shaped nosepiece are part of the mechanism that uses the patient's exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The medication capsule is intended for single dose administration and is not refillable or removable from the nosepiece.

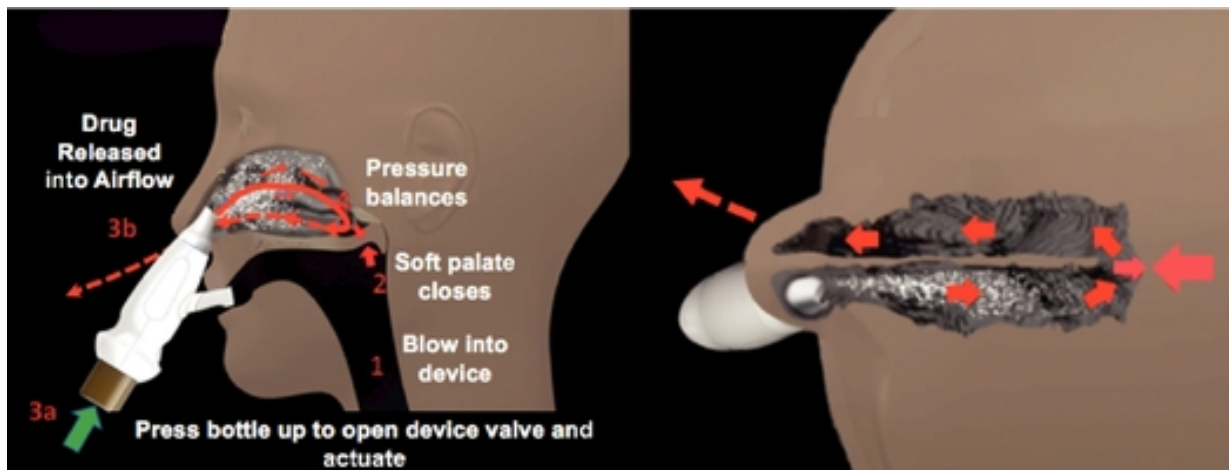
Following drug administration, the disposable nosepiece, including the dose-expended medication capsule, is then removed and discarded.





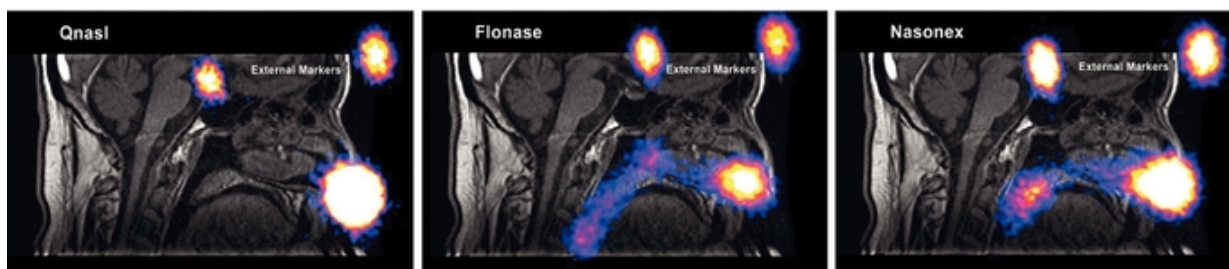
*How an Optinose EDS works*

When exhaling into an EDS, the soft palate automatically elevates and creates an air-tight seal separating the nasal cavity from the throat and lungs. This natural action is the same as that which prevents air from escaping from the nose when trying to blow up a balloon or blow a trumpet. The exhaled air is then routed through the EDS which introduces medication into the air flow and then directs the air and medication through the sealing nosepiece. The positive air pressure, which is the opposite of the negative pressure produced by sniffing with ordinary nasal sprays, acts to dynamically expand the nasal valve and the narrowed nasal passages, helping to "float" the drug around obstructing anatomic barriers and fill one side of the nasal cavity. This enables high and deep deposition of medication in the nasal passages. The positive air pressure, proportional to the pressure on the other side of the soft palate, helps to open a passage between the two sides of the nasal cavity, behind the back edge of the nasal septum. The picture below illustrates this action, which allows the exhaled air pressure to escape from the opposite nostril.



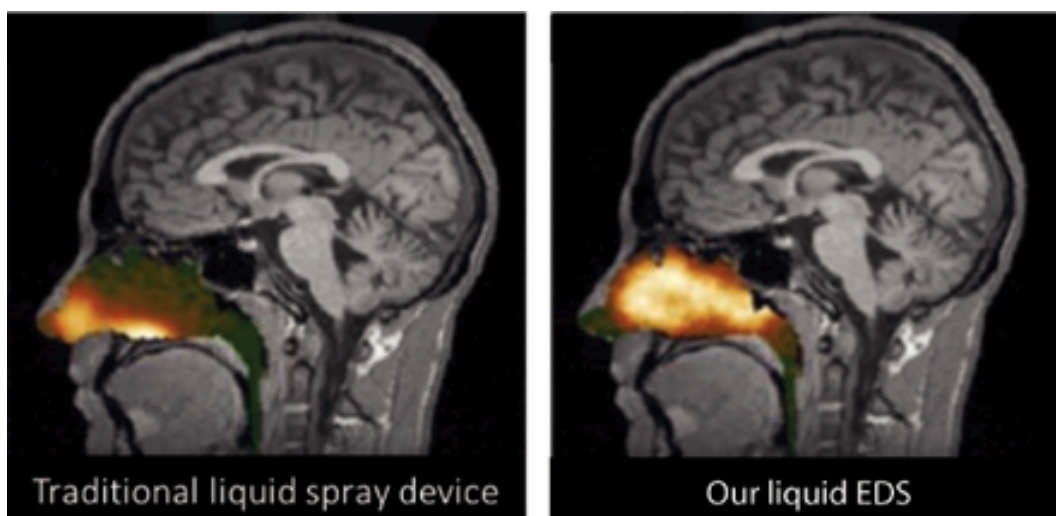
The drug delivery mechanism of an Optinose EDS is designed to overcome the drug deposition shortcomings of conventional nasal sprays and nasal aerosols. In conventional nasal sprays and nasal aerosols, the medication is inhaled or sniffed into the nose creating negative pressure within the nasal passages, which does not facilitate the expansion of the nasal valve or the nasal passages and may obstruct the drug from reaching deep into the nose where most nasal polyps and inflamed and swollen sinus membranes exist.

The pattern of drug deposition produced by conventional nasal sprays and an Optinose EDS has been evaluated in multiple studies using a combination of advanced imaging modalities to depict the regions of the nasal passages where drug is deposited after administration in human volunteers. In an open label, crossover study conducted by a third party in nine patients with allergic rhinitis, investigators examined the nasal deposition of radio-labeled materials that allow for traceability following use of Qnasl (HFA-beclomethasone, nasal aerosol), Flonase (fluticasone propionate, nasal spray) and Nasonex (mometasone furoate monohydrate, nasal spray). In this study, gamma cameras were used to capture emitted radiation from these tracers to create two-dimensional images in a similar process to the capture of x-ray images. These gamma images were merged with magnetic resonance images, or MRI, to quantify regional deposition within the nasal passages. The images below illustrate how the pattern of drug deposition in the nasal passages produced by Qnasl, Flonase and Nasonex was concentrated in the front and lower regions of the nasal passages, as opposed to the high and deep regions of the nasal passages targeted in the treatment of chronic rhinosinusitis.



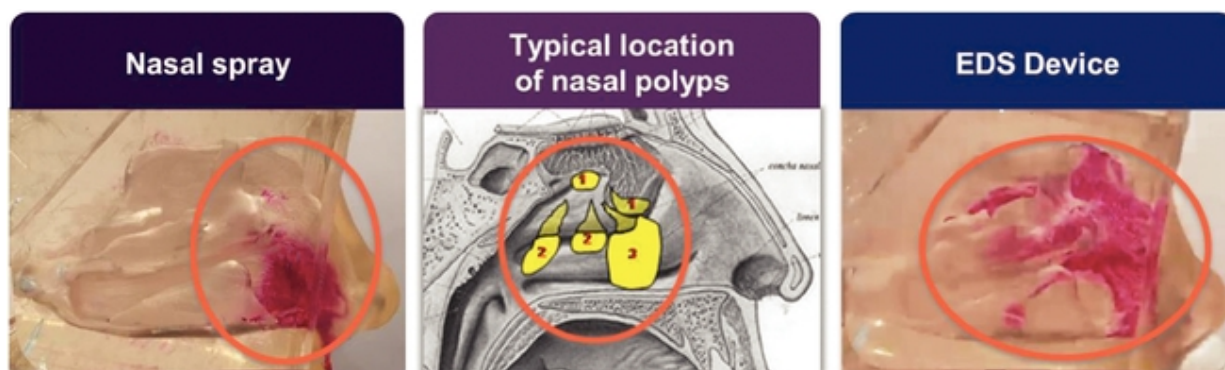
Reprinted with permission from JOURNAL OF AEROSOL MEDICINE & PULMONARY DRUG DELIVERY 28/8, 2015, by Leach et al, published by Mary Ann Liebert, Inc., New Rochelle, NY.

We conducted six deposition studies evaluating 53 healthy subjects that produced approximately 250 images. As depicted in the representative figures below, an Optinose EDS produced a differentiated pattern of drug delivery with significantly more drug deposited in the high and deep regions of the nasal passages.



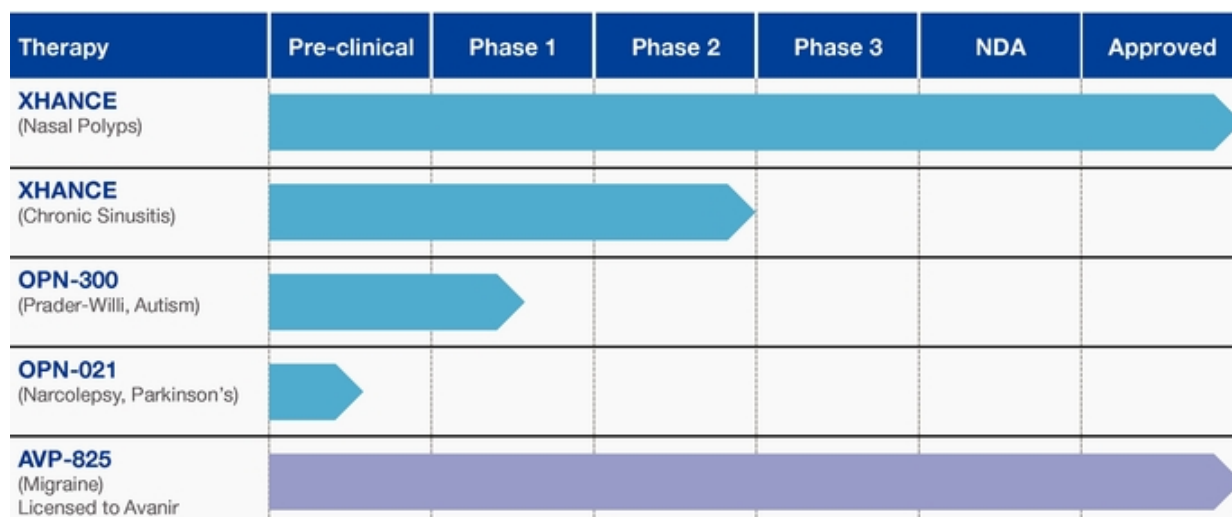
The pictures above use gamma camera image information, which was then superimposed on the corresponding MRI section. These images represent deposition in healthy subjects two minutes after delivery using a traditional liquid nasal spray and a version of our liquid EDS device. Deposition with traditional liquid nasal spray was greatest in the front parts of the nose, whereas deposition with an Optinose EDS was greatest in the high and deep regions of the nose.

The pictures below illustrate how an Optinose EDS (with exhalation) places medication higher and deeper in the nasal passages than a conventional nasal spray (without sniffing) in nasal cast models. As depicted below, although conventional nasal spray systems can reach, and therefore treat, large nasal polyps, they are not suitable for reaching nasal polyps or inflammation in the higher and deeper regions where obstruction of the sinus openings occurs.



An Optinose EDS is also designed to address user dissatisfaction with standard nasal delivery by reducing drug drip-out from the front and back of the nose and the bad taste that often accompanies drug entering the throat. By reducing the loss of drug to non-targeted sites, such as the gastrointestinal tract by swallowing, or lungs, an Optinose EDS has the potential to improve the efficiency of drug activity and to improve tolerability by reducing off-target effects.

**Our Pipeline**



**XHANCE for Chronic Sinusitis**

We plan to initiate additional clinical trials of XHANCE in the fourth quarter of 2018 to seek a follow-on indication for the treatment of chronic sinusitis. We believe XHANCE would be the first drug therapy product approved for the treatment of chronic sinusitis. In the future, as appropriate, we intend to broaden our commercialization efforts to additional primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. In addition, at some point in the future, we intend to consider directing promotional resources to an additional estimated 20 million adults who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

**Other Product Candidates**

Although our initial focus is to prioritize the development of XHANCE in the ENT and allergy specialty segments, we have applied an Optinose EDS to other product candidates in our pipeline across a broad range of disease areas. By placing drug high and deep in the nose, in regions where cranial nerves connect directly with the brain, we believe it may be possible to deliver medications directly into the brain and avoid the difficulties of getting drug past the blood-brain barrier. This may enable treatment of brain diseases using small or large molecules that otherwise do not readily enter the nervous system.

*OPN-300*

We have engaged in early clinical development activities for OPN-300, which combines an Optinose EDS with oxytocin. Oxytocin is a small, naturally occurring peptide currently used to stimulate lactation in breastfeeding women. Oxytocin acts as a neurotransmitter in the brain and has recently been considered a potential novel treatment alternative in several brain disorders due to a growing body of evidence of its critical role in social cognition and behavior. Because oxytocin is a peptide with poor oral bioavailability, nasal administration with an Optinose EDS may allow for improved delivery. With standard liquid nasal spray delivery, only a small amount of the drug reaches systemic circulation. It is estimated that less than 0.01% of oxytocin in the blood enters the brain across the blood-brain barrier.

OPN-300 is being developed to target two orphan indications: Prader-Willi syndrome, a rare genetic disorder that is the leading genetic cause of obesity; and autism spectrum disorder. We conducted a Phase 1 clinical trial in late 2013 using OPN-300 in healthy volunteers. In that trial, a low dose of oxytocin delivered using an Optinose EDS produced a statistically significantly greater social-cognitive effect as measured with functional magnetic resonance imaging, performance on cognitive tests, and physiological markers, than intravenous administration of the same active ingredient that produced blood levels that were not statistically different. We believe this clinical trial supports the possibility of direct nose-to-brain activity of medication delivered using an Optinose EDS. We recently completed a second pilot clinical trial of OPN-300 in adult male patients with autism spectrum disorder. In that trial, adult men with autism spectrum disorder receiving nasal oxytocin showed statistically significant differences in interpretation of

facial expressions. We are preparing for additional clinical development activities in pursuit of an indication for Prader-Willi syndrome.

#### *OPN-021*

We are in preclinical development of OPN-021, which combines an Optinose EDS with orexin-A, also known as hypocretin-A, a peptide that acts as a neurotransmitter in the brain. OPN-021 is being developed for the treatment of narcolepsy or symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease. Narcolepsy is a chronic neurodegenerative disease caused by a deficiency of orexin-producing neurons in the lateral hypothalamus region of the brain. It is clinically characterized by excessive daytime sleepiness, sudden and uncontrollable muscle weakness or paralysis and by intrusions into wakefulness of physiological aspects of rapid eye movement sleep. We are in the process of developing the formulation for OPN-021 and are planning to initiate a Phase 1 clinical trial when a suitable formulation is prepared.

#### *Other*

We are evaluating the use of an Optinose EDS to deliver other drugs or drug combinations, including antibiotics, anticholinergics, antihistamines, mucolytics, leukotriene inhibitors and other medication classes used to treat diseases primarily managed by ENT and allergy specialists. We have also identified several other product candidates with the potential to leverage an Optinose EDS to create clinically differentiated drug treatments for indications such as central nervous system disorders and pain. We will continue to evaluate opportunities to develop product candidates indicated for markets outside of our ENT and allergy focus through business development activities.

### **Our Commercial Strategy**

We are implementing our commercial strategy for XHANCE to focus on the following three phases of penetrating the chronic rhinosinusitis markets and becoming part of the standard of care treatment:

- **Efficient entry in the ENT and Allergy specialty segments:** We plan to deploy an efficient, go-to-market commercialization model and have completed the build out of our commercial team and organization. Our fully dedicated specialty sales force of approximately 80 territory managers completed training and initiated promotion of XHANCE in early March 2018 to a defined prescriber base of approximately 6,000 ENT and allergy specialists, as well as approximately 2,000 high-decile INS-prescribing primary care physicians. Because we expect to secure broader market access over the next 12 to 18 months, we intend to increase the size of our sales force to approximately 120 territory managers based upon an expanded target audience of approximately 14,000 specialists or specialty like primary care physicians. Additionally, we expect to target an additional approximately 1,000 physicians through digital and non-personal promotion in areas where we do not have territory managers. We believe these approximately 15,000 physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps.
- **Facilitate broader adoption:** We intend to pursue a follow-on indication of XHANCE for the treatment of chronic sinusitis. Upon approval for the follow-on indication, we intend to broaden our commercialization efforts to target primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We may target these physicians through a commercial partnership.
- **Activate patient demand:** At some point in the future, we intend to consider directing promotional resources to an additional estimated 20 million chronic rhinosinusitis sufferers who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

We intend to efficiently launch XHANCE into the ENT and allergy specialty segments by utilizing the following strategies:

- **Define a clear patient type for XHANCE.** We intend to focus on moderate-to-severely symptomatic patients who have not achieved satisfactory results with currently available INS.
- **Establish a compelling brand position in the medical continuum of care.** In an effort to establish our brand position within the continuum of care, we intend to, among other things, educate physicians, payors and patients on XHANCE's unique mechanism of action and differentiated efficacy profile.



- **Develop a meaningful payor-friendly value proposition.** We intend to establish a meaningful value proposition for physicians, payors and patients by highlighting the potential for XHANCE to reduce or delay the need for surgical intervention, reduce antibiotic prescribing and increase patient satisfaction with treatment outcomes. We believe the health economic data related to XHANCE are compelling. Our analyses show that XHANCE will have a comparatively low pharmacy budget impact and our clinical trial data suggest that XHANCE may produce an offsetting benefit by helping reduce the rate of surgery with its related costs. For an insurance plan, this could represent a potential overall cost reduction for the population of patients with chronic rhinosinusitis with nasal polyps, as the overall cost of XHANCE would be less than the offsetting costs related to the reduction in surgeries. During clinical studies, XHANCE was also associated with an improvement in reported work productivity in treated patients, which should be valued by employers and patients. Further, we believe the cost of XHANCE to insurance plans will likely be significantly less than the projected costs of monoclonal antibodies that are currently in development for the treatment of nasal polyps.
- **Drive awareness, adoption and access.** We are engaging with physicians and payors to educate both constituencies about XHANCE and its benefits, with the goal of securing broad market access for the expected availability of XHANCE through retail pharmacies in early April 2018.
  - **Physicians:** We are utilizing a clinical nurse educator team to target ENT and allergy specialists to (i) introduce us and highlight the unmet medical need and limitations of current treatments, (ii) increase awareness about XHANCE along with differentiating the EDS and (iii) familiarize healthcare professionals with the proper administration of XHANCE. In addition, beginning in early March 2018 our dedicated sales force started to introduce the XHANCE Xperience program to select physicians.
  - **Payors:** We are engaging with payors prior to launch with the objective of securing broad market access in the commercial segment by targeting Tier 3 payor coverage, single step edit with no prior authorization. Specifically, we are targeting pharmaceutical benefit managers, national plans and regional plans representing, in the aggregate, up to approximately 160 million of the estimated 180 million U.S. covered commercial lives.
  - **Patients:** We are building a patient and physician support infrastructure in an effort to accelerate physician adoption and reduce the risk of patient abandonment during the fulfillment process. We expect that this infrastructure may include (i) patient samples, (ii) a co-pay assistance program for patients who have commercial coverage, (iii) savings cards for cash payors, (iv) reimbursement support programs for the retail channel, (v) a "specialized" distribution channel to assist patients with the complexities of the payor landscape, and (vii) a patient assistance program to provide access to XHANCE to people who have no or inadequate insurance.

Since FDA approval on September 18, 2017, the commercial team has been executing a differentiated, purposeful launch model with the objective of enabling our commercial team to achieve levels of customer awareness, design and implement our customer model, and build market access for XHANCE to facilitate adoption upon making XHANCE broadly available through retail pharmacies in the second quarter of 2018; we now believe XHANCE will be available in retail pharmacies in early April 2018. Our progress across each of these key strategic areas is described below:

- **Drive product awareness and appreciation of the clinical differentiation of XHANCE**
  - Executed broad multi-channel awareness campaign leveraging digital, non-personal promotion and journal advertising and have already reached over 10,000 ENT and allergists
  - Launched approximately 85 person nurse educator team calling on a universe of about 7,000 ENT and allergists. This team has reached approximately 5,000 ENT and allergy prescribers and delivered approximately 10,000 presentations to their target audience. Initial reaction to core brand messages among target physicians has been positive.
  - Finalized XHANCE core marketing strategies and launch tactic including a compliant, value optimizing and cost-effective promotion mix to appropriately engage our target audience
  - Introduced the XHANCE Xperience program to select physicians in early March 2018. This program will offer these physicians and their patients an opportunity to gain initial experience with XHANCE

- **Design and deploy our customer facing model**
  - Designed hybrid sales model that leverages a fully dedicated contract sales organization reporting into an Optinose Sales Leadership Team
  - Defined footprint of approximately 120 territories that will ultimately target approximately about 14,000 ENTs, allergists and “specialty like” primary care physicians
  - Recruited, hired and trained 11 Optinose Regional Business Leaders with an average of approximately 11 years of sales leadership experience
  - In partnership with our contract sales organization, approximately 80 Territory Managers, or TMs, were recruited, hired and trained. The TMs have an average of 13 years of pharmaceutical sales experience and over 70% have experience in the respiratory therapeutic category. The TMs were deployed in early March 2018 in geographies where we expect to have greater than 65% coverage of commercial lives during launch.
  
- **Engage commercial payors with the objective of securing tier 3 commercial coverage**
  - Developed compelling economic value proposition
  - Created value pack, budget impact model, supporting health economics and outcomes research, or HEOR, payor messages and payor partnership models
  - Completed pricing study to inform pricing decision and contracting strategy and will launch with a Wholesaler Acquisition Cost, or WAC, of \$425 per unit of XHANCE
  - Created HEOR-related communication tools for use with payors
  - Completed development of our clinical and economic evidence of pharmaceuticals in support of formulary consideration using the Academy of Managed Care Pharmacy, or AMCP, Dossier format
  - Engaged with approximately 40 plans representing approximately 85% of commercial lives
  - Intend to introduce co-pay assistance program and other patient affordability programs to appropriately support patient access to XHANCE

## **XHANCE Clinical Development**

### **Overview**

We have evaluated XHANCE in the following five clinical trials comprised of over 1,500 patients:

- two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials designed to compare the safety and efficacy of XHANCE to a placebo EDS in adults with bilateral nasal polyps, which we refer to as NAVIGATE I and NAVIGATE II or collectively, our pivotal clinical trials;
- two open-label Phase 3 clinical trials to evaluate the safety of XHANCE in adults with symptoms of chronic sinusitis with or without nasal polyps, which we refer to as EXHANCE-3 and EXHANCE-12 or collectively, our supportive clinical trials; and
- one Phase 1, open-label, randomized, single-dose, bioavailability study to compare the bioavailability of fluticasone propionate from XHANCE to Flonase and Flovent HFA in healthy patients and patients with mild-to-moderate asthma.

### **Clinical Trial Highlights**

Our Phase 3 clinical development program included a population of patients generally reflective of our intended patient population, with approximately 90% having previously tried currently available INS and almost one-third having previously undergone sinus surgery. Key results from our Phase 3 clinical trial program include:

- In our pivotal clinical trials, XHANCE produced statistically significant benefits on both of the co-primary endpoints: a reduction of nasal congestion/obstruction symptoms at week 4 and a reduction in total polyp grade at week 16.

- Patients with nasal polyps generally experienced greater improvements in symptoms and reductions in polyp grade with longer duration of use.
- In our pivotal clinical trials, approximately 16% of patients treated with XHANCE had nasal polyps eliminated in at least one nostril after 16 weeks of treatment, and approximately 27% had nasal polyps eliminated in at least one nostril after an additional eight weeks of treatment. In our supportive clinical trials, we observed complete response rates in at least one nostril of 48% of patients in EXHANCE-3 and 47.1% of patients in EXHANCE-12.
- In our pivotal clinical trials, XHANCE produced improvement across all four defining symptoms of chronic rhinosinusitis.
- Over 85% of patients receiving XHANCE across our pivotal clinical trials reported improvement, and approximately two-thirds reported being "much" or "very much" improved, compared to approximately one-third of patients in the placebo EDS group. In our supportive clinical trials, approximately 70% of patients with symptoms of chronic sinusitis, both with and without nasal polyps, reported that they were "much" or "very much" improved after treatment with XHANCE.
- On a Sinonasal Outcome Test-22, the improvement with the 186- and 372-microgram, or mcg, doses of XHANCE was superior to the placebo EDS in both NAVIGATE I and NAVIGATE II. The magnitude of improvement associated with treatment with XHANCE was approximately 20 points. Although cross-trial comparisons have significant limitations and must be interpreted with caution, in a previous third-party study evaluating a large cohort (n=1468) of patients who were underwent sinus surgery, the degree of change on this outcome measure was approximately 18 points.
- After 12 months of treatment with XHANCE in our supportive clinical trials, at least 50% of patients had a Sinonasal Outcome Test-22 score that was at or below 9.3, which is the average score that has been reported for healthy individuals.
- XHANCE was well tolerated and had an adverse event profile generally similar to that observed in several comparably designed third party studies, including those of mometasone furoate in nasal polyps patients and of fluticasone propionate formulations in polyposis and allergic rhinitis patients.

### ***Phase 3 Pivotal Clinical Trials (NAVIGATE I and NAVIGATE II)***

We have conducted two independent but comparable randomized double-blinded, placebo controlled Phase 3 clinical trials to examine the safety and efficacy of XHANCE versus a placebo EDS in adults with bilateral nasal polyps and moderate nasal congestion/obstruction. These clinical trials, which we refer to as NAVIGATE I and NAVIGATE II, also provided dose-ranging information to support the selection of clinically appropriate dose(s) for commercialization of XHANCE and served as pivotal clinical trials in our NDA for the treatment of adults with nasal polyps. These pivotal clinical trials were conducted in the United States, Canada, South Africa and several European countries.

#### *Study Design*

Each pivotal clinical trial included a single-blind EDS-placebo lead-in and a placebo EDS control group, a multi-center, multi-national study population to increase generalizability, an assessment of the efficacy of multiple doses (93, 186 or 372 mcg twice daily) over a 16-week period and experts in nasal endoscopy to assess objective efficacy outcomes and adverse events, or AEs, in all patients. Patients who completed the double-blinded phase of the pivotal clinical trials were allowed to continue in an open-label extension phase in which all patients received 372 mcg of XHANCE twice daily for up to eight additional weeks. All patients and investigators remained blinded to the original treatment during the open-label phase, allowing for a comparison of as-randomized initial treatments through the end of the open-label extension phase at week 24. We treated a total of 646 adults across both pivotal clinical trials with 568 adults completing the open-label extension phase.

Each of NAVIGATE I and NAVIGATE II had co-primary endpoints of (i) change in subjective nasal congestion/obstruction symptoms from baseline to week 4 and (ii) change in objectively-measured total (bilateral) nasal polyp grade from baseline to week 16. The severity of nasal symptoms was recorded by patients in an electronic diary immediately before dosing in the morning (AM) and evening (PM), and was measured using 7-day average instantaneous AM diary scores. Total (bilateral) nasal polyp grading was assessed with nasoendoscopy and is based on polyp protrusion past certain anatomical landmarks. These grading assessments were performed at screening (baseline) and at weeks 4, 8, 12, 16 (which was the end of the double-blinded phase) and 24 (which was

the end of the open-label phase) using a 0 to 3 point scale for each nostril, with 0 representing no polyps and 3 representing severe polyposis. The scores for each nostril were summed to yield a range of 0 to 6 for both nostrils.

These trials also evaluated several secondary endpoints, including the impact of XHANCE treatment on surgical eligibility and changes in the Sinonasal Outcome Test-22 score, which considers the core defining signs and symptoms of nasal polyps and the impact on functioning, quality of life and sleep. We also conducted a complete response analysis to evaluate the percentage of patients with a recorded nasal polyp grade of zero on at least one side of the nasal cavity.

*Efficacy Results*

The 186- and 372-mcg treatment groups achieved statistically significant reductions in the primary assessments of congestion severity at week 4 and reductions in polyp grade at week 16 relative to a placebo EDS. In NAVIGATE I, the differences from the placebo EDS generally increased with each increasing dose of XHANCE for both co-primary endpoints, meaning that administering higher doses to a patient led to a greater decrease in nasal congestion/obstruction symptoms and bilateral nasal polyp grade. In NAVIGATE II, the 186-mcg group achieved the largest numerical reduction in the primary assessment of congestion symptom severity, and the 372-mcg group achieved the largest numerical reduction in the primary assessment of polyp grade. On average, patients in both pivotal clinical trials had moderate nasal polyps (with an average bilateral score of approximately 3.9) at baseline. Patients treated with 372 mcg had the largest mean change in polyp grade in each pivotal clinical trial, with decreases in grade after 16 weeks of 1.1 and 1.4 in NAVIGATE I and NAVIGATE II, respectively. There was also a consistent decrease in average polyp grade over time through 24 weeks.

The following table summarizes the mean change in congestion scores in each of the pivotal clinical trials:

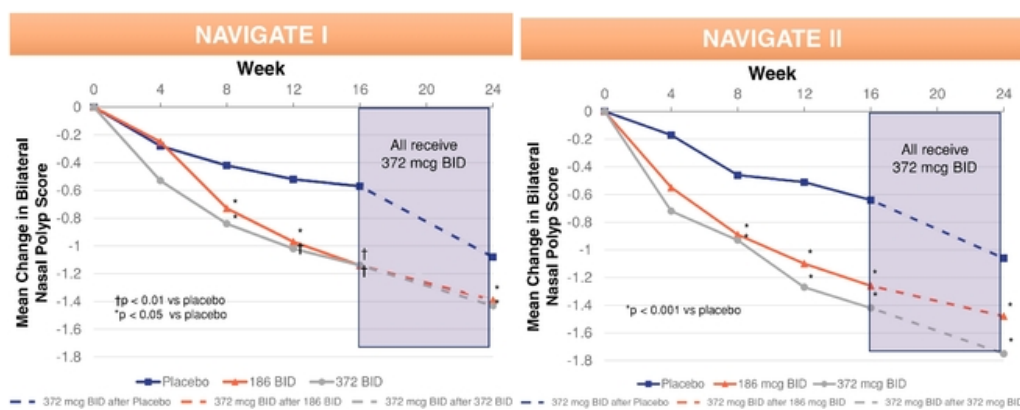
**Mean Changes from Baseline in AM Congestion Score After 4 Weeks of Treatment in Adult Patients with Nasal Polyps**

| Treatment          | N  | Baseline Score<br>(Standard Deviation) | Mean (Standard Error) Change from Baseline | Difference from Placebo EDS |                         |                        |
|--------------------|----|--|--|-----------------------------|-------------------------|------------------------|
|                    |    |  |  | Mean                        | 95% confidence interval | p-value <sup>(1)</sup> |
| <b>NAVIGATE I</b>  |    |  |  |                             |                         |                        |
| XHANCE 372 mcg     | 79 | 2.29 (0.44)                            | -0.62 (0.08)                               | -0.38                       | -0.57, -0.19            | <0.001                 |
| XHANCE 186 mcg     | 80 | 2.24 (0.42)                            | -0.54 (0.08)                               | -0.30                       | -0.48, -0.11            | 0.002                  |
| Placebo EDS        | 82 | 2.31 (0.41)                            | -0.24 (0.07)                               |                             |                         |                        |
| <b>NAVIGATE II</b> |    |  |  |                             |                         |                        |
| XHANCE 372 mcg     | 82 | 2.25 (0.42)                            | -0.62 (0.07)                               | -0.38                       | -0.58, -0.18            | <0.001                 |
| XHANCE 186 mcg     | 80 | 2.20 (0.37)                            | -0.68 (0.07)                               | -0.45                       | -0.65, -0.25            | <0.001                 |
| Placebo EDS        | 79 | 2.29 (0.43)                            | -0.24 (0.07)                               |                             |                         |                        |

<sup>(1)</sup> The p-value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance.



The following charts summarize the mean change in bilateral nasal polyps score in each of the pivotal clinical trials:



In addition to the co-primary efficacy endpoints described above, we also assessed a number of secondary endpoints in the pivotal clinical trials, including the following:

- Sinonasal Outcome Test-22.** In a Sinonasal Outcome Test-22, which broadly assesses the impact of nasal polyps on certain outcomes, including the symptoms of nasal polyps, functioning and quality of life, the change observed with the 186- and 372-mcg doses of XHANCE was superior to the placebo EDS in both of the pivotal clinical trials. The magnitude of improvement associated with treatment with XHANCE was approximately 20 points.
- Quality of Sleep.** A positive impact of XHANCE on sleep was shown for the 372-mcg dose in both pivotal clinical trials through the "Sleep" sub-scale of the Sinonasal Outcome Test-22 and, in NAVIGATE II, a positive effect was further shown across a number of the sub-scales of the MOS-Sleep-R, a validated set of measures commonly used in clinical studies to assess changes in sleep quality.
- Defining Symptoms.** The 186- and 372-mcg treatment groups, in pooled data for NAVIGATE I and NAVIGATE II, achieved statistically significant improvement in all four of the core defining symptoms of nasal polyps at the end of the double-blinded phase.
- Patient Global Impression of Change.** Patient global impression of change is a summary measure of treatment benefit from the perspective of the patient measuring their perception of improvement or worsening of their condition. At the end of the double-blinded phase, the percentage of patients who were improved was substantially higher with XHANCE compared with the placebo EDS. Of the patients receiving 186 or 372 mcg of XHANCE, 86% reported improvement combined across both pivotal clinical trials, and 65.9% reported being "much" or "very much" improved. A post-hoc analysis of a subgroup of patients in the NAVIGATE I and II trials who were using a marketed INS at the time of study entry showed similar results, with 65% of patients treated with 186 or 372 mcg of XHANCE reporting being "much" or "very much improved" after 16 weeks of treatment compared with 28% of patients treated with the placebo EDS.
- Need for Surgery.** Surgical eligibility was assessed using standardized criteria defined prior to trial initiation. Surgery was not necessarily planned or pending for these patients. The proportion of patients considered eligible for surgery among the 186-mcg and 372-mcg dose groups combined across both pivotal trials was reduced by 54% after 16 weeks of treatment with XHANCE versus 36% with the EDS-placebo group and was reduced by approximately 64% after the additional eight weeks of active treatment with the 372-mcg dose.
- Complete Response Analysis.** The polyp grading scale is neither linear nor a direct measure of polyp mass, making it difficult to interpret mean change scores. Therefore, we also performed a complete response analysis to evaluate the percentage of patients who had nasal polyps eliminated on at least one side of the nasal passages. The percentage of patients who had nasal polyps eliminated on at least one side of the nasal passages at the end of the double-blinded phase was 14.1% in the 186- and 372-mcg dose groups combined across both pivotal clinical trials, compared to 7.8% of placebo EDS recipients. By the end of 24 weeks, after all patients received up to an additional eight weeks of active treatment with the 372-mcg dose, the complete response rate was 17.3% in patients previously treated with the placebo EDS compared

to 26.2% in patients who previously received XHANCE across the 186- and 372-mcg dose groups in both pivotal clinical trials.

*Safety Results*

XHANCE was generally well tolerated across the 186- and 372-mcg dose groups in NAVIGATE I and NAVIGATE II. The most commonly reported AEs in the active treatment groups in the pivotal clinical trials, which are shown in the table below, were associated with local effects at the site of administration in the nasal passages or associated with the underlying disease. Most local AEs were not spontaneously reported but were identified as a result of active monitoring of all patients at scheduled intervals by endoscopic nasal examination at each visit. The majority of these AEs were reported to be mild and were observed to resolve with continued use of XHANCE. A total of six patients in the pivotal clinical trials experienced a total of seven serious adverse events, or SAEs, only one of which, in a patient in the placebo group, was determined to be treatment-related. 5.0% of subjects treated with XHANCE 186 mcg twice daily and 1.2% of subjects treated with 372 mcg twice daily discontinued from the clinical trials prior to the open-label extension phase based of adverse reactions compared to 4.3% of subjects treated with placebo.

**Summary of Adverse Events with XHANCE Reported in ≥ 3% of Patients with Nasal Polyps and More Common Than Placebo EDS in Phase 3 Pivotal Clinical Trials**

| Adverse Event                         | Placebo EDS<br>(N = 161)<br>n (%) | XHANCE                            |                                   |
|---------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|                                       |                                   | 186 mcg bid<br>(N = 160)<br>n (%) | 372 mcg bid<br>(N = 161)<br>n (%) |
| Epistaxis <sup>1</sup>                | 4 (2.5)                           | 19 (11.9)                         | 16 (9.9)                          |
| Nasopharyngitis                       | 8 (5.0)                           | 3 (1.9)                           | 12 (7.5)                          |
| Nasal septal ulceration <sup>2</sup>  | 3 (1.9)                           | 11 (6.9)                          | 12 (7.5)                          |
| Nasal congestion                      | 6 (3.7)                           | 7 (4.4)                           | 9 (5.6)                           |
| Acute sinusitis                       | 6 (3.7)                           | 7 (4.4)                           | 8 (5.0)                           |
| Headache                              | 5 (3.1)                           | 8 (5.0)                           | 6 (3.7)                           |
| Pharyngitis                           | 2 (1.2)                           | 2 (1.3)                           | 5 (3.1)                           |
| Nasal mucosal ulceration <sup>2</sup> | 2 (1.2)                           | 6 (3.8)                           | 4 (2.5)                           |
| Nasal mucosal erythema                | 6 (3.7)                           | 9 (5.6)                           | 8 (5.0)                           |
| Nasal septal erythema                 | 3 (1.9)                           | 6 (3.8)                           | 7 (4.3)                           |

bid = twice daily.

N = number of patients; n = number of patients in subset.

<sup>1</sup> Includes spontaneous adverse reaction reports.

<sup>2</sup> Includes ulcerations and erosions

**Phase 3 Open-Label Clinical Trials (EXHANCE-3 and EXHANCE-12)**

We also conducted two supportive, open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. The supportive clinical trials, which we refer to as EXHANCE-3 and EXHANCE-12, were conducted in the United States with a primary objective to assess the safety of twice-daily intranasal administration of the 372 mcg dose of XHANCE in an expanded number of patients and over an extended period of time. We also assessed a variety of objective and subjective efficacy parameters, including an assessment of each patient's symptoms and functioning and qualification for surgical intervention.

*Study Design*

Eligibility for enrollment, endpoint and study design were similar in EXHANCE-3 and EXHANCE-12 with the exception of duration (3 months in the case of EXHANCE-3 and 12 months in the case of EXHANCE-12). Across both supportive clinical trials, a total of 898 adults were treated, including 762 adults with chronic sinusitis without nasal polyps and 136 adults with symptoms of chronic sinusitis with nasal polyps.

*Safety Results*

XHANCE was generally well tolerated. As shown in the table below, 59.2% of patients in the supportive clinical trials experienced at least one treatment-emergent AE, with the most common being similar to those in the XHANCE

treatment groups of the pivotal clinical trials. The most common AEs were local (in the nose) and not systemic. Most AEs were mild and resolved with continued use of XHANCE. A total of 12 patients experienced a total of 14 SAEs in the supportive clinical trials, none of which were deemed treatment-related. Approximately 80% of patients completed the supportive clinical trials, with approximately 5% discontinuing due to an AE and 1% discontinuing for lack of efficacy.

**Summary of Adverse Events Reported in ≥3% of Patients in EXHANCE 3 AND EXHANCE 12**

| Adverse Event   | XHANCE<br>372 mcg<br>(N = 898)<br>n (%) |
|---|---|
| Patients with at least 1 Adverse Event                                  | 532 (59.2)                              |
| Epistaxis <sup>1</sup>  | 73 (8.1)                                |
| Nasal mucosal disorder (erythema or ulceration not at the nasal septum) | 109 (12.1)                              |
| Nasal septum disorder (erythema)  | 71 (7.9)                                |
| Nasal septum ulceration   | 53 (5.9)                                |
| Acute sinusitis   | 48 (5.3)                                |
| Upper respiratory tract infection                                       | 46 (5.1)                                |
| Headache  | 44 (4.9)                                |
| Nasal congestion  | 34 (3.8)                                |
| Cough   | 27 (3.0)                                |

<sup>1</sup> Includes spontaneous adverse reaction reports.

*Efficacy Results*

Efficacy was also measured in EXHANCE-3 and EXHANCE-12. Key efficacy results from EXHANCE-3 and EXHANCE-12 included:

- On the Lund-Mackay scale, which is an endoscopic objective assessment of disease in the nasal passages, scores for edema, nasal discharge and nasal polyps decreased through up to 12 months of treatment, with similar benefits observed in patients who did or did not have nasal polyps at baseline. Among those patients entering the clinical trials with endoscopic evidence of edema within the nasal cavity, approximately 35% with polyps and 53% without polyps in EXHANCE-3 and 50% with polyps and 56% without polyps in EXHANCE-12 no longer had observable edema by the end of the study.
- Patients with nasal polyps experienced improvement in nasal polyp grades. As observed in the pivotal clinical trials, mean nasal polyp grading scale scores improved more with longer durations of treatment. In addition, the percentage of nasal polyp patients with a polyp grade of 0 on at least one side of the nose was 47.1% in EXHANCE-12 and 48.0% in EXHANCE-3 by the end of their participation in the study.
- Mean total Sinonasal Outcome Test-22 scores improved throughout both supportive clinical trials. After 12 months of treatment with XHANCE in our supportive clinical trials, at least 50% of patients had a score that was at or below 9.3, which is the average score that has been reported for healthy individuals.

**Phase 1 Bioavailability Clinical Trial**

We performed a Phase 1, open-label, randomized, single-dose, bioavailability clinical trial of XHANCE and Flonase in healthy patients and XHANCE and Flovent HFA in patients with mild-to-moderate asthma. We conducted the Phase 1 clinical trial to establish a bridge between XHANCE, which consists of our fluticasone propionate formulation combined with an Optinose EDS, and Flonase and Flovent HFA, the reference listed drugs for our NDA. We chose fluticasone propionate in part because it has limited absorption into the body. In our NDA, we relied in part on the FDA's previous findings of safety for Flonase and Flovent HFA, including non-clinical toxicology findings and findings of systemic safety risks related to hypothalamic-pituitary-adrenal, or HPA, axis suppression, which is a known side effect of corticosteroids. To do so, we were required to establish that the systemic exposure, or the

amount of drug absorbed into the body, to fluticasone propionate following use of XHANCE did not exceed the exposure produced by Flovent HFA.

### *Study Design*

Part one of the clinical trial was a three-way, three-treatment, three-sequence crossover study in healthy patients in which patients were randomized to a sequence containing the following treatments: 186 mcg (1 × 93 mcg to each nostril) of XHANCE; 372 mcg (2 × 93 mcg to each nostril) of XHANCE; and 400 mcg (4 × 50 mcg to each nostril) of Flonase. The primary objective of part one was to assess and compare the systemic exposure of a single dose of 186 mcg and 372 mcg of XHANCE with 400 mcg of Flonase in healthy patients. If one or both of the test doses resulted in a systemic exposure that was at least 125% of that of Flonase, then part two was to be conducted. Part two of the clinical trial was a two-way, two-treatment, two-sequence crossover study in mild-to-moderate asthmatic patients in which patients were randomized to a sequence containing the following: 372 mcg (4 × 93 mcg) of XHANCE and 440 mcg (2 × 220 mcg) of Flovent HFA. The primary objective of part two was to assess and compare the systemic exposure produced by a single dose of 372 mcg of XHANCE with 440 mcg of Flovent HFA in mild-to-moderate asthmatic patients. A total of 112 adults were examined across both parts of the clinical trial.

### *Results*

In part one of the clinical trial, peak and total exposure to fluticasone propionate was higher following 372 mcg of XHANCE compared to 400 mcg of Flonase. Peak exposure to fluticasone propionate was also higher for 186 mcg of XHANCE than 400 mcg of Flonase, but total exposure was higher for 400 mcg of Flonase than 186 mcg of XHANCE. In part two of the clinical trial, doses of 372 mcg of XHANCE produced systemic exposure substantially lower than that of 440 mcg of Flovent HFA. In particular, peak plasma of the drug, or  $C_{max}$ , and the total amount of absorption, known as the area under the curve from time 0 to infinity, or  $AUC_{0-\infty}$ , were approximately 37% and 50% lower following administration of 372 mcg of XHANCE relative to 440 mcg of Flovent HFA, respectively. We believe these results support our use of Flonase and Flovent HFA as referenced listed drugs in our NDA for XHANCE.

### **Regulatory Exclusivity and Barriers to Entry**

XHANCE benefits from substantial intellectual property and regulatory barriers to entry, including the following:

- **Strong patent protection.** Our XHANCE U.S. patent portfolio consists of nine issued device and method of use patents expiring through 2030, three issued design patents expiring through 2030 and U.S. patent applications that, if granted, would expire through 2034. We rely primarily on the protections afforded by device and method of use patents. Our issued U.S. patents and patent applications for XHANCE are based on an Optinose EDS, including the combination of this technology with fluticasone propionate.
- **Complex drug-delivery system.** We believe the unique features of an Optinose EDS, as well as its delivery of a topical-acting corticosteroid, affords us significant protection against generic competition, as well as against a potential 505(b)(2) NDA, that seeks to reference XHANCE in order to obtain approval for a therapeutically equivalent, substitutable competitor product. XHANCE, utilizing our proprietary EDS, presents human factors engineering complexities for drug-device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. Any future substitutable generic entrant will need to have considerable combination product know-how to develop and validate a substitutable drug delivery device or technology to compete with an Optinose EDS.
- **Clinical and regulatory complexity.** We have conducted a clinical development program comprised of over 1,500 patients to support our NDA for XHANCE to treat nasal polyps, including human factors studies and Phase 3 clinical trial assessments evaluating and validating the use of an Optinose EDS. As with other drugs that primarily have local activity, we believe the regulatory pathway for products seeking approval as substitutable generic equivalents to XHANCE will be more complex and costly than the pharmacokinetic studies generally required for systemically-acting medications. We believe current FDA guidance for substitutable INS generally requires the demonstration of "clinical bioequivalence," which has caused developers to conduct non-inferiority clinical trials. Clinical trials in nasal polyps are different from those that have been performed to support approval of generic INS for allergic rhinitis. We believe potential generic competitors to XHANCE must not only demonstrate efficacy versus placebo, but must also show equivalent efficacy and safety outcomes to establish clinical bioequivalence to XHANCE, requiring a significant amount of time and capital investment and presenting clinical development uncertainties.

- **Three-year regulatory exclusivity.** The FDA has granted XHANCE a three-year period of regulatory exclusivity that will end in September 2020. This exclusivity means that we are afforded at least three years in which to market our product free of generic or 505(b)(2) competition post-NDA approval.

## **Intellectual Property**

We strive to protect our proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and technologies that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, as well as know-how, trademarks, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We internally developed our intellectual property related to the Optinose EDS, AVP-825, XHANCE and our product candidates. We have sought and intend to continue to seek appropriate patent protection for our product candidates, as well as other proprietary technologies and their uses by filing patent applications in the United States and selected other countries.

### **Patents**

As of December 31, 2017, we owned a total of 43 U.S. patents and 43 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2030. These U.S. patent applications, subject to issuance, would be projected to expire between 2020 and 2035, with potential patent term adjustments that would extend the patent term. In addition to our U.S. intellectual property, we also own 213 foreign issued patents, which will expire between 2020 and 2033 and 117 foreign patent applications, which will expire between 2020 and 2035, subject to issuance.

Our XHANCE U.S. patent portfolio consists of 9 issued device and method of use patents, three issued design patents and 12 pending patent applications. The 9 device and method of use patents expire between 2020 and 2030, the three design patents expire between 2029 and 2030 and the 12 pending patent applications would be projected to expire, subject to issuance, between 2022 and 2034, with potential patent term adjustments that would extend the patent term. The 9 device and method of use patents are published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated NDA, or ANDA, or a 505(b)(2) NDA. If any of these potential generic competitors claim that their product will not infringe XHANCE's listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The rest of our patent portfolio largely relates to patents and applications owned by us and directed to AVP-825 and other product candidates, including OPN-300 and OPN-021.

### **Trade Secrets and Other Proprietary Information**

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information.

### **Trademarks**

We also rely on trademarks and trade designs to develop and maintain our competitive position. OPTINOSE®, XHANCE™ and Breath Powered® are trademarks or registered trademarks of ours in the United States.

### **AVP-825 License Agreement**

In July 2013, we, through our wholly-owned subsidiary, OptiNose AS, entered into a license agreement, or the AVP-825 License Agreement, with Avanir pursuant to which we granted an exclusive license to Avanir to further

develop and commercialize AVP-825, a combination of an Optinose EDS with a lose-dose sumatriptan powder, for the acute treatment of migraines in adults, in the United States, Canada and Mexico, which we refer to collectively as the Licensed Territory. AVP-825 was approved by the FDA in January 2016 for the acute treatment of migraines in adults and became commercially available in May 2016 under the brand name Onzetra Xsail.

We have received \$70.0 million in aggregate licensing revenues to date, consisting of an up-front fee of \$20.0 million received in 2013, a \$2.5 million payment received in June 2014 upon the achievement of a development milestone and a \$47.5 million payment received in February 2016 upon FDA approval of AVP-825. We are eligible to receive up to an additional \$50.0 million upon the achievement of annual sales milestones and tiered low double-digit royalty payments once and if net sales of the product exceed a specified cumulative threshold.

Unless earlier terminated in accordance its terms, the AVP-825 License Agreement, including the royalty payments, will remain in effect on a country-by-country basis in the Licensed Territory until the commercial launch of a generic product in such country, at which time the AVP-825 License Agreement, including the royalty payments, will expire as to that particular country. In the United States, which to date is the only jurisdiction in the Licensed Territory in which AVP-825 has been approved for marketing, the commercial launch of a generic version of AVP-825 can occur as soon as the FDA grants marketing approval to a product as a generic to AVP-825. Several patents with respect to AVP-825 are published in the Orange Book, with the last patent expiring in December 2030. A sponsor of a generic version of AVP-825 must use AVP-825 as a reference listed drug in its ANDA, thereby requiring the sponsor to make one of several certifications regarding each AVP-825 patent listed in the Orange Book. A "Paragraph III" certification is the sponsor's statement that it will wait for the applicable patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the applicable patent does not block approval of the generic product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the generic product. If a sponsor of a generic version of AVP-825 files a "Paragraph III" certification with respect to each of the AVP-825 patents listed in the Orange Book, then the earliest the FDA will grant marketing approval to the generic product is December 2030. If, however, a sponsor of a generic version of AVP-825 files a "Paragraph IV" certification challenging AVP-825's Orange Book-listed patents, then, within 20 days of the FDA accepting the filing, the sponsor must provide notice to us and Avanir that an ANDA has been filed with the FDA, and provide the factual and legal basis for the sponsor's assertion that the patent is invalid or not infringed. If we or Avanir file suit against the applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. If the sponsor is unsuccessful in its defense of non-infringement or unable to prove invalidity of the listed patents, the court could issue an injunction prohibiting the launch of the generic version of AVP-825 until the last patent expires in December 2030.

Avanir may terminate the AVP-825 License Agreement in its sole discretion upon prior written notice to us as described in the agreement. We may terminate the AVP-825 License Agreement if Avanir commences any legal or administrative proceeding to revoke or challenge the validity of certain of the intellectual property we licensed to Avanir pursuant to the AVP-825 License Agreement. In addition, the AVP-825 License Agreement provides for customary termination rights in the event of a breach of the AVP-825 License Agreement by the other party.

## **Manufacturing and Distribution**

### ***Manufacturing***

As of February 2018, our third-party manufacturers have met our manufacturing requirements for the initial commercial supply of XHANCE and for the XHANCE Xperience program.

We currently contract with third parties for the manufacture, testing and storage of our product candidates. In our experience, contract manufacturers, or CMOs, are generally cost-efficient and reliable and therefore we currently have no plans to build our own clinical or commercial manufacturing capabilities. Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program.



We have entered into the following key supply agreements for the commercial manufacture and supply of XHANCE:

- In July 2017, we entered into a supply agreement with Hovione Inter Ltd, or Hovione, for the supply of fluticasone propionate, the active pharmaceutical ingredient included in the liquid suspension formulation. This agreement has a term of five years from commercial launch of XHANCE, subject to earlier termination or extension in accordance with the terms of the agreement. Either we or Hovione may terminate the agreement prior to that date for uncured material breach or insolvency of the other party. We may also terminate the agreement in the event Hovione, among other things, (i) loses any required FDA approval rendering it unable to fulfill its contractual obligations, (ii) is engaged in felonious or fraudulent activities or (iii) does not submit a Corrective and Preventive Action plan to the FDA within a specified period of time of being notified of deficiencies in Hovione's facility.
- In August 2017, we entered into a manufacture and supply agreement with Contract Pharmaceuticals Limited Canada, or CPL, for the formulation and assembly of the finished drug product during the fill/pack operation. This agreement has a term of five years from the date on which we provide a purchase order for validation batches to CPL, subject to earlier termination or extension in accordance with the terms of the agreement. Either we or CPL may terminate the agreement prior to that date by mutual consent or for uncured material breach by or insolvency of the other party. We may also terminate the agreement if, among other things, any intellectual property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the manufacture, import, use, sale or distribution of XHANCE or if any regulatory authority requires us to cease production of the sale of XHANCE.
- In August 2017, we entered into a manufacturing services agreement with Ximedica, LLC for the manufacture of the liquid delivery sub-assembly, which consists of injection molded parts and other purchased components. This agreement has a term of two years from September 18, 2017, subject to earlier termination in accordance with the terms of the agreement. Either we or Ximedica may terminate the agreement prior to that date for uncured material breach or insolvency of the other party. We may also terminate the agreement for any reason upon prior written notice or if Ximedica (i) fails an inspection or suffers a disciplinary action by a governmental authority and fails to cure such issue within a specified period of time or (ii) fails to gain recommendation for approval by the FDA to manufacture the liquid delivery subassembly component to be manufactured pursuant to the agreement.

We believe our third-party manufacturers have adequate capacity to manufacture sufficient quantities of XHANCE to meet anticipated commercial demands.

### **Distribution**

We have established a distribution channel in the United States for the commercialization of XHANCE. We will be selling XHANCE to wholesale pharmaceutical distributors, who, in turn, will sell XHANCE to pharmacies, hospitals and other customers. We have also established a full-service pharmacy channel to whom we will sell XHANCE, who, in turn, will sell XHANCE directly to patients. We have contracted with a third-party logistics provider for key services related to logistics, warehousing and inventory management, and distribution. Further, our third-party logistics provider will provide customer order fulfillment services and accounts receivable management.

The initial supply of XHANCE necessary for our XHANCE Xperience program has been manufactured and delivered to a full-service pharmacy which coordinates fulfillment, shipping product directly to patients. XHANCE has already been provided to initial patients in this program. Our initial commercial supply of XHANCE has been delivered to our third-party logistics provider and we expect XHANCE to be in retail distribution channels by late March 2018 so that it is available in retail pharmacies in early April 2018.

### **Competition**

Our industry is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We believe our scientific knowledge, technology, and development capabilities provide us with substantial competitive advantages, but we face potential competition from multiple sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies.

XHANCE will compete primarily with INS, oral steroids and other medical management products, including locally compounded liquid budesonide in high-volume nasal rinses. XHANCE will also compete with surgical procedures, balloon sinus dilation products and steroid-releasing sinus implants. Key competitive factors affecting the

commercial success of XHANCE and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

The only other branded INS on the market indicated for the treatment of nasal polyps is Nasonex, which is marketed by Merck & Co., Inc. A generic version of Nasonex, mometasone furoate monohydrate, was approved by the FDA for, among other indications, the treatment of nasal polyps and launched in 2016. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. There are no products approved for the treatment of chronic sinusitis without nasal polyps. There are two categories of INS: first-generation INS products, which include Rhinocort, Nasacort AQ and Qnasl; and second-generation INS products, which include Flonase, Veramyst, Omnaris and Zetonna. The primary difference between first- and second-generation INS products is that first-generation INS are absorbed into the blood to a greater extent than second-generation INS, with systemic bioavailability ranging from 10% to 50% compared to a systemic bioavailability with fluticasone propionate, a second-generation INS, of less than 2%. Many of the most widely-prescribed INS products are available in generic form and some, such as Flonase (which contains the same active pharmaceutical ingredient as XHANCE), are available over-the-counter.

Several companies are also currently developing biologic monoclonal antibodies for the treatment of nasal polyps. These biologic monoclonal antibodies, which inhibit specific pathways of inflammation present in nasal polyps, include omalizumab, reslizumab, mepolizumab and dupilumab. Omalizumab has been studied in investigator-initiated Phase 2 clinical trials. GlaxoSmithKline has studied mepolizumab in a sponsor-initiated Phase 2 clinical trial and has initiated patient enrollment in a Phase 3 clinical trial with study completion anticipated in 2019. Dupilumab has been studied in a sponsor-initiated Phase 2 clinical trial and Sanofi is currently investigating it in two Phase 3 clinical trials that is expected to be completed in the second half of 2018. If these biologic monoclonal antibodies are successfully developed and approved for marketing, they could represent significant competition for XHANCE.

## **Research and Development**

We expense research and development costs as they are incurred. For the years ended December 31, 2017, 2016 and 2015, we incurred total research and development expenses of approximately \$16.8 million, \$15.3 million, and \$22.2 million respectively.

## **Government Regulation**

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act, or the FD&C Act, and FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, advertising and promotion of our product candidates. Although the discussion below focuses on regulation in the United States, because that is currently our primary focus, we anticipate seeking approval for, and marketing, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

## ***Development and Approval***

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the United States. NDAs require extensive studies and submission of a large amount of data by the applicant.

***Preclinical Testing.*** Before testing any compound in human patients in the United States, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

***IND Application.*** Human clinical trials in the United States cannot commence until an investigational new drug, or IND, application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.



*Clinical Trials.* Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board, or IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., <http://clinicaltrials.gov>). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human patients, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

*NDA Submission and Review.* The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval for new formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference listed drug, or RLD, and submit its own product-specific data — which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the RLD. We obtained FDA approval of XHANCE through the Section 505(b)(2) regulatory approval pathway, with Flonase and Flovent HFA as the RLDs. Flonase and Flovent HFA contain fluticasone propionate, which is also used in XHANCE.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations.

Our product and product candidates include products that combine drug and device components in a manner that the FDA considers to meet the definition of a "combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. For XHANCE, FDA's Center for Drug Evaluation and Research, or CDER, had primary jurisdiction for review of the NDA, and both the drug and device were reviewed under one marketing application. However, for a drug-device combination product CDER typically consults with the Center for Devices and Radiological Health in the NDA review process.

The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice, or cGMP, requirements and adequate to assure consistent production of the product within required specifications.

Once an NDA submission has been accepted for filing — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification. After review of an NDA, the FDA may decide to not approve the application or may issue a complete response letter outlining the deficiencies in the submission. The complete response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies. For example, the FDA originally required us to conduct a randomized, double-blind, placebo controlled, parallel group clinical study in children and adolescents 6 to 17 years of age with bilateral nasal polyps associated with nasal congestion to assess the safety, efficacy, pharmacokinetics, and pharmacodynamics of XHANCE in improving nasal polyp grade and symptoms (nasal congestion/obstruction, sense of smell, rhinorrhea and facial pain or pressure). On October 30, 2017, the FDA notified us that in response to our request it had modified the required age range to 12 to 17 years of age. We submitted our final protocol to the FDA with respect to the pediatric study by January 2018 as required, and we are required to complete the study by January 2022 and submit a final report with respect to the study by July 2022.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

### ***Post-Approval Regulation***

Once approved, products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials if new safety information develops.

**Good Manufacturing Practices.** Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

It is also likely that we will need to comply with some of FDA's manufacturing regulations for devices. FDA has discretion in determining post-approval compliance requirements for products that combine a drug substance with a delivery system device. In addition to cGMP, FDA may require that our drug-device combination product, if approved, comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices.

**Advertising and Promotion.** The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

**Other Requirements.** NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

### **Hatch-Waxman Act**

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

**Generic Drugs.** A generic version of an approved drug is approved by means of an ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

**505(b)(2) NDAs.** As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective, and must submit its own

product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

**RLD Patents.** In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

**Regulatory Exclusivities.** The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

**Patent Term Restoration.** A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate.

### **Other Exclusivities**

**Pediatric Exclusivity.** Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

**Orphan Drug Exclusivity.** The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We may seek orphan drug designation and exclusivity for OPN-300, which we are developing for the treatment of Prader-Willi syndrome and autism spectrum disorder.

### **U.S. Healthcare Reform**

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed under the risk factor "*If we are able to successfully commercialize XHANCE and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in the "Risk Factors" section of this 10-K.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval, business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has announced delays in the implementation of key provisions of the Affordable Care Act.

Certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. In addition, the Bipartisan Budget Act of 2018 increased the Affordable Care Act required manufacturer point-of-sale discount from 50% to 70% off the negotiated price for Medicare Part D beneficiaries during their coverage gap period beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible.

We expect that the Affordable Care Act, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

### **U.S. Tax Reform - 2017 U.S. Tax Reform**

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%.



## **Coverage and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Sales of any of our products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products and product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

Participation in the Medicaid Drug Rebate program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations. Health care reform also made changes to the 340B program by expanding the list of covered entities eligible for 340B participation to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. Health care reform obligates the Secretary of the U.S. Department of Health and Human Services, (HHS), to create regulations

and processes to improve the integrity of the 340B program. On January 5, 2017, the U.S. Health Resources and Services Administration (HRSA), an agency of the HHS that administers the 340B drug pricing program, issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways that we cannot presently anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

In the U.S. Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

The availability of coverage under Medicare Part D may increase demand for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we expect to participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we would be obligated to make our "innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also expect to participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. Civil monetary penalties can be applied if a manufacturer is found to have knowingly submitted any false price information to the government or fails to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the manufacturer's Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal Civil False Claims Act.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment legislation could have a similar effect.

Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of \$4.1 billion in 2018, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Legislative changes to and regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration, as discussed above under the heading "U.S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for any products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additional information regarding these programs is discussed under the risk factor *"If we are able to successfully commercialize XHANCE and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects"* in the "Risk Factors" section of this 10-K.

### **Healthcare Fraud and Abuse Laws**

In addition to FDA restrictions on marketing of pharmaceutical products, our business will be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. These laws include, but are not limited to, anti-kickback and false claims statutes.

The federal Anti-kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The Affordable Care Act amended federal law to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance



programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the statute.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the federal civil False Claims Act may be brought by private individuals known as qui tam relators in the name of the government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal civil False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, inflating prices reported to private price publication services which are used to set drug payment rates under government healthcare programs, and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

## **Healthcare Privacy Laws**

We may be subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA.

## **Foreign Corrupt Practices Act**

In addition, the U.S. Foreign Corrupt Practices Act prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

## **Employees**

As of March 1, 2017, we had a total of 78 full-time employees (including 3 in the United Kingdom and 1 in Norway) and 4 part-time employees. We have no collective bargaining agreements with our employees and none are represented by labor unions. We consider our current relations with our employees to be good.

## **Properties**

Our principal office is located in Yardley, Pennsylvania, where we lease approximately 30,000 square feet of office space pursuant to a lease that expires in May 2021. We also lease facilities in Ewing, New Jersey, Oslo, Norway and Swindon, England. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

## **Legal Proceedings**

We are not currently a party to any legal proceedings.

## **Corporate Information**

We were incorporated under the laws of the State of Delaware in May 2010. Our predecessor entity OptiNose AS was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became our subsidiary as part of an internal reorganization. Our corporate office is located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067. Our telephone number is (267) 364-3500. We maintain an Internet website at [www.optinose.com](http://www.optinose.com). The information contained on our website is not incorporated by reference into this Form 10-K.

We file reports, proxy and information statements and other information with the SEC. We make available free of charge under the "Investors—SEC Filings" section of our website all of our filings with the SEC, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file the information with the SEC.

The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

## **ITEM 1A. RISK FACTORS**

*Investing in our common stock involves a high degree of risk. Before deciding to invest in our common stock, you should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this 10-K, including our consolidated financial statements and the*

*related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occur, our business, financial condition, results of operations and prospects could be harmed. In that event, the price of our common stock could decline and you could lose all or part of your investment. This 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below. See "Note Regarding Forward-Looking Statements."*

## **Risks Related to Our Financial Position and Capital Resources**

**We have incurred significant losses since our inception and anticipate that we will incur continued losses in the future.**

We are a specialty pharmaceutical company with a limited operating history. To date, we have focused primarily on developing XHANCE as well as other product candidates using our proprietary Breath Powered exhalation delivery system, or EDS, technology. Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. To date, we have generated revenue primarily from our license agreement, or the AVP-825 License Agreement, with Avanir Pharmaceuticals, Inc., or Avanir, pursuant to which we granted them the exclusive right to further develop and commercialize AVP-825 for the acute treatment of migraines in adults. We had net income of \$22.6 million for the year ended December 31, 2016 due primarily to the achievement of a milestone under the AVP-825 License Agreement. However, we incurred net losses of \$48.9 million and \$28.3 million for the years ended December 31, 2017 and 2015, respectively. We incurred net losses in all other prior periods. As of December 31, 2017, we had an accumulated deficit of \$211.3 million.

We expect to incur losses for the foreseeable future, and we expect these losses to increase as we:

- begin to commercialize XHANCE and further scale up external manufacturing and distribution capabilities to commercialize XHANCE or any other product candidate for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- continue clinical development activities for XHANCE, including the U.S. Food and Drug Administration, or FDA, mandated pediatric studies, and seek regulatory approval for XHANCE for a follow-on indication for the treatment of chronic sinusitis;
- seek to discover and develop, in-license or acquire additional products, product candidates and technology;
- maintain, expand and protect our intellectual property portfolio;
- hire additional commercial, clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

### **We may never achieve or maintain profitability.**

Our ability to become and remain profitable will depend on our ability to generate revenue. Although we may be entitled to future milestone payments and royalties under the AVP-825 License Agreement, to date we have not commercialized any of our other product candidates and will therefore depend upon our ability to successfully commercialize XHANCE and any of our other product candidates or any other product candidates that we may in-license or acquire in the future. We do not know when XHANCE or any of our other product candidates, if approved, will generate revenue for us, if at all. Our ability to generate revenue from our current or future products and product candidates will depend on a number of factors, including:

- our ability to successfully commercialize XHANCE for the treatment of nasal polyps;

- our ability to successfully complete required clinical trials and submit a supplemental new drug application to the FDA and obtain regulatory approval for XHANCE for the treatment of chronic sinusitis;
- our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize XHANCE outside the United States;
- the size of the markets in the territories for which we gain regulatory approval;
- the performance of our contract sales organization in marketing and promoting XHANCE;
- our ability to develop a commercial organization capable of sales, marketing and distribution for XHANCE and any of our other product candidates for which we may obtain marketing approval;
- our ability to maintain commercially reasonable agreements with wholesalers, distributors and other third parties in our supply chain;
- our success in establishing a commercially viable price for our products;
- our success in defending against potential generic competition and other developments in our market generally;
- our ability to manufacture commercial quantities of our products at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third parties, including government payors; and
- our ability to successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates.

XHANCE, as well as any of our other product candidates, if approved for commercial sale, may not gain market acceptance or achieve commercial success. If our addressable market is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or clinical practice guidelines, we may not generate significant revenue from sales of XHANCE. In addition, we would anticipate incurring significant costs associated with commercializing any approved product. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without continued funding.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain drug approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

**We will likely require additional capital to fund our operations and, if we fail to obtain necessary financing, we may be unable to complete the commercialization of XHANCE and the development of our other product candidates.**

Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale and issuance of common and preferred stock, debt, licensing revenues under the AVP-825 License Agreement and research grants. We expect to continue to spend substantial amounts to commercialize XHANCE and to advance the clinical development of XHANCE for the treatment of chronic sinusitis and our other product candidates. As of December 31, 2017, we had cash and cash equivalents of \$234.9 million. We believe our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations through the end of 2019. During this period, we expect to launch XHANCE in the United States, continue our clinical development plans to seek approval for XHANCE for the treatment of chronic sinusitis and continue our early-stage development efforts with respect to our other product candidates. Our estimate of the period of time through which our financial resources will be adequate to support our operations is based on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the success of our commercialization of XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to obtain adequate coverage and reimbursement for XHANCE;

- the cost and timing of commercialization activities for XHANCE, including product manufacturing, marketing, sales and distribution;
- revenue received from commercial sales of XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the follow-on indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- potential future licensing revenue from the AVP-825 License Agreement;
- fluctuations in the three-month LIBOR-based floating interest rate of our senior secured notes;
- the initiation, progress, timing, costs and results of clinical trials for our other product candidates; and
- the extent to which we in-license or acquire other products, product candidates or technologies.

We cannot be certain that additional funding will be available when needed on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- seek strategic collaborations to assist in the commercialization of XHANCE in the United States and other markets;
- significantly delay, scale back or discontinue the development of XHANCE for the treatment of chronic sinusitis;
- relinquish or license on unfavorable terms our rights to an Optinose EDS technology or other product candidates that we otherwise would seek to develop or commercialize ourselves;
- delay, limit, reduce or terminate the drug development of our current or future product candidates, or seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- significantly curtail our operations.

Although we have the ability to obtain an additional \$25 million through the issuance of additional senior secured notes pursuant to the Note Purchase Agreement, the availability of this \$25 million is subject to certain conditions that we may not be able to meet.

**Our failure to comply with the covenants or other terms of the Note Purchase Agreement, including as a result of events beyond our control, could result in a default under the Note Purchase Agreement that could materially and adversely affect the ongoing viability of our business.**

On December 29, 2017, we entered into a Note Purchase Agreement with Athyrium Opportunities III Acquisition LP, as collateral agent, or the Collateral Agent, and the purchasers party thereto, or the Purchasers, that provides for the issuance of up to \$100 million of senior secured notes, or the Notes. \$75 million of the Notes were issued on December 29, 2017, of which \$50 million were issued by OptiNose AS and \$25 million were issued by OptiNose US, Inc., or the Issuers. The remaining \$25 million of Notes, or the Delayed Draw Notes, may be issued by OptiNose US, Inc. and sold to the Purchasers between April 1, 2019 and August 14, 2019, subject to us and our consolidated subsidiaries achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Note Purchase Agreement) of \$15 million, a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00 and other specified conditions.

The unpaid principal amount under the Notes is due and payable on June 29, 2023, or the Maturity Date. The proceeds of the Notes will be used to provide ongoing working capital to support the launch and commercialization

of XHANCE, as well as for general corporate purposes. The Notes bear interest at a per annum rate of three-month LIBOR rate (subject to a 1.0% floor) plus 9.0%. The interest rate was 10.75% at December 31, 2017. The Issuers are required to make quarterly interest-only payments until the Maturity Date. In addition, the Issuers paid an upfront fee of 1% of the aggregate commitment amount of the Notes on December 29, 2017. We are also required to pay an exit fee of 2% of any principal payments (whether mandatory, voluntary or at maturity) made throughout the term of the Note Purchase Agreement.

In addition, each Note holder may elect to accelerate the repayment of all unpaid principal and accrued interest under such holder's Note upon consummation of a specified change of control transaction or occurrence of certain events of default (as specified in the Note Purchase Agreement), including, among other things:

- our default in a payment obligation under the Notes;
- our breach of the restrictive covenants or other terms of the Notes;
- our breach of reporting obligations;
- our failure to properly maintain the collateral; and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Notes, all amounts outstanding with respect to the Notes (principal and accrued interest) would become due and payable immediately upon an event of default. Our assets or cash flow may not be sufficient to fully repay our obligations under the Notes if the obligations thereunder are accelerated upon any events of default. Further, if we are unable to repay, refinance or restructure our obligations under the Notes, the holders of such Notes could proceed to protect and enforce their rights under the Notes by exercising such remedies as are available to the holders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Notes or in aid of the exercise of any power granted in the Notes. The foregoing would materially and adversely affect the ongoing viability of our business.

**Our Note Purchase Agreement contains restrictions that limit our flexibility in operating our business.**

The Note Purchase Agreement contains various covenants that limit our ability to engage in specified types of transactions without our lenders' prior consent. These covenants limit our ability to, among other things:

- sell, transfer, lease or dispose of our assets;
- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- grant certain license rights related to our products, technology and other intellectual property rights; and
- permit our cash and cash equivalents held in certain deposit accounts to be less than \$10,000,000 at any time.

The covenants in our Note Purchase Agreement and related security agreements may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, terminate their commitments to extend further credit and foreclose on the collateral granted to them to secure such indebtedness. Such repayment could have a material adverse effect on our business, operating results and financial condition.



**Provisions of the Notes for certain potential payments to the holders of such Notes that could impede a sale of the Company.**

Subject to certain exceptions, the Issuers are required to make mandatory prepayments of the Notes, with the proceeds of assets sales, extraordinary receipts and prohibited debt issuances, and upon the occurrence of a change of control. In addition, the Issuers may make voluntary prepayments of the Notes, in whole or in part. All mandatory and voluntary prepayments of the Notes are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the second anniversary of the applicable date of issuance, an amount equal to the amount by which (a) the present value of 102% of the principal prepaid plus all interest that would have accrued on such principal through such second anniversary exceeds (b) the amount of principal prepaid, (ii) if prepayment occurs on or after the second anniversary of the applicable date of issuance but prior to the third anniversary of such issuance, an amount equal to 2% of the principal prepaid, and (iii) if prepayment occurs on or after the third anniversary of the applicable date of issuance but prior to the fourth anniversary of such issuance, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid after the fourth anniversary of the applicable date of issuance of any Notes. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

**Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.**

We do not have any committed external source of funds other than potential milestone payments and royalties under the AVP-825 License Agreement and the additional \$25 million that may become available under the Note Purchase Agreement between April 1, 2019 and August 14, 2019, subject to us and our consolidated subsidiaries achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Note Purchase Agreement) of \$15 million, a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00 and other specified conditions. Until such time, if ever, as we can generate substantial revenue, we may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

**Our ability to use our net operating loss carryforwards and other tax attributes may be limited.**

As of December 31, 2017, we had U.S. net operating loss, or NOL, carryforwards of approximately \$30.3 million available to offset future U.S. taxable income and U.S. research and development (R&D) tax credits of \$2.4 million. These amounts are potentially subject to annual utilization limits under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. Our U.S. NOL carryforwards will begin to expire in 2030 if not utilized. In addition, we have total foreign NOL carryforwards of \$96.6 million as of December 31, 2017 in our Norwegian and United Kingdom subsidiaries. These foreign NOL carryforwards do not expire but can only be used to offset profits generated in Norway or the United Kingdom, respectively.

Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Under Sections 382 and 383, if a corporation undergoes an "ownership change", generally defined as a greater than 50% change, by value, in equity ownership during a three-year period, the corporation's ability to offset pre-change tax attributes, such as NOLs and R&D tax credits, against post-change income or tax may be limited. We have not performed an analysis under Section 382 and cannot predict or otherwise determine whether our federal tax attribute carryforwards may be limited. As a result, if we have taxable income in the future, our ability to use existing U.S. NOL and R&D tax

credit carryforwards to reduce U.S. taxable income or tax liability may be subject to limitation. This could result in increased future tax liabilities. Similar rules at the state level may also limit our ability to use state NOLs. Also, there may be periods when the use of NOLs is suspended or otherwise limited at the state level, which could accelerate or permanently increase state taxes owed.

We may have ownership changes in the future due to further changes in our stock ownership. Some of these ownership changes could be outside of our control. If an ownership change occurs and our ability to use our historical net operating loss and tax credit carryforwards is limited, it could adversely impact our future operating results by increasing our tax obligations.

### **Foreign exchange risks and controls may affect our financial position and results of operations.**

Through the operation of our subsidiaries based in the United Kingdom and Norway, we are exposed to foreign currency fluctuations and exchange rate risks. In addition to the operations of our foreign subsidiaries, we also contract with vendors that are located outside the United States, and in some cases make payment of invoices denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements and we do not currently hedge our foreign currency exchange rate risk. In addition, because we maintain our consolidated financial statements in U.S. dollars, our financial results are vulnerable to fluctuations in the exchange rate between the U.S. dollar and foreign currencies, such as the British pound sterling, the euro, and the Norwegian krone. In preparing our consolidated financial statements, we must convert all non-U.S. dollar results to U.S. dollars, which impacts our results of operations, is reflected as a component of our stockholder's equity (deficit), and may be credited or charged to operations and reflected in other income (expense), net. The impact of changes in exchange rates has not been significant historically. However, changes in exchange rates could cause significant changes in our financial position and results of operations in the future.

### **Risks Related to Commercialization of XHANCE**

#### **We have no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.**

Although our predecessor and subsidiary OptiNose AS commenced operations in 2000, our operations to date have been largely focused on raising capital and developing AVP-825 and XHANCE, including undertaking preclinical studies and conducting clinical trials. While we conducted the pre-approval stages of clinical development for AVP-825, Avanir was responsible for completing the clinical development of, obtaining regulatory approval for, and initiating the commercial launch of that product under our license agreement with them. To date, we have manufactured the initial commercial supply for the launch of XHANCE but we have not yet demonstrated our ability to successfully manufacture for on-going commercial scale or, with the exception of AVP-825, arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

#### **If we are unable to successfully commercialize XHANCE, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.**

Our ability to successfully commercialize XHANCE depends on many factors, including:

- our ability to manufacture commercial quantities of XHANCE at a reasonable cost and with sufficient speed to meet commercial demand;
- our ability to manage our third-party sales organization to market, promote and sell XHANCE;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of XHANCE;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products;
- the availability of coverage and adequate reimbursement for XHANCE;
- our ability to contract with wholesalers and/or specialty pharmaceutical distributors on acceptable terms;
- the effectiveness of our marketing campaigns;
- our effective use of promotional resources;

- a continued acceptable safety profile for XHANCE;
- our ability to obtain and maintain appropriate state licenses in the states in which we intend to sell XHANCE; and
- our ability to successfully defend any challenges to our intellectual property relating to XHANCE.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate revenue from XHANCE. If we cannot do so, or are significantly delayed in doing so, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

**The commercial success of XHANCE will depend upon its acceptance by multiple stakeholders, including physicians, patients and healthcare payors.**

Physicians may not prescribe XHANCE, in which case we would not generate the revenues we anticipate. The degree of market acceptance of XHANCE will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience and ease of administration;
- pricing and cost-effectiveness;
- availability of alternative treatments and perceived advantages over such alternative treatments;
- the clinical indications for which XHANCE is approved;
- the prevalence and severity of any AEs;
- restrictions placed on XHANCE in connection with its approval;
- limitations or warnings contained in the FDA-approved label for XHANCE;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- consolidation among healthcare providers, which increases the impact of the loss of any relationship;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If XHANCE does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenue in order to become or remain profitable.

**If third-party payors do not reimburse patients for XHANCE or if reimbursement levels are set too low for us to sell XHANCE at a profit, our ability to successfully commercialize XHANCE and our results of operations will be harmed.**

Our ability to commercialize XHANCE successfully will depend in part on the extent to which coverage and adequate reimbursement for XHANCE will be available in a timely manner from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for XHANCE from government authorities or other third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of XHANCE to each government authority or other third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement from government authorities or other third-party payors.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for XHANCE, which in turn, could negatively impact pricing. Further, payors, including healthcare insurers, pharmacy benefit managers and group purchasing organizations, increasingly seek ways to reduce their costs. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payors also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Payors may also control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorizations or "step-edits," and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, insurers may establish a step-edit system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Some providers may not complete the burdensome administrative process required to demonstrate or document that the patients for whom XHANCE has been prescribed meet the payors' utilization management criteria (i.e., prior authorizations or step-edits) and, as a result, patients will not gain access to XHANCE treatment. Further, other patients may obtain coverage for XHANCE but abandon their prescriptions rather than pay their co-pay payment which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects, results of operations and financial condition.

Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors, including through integrated delivery systems, would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

**If we are unable to differentiate XHANCE from current and future products or existing methods of treatments, our ability to successfully commercialize XHANCE would be adversely affected.**

We initially intend to commercialize XHANCE for the treatment of nasal polyps and seek FDA approval for a follow-on indication of XHANCE for the treatment of chronic sinusitis. Currently, Nasonex, marketed by Merck, is the only other branded drug therapy approved by the FDA for the treatment of nasal polyps. A generic version of Nasonex, mometasone furoate monohydrate, was approved by the FDA for, among other indications, the treatment of nasal polyps and launched in 2016. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. We are not aware of any product approved for the treatment of chronic sinusitis. In addition to competition from Nasonex and Beconase AQ, we will also need to differentiate XHANCE from other products and treatments identified in current clinical practice guidelines for the treatment of chronic rhinosinusitis with and without nasal polyps. Such products and treatments include the use of nasal rinses, decongestants, over-the-counter and INS products, oral steroids, antibiotics, and sinus surgery and other procedures, including functional endoscopic sinus surgery, balloon sinus dilation and steroid-releasing sinus implants. In addition, several biologic monoclonal antibodies are in clinical development for the treatment of nasal polyps, including omalizumab, reslizumab, mepolizumab and dupilumab. If we are unable to achieve significant

differentiation for XHANCE against these other products and treatments, including on the basis of efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement, the opportunity for XHANCE to be commercialized successfully would be adversely affected.

**If the market opportunities for XHANCE are smaller than we believe, our revenue may be adversely affected, and our business may suffer.**

Our initial target market for XHANCE will consist of ENT physicians, allergists and high-decile INS-prescribing primary care physicians that we believe treat an estimated 3.5 million U.S. patients with chronic rhinosinusitis, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. If we are able to obtain a follow-on indication of XHANCE for the treatment of chronic sinusitis, we intend to broaden our reach and target primary care physicians that we believe treat an additional estimated 6.25 million patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps.

Our projections of both the number of people who suffer from chronic rhinosinusitis with and without nasal polyps, as well as the subset of people with these diseases who have the potential to benefit from the use of XHANCE, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys we commissioned, prescription data or other market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of chronic rhinosinusitis or nasal polyps. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for XHANCE may be limited or may not be amenable to treatment with XHANCE, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

**Clinical practice guidelines and recommendations published by various organizations could have significant influence on the use of XHANCE.**

Government agencies may promulgate clinical practice guidelines directly applicable to XHANCE. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of XHANCE or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of XHANCE.

**If we are unable to maintain agreements with third parties to market and sell XHANCE we may be unable to generate any revenue for XHANCE.**

We currently have limited sales, marketing or distribution capabilities. We have contracted to use an outsourced contract sales organization, or CSO, to promote XHANCE to our defined specialty audience of ENT and allergy specialists and high-decile INS-prescribing primary care physicians. Our CSO may not dedicate sufficient resources to the commercialization of XHANCE or may otherwise fail in its commercialization due to factors beyond our control. Additionally, our CSO may fail to comply with applicable legal or regulatory requirements, or may enter into agreements with other parties that have products and services that could compete with XHANCE.

In the event that we fail to successfully launch and commercialize XHANCE through our CSO, we may also enter into a strategic collaboration with a third party. We face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic partnerships.

**XHANCE may become associated with undesirable adverse reactions or have other properties that could result in significant negative consequences following regulatory approval.**

If we or others identify adverse events, or AEs, associated with XHANCE, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of XHANCE;
- the FDA may withdraw its approval of XHANCE or impose restrictions on its distribution;

- the FDA may require additional warnings or contradictions in the label that could diminish the usage or otherwise limit the commercial success of XHANCE;
- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of XHANCE.

**If the FDA or other applicable regulatory authorities approve generic or similar products that compete with XHANCE, or if the FDA or other applicable regulatory authorities change or create new pathways that may expedite approval of such products, it could decrease our expected sales of XHANCE.**

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. The FD&C Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. Manufacturers may be able to bring a generic product to market in a much more cost-efficient pathway than we currently anticipate. If the costs involved in bringing such a product to market are significantly less than our costs with respect to the development of XHANCE, companies that produce generic equivalents to XHANCE may be able to offer their products at lower prices. Further, if the timeline for bringing such a product to market is expedited, companies that produce generic equivalents to XHANCE may compete with XHANCE faster than we currently anticipate. For example, the FDA has communicated a priority to build on initiatives to accelerate generic entry of complex generics, which include locally acting nasal drug products. If the FDA provides for alternatives to comparative clinical endpoint bioequivalence studies for generic versions of locally-acting orally inhaled and nasal drug products, companies that produce generic equivalents to XHANCE may compete with XHANCE faster than we currently anticipate and a significant percentage of any future sales of XHANCE could be lost to such generic products. Moreover, in addition to generic competition, we could face competition from other companies seeking approval of products that are similar to ours using the Section 505(b)(2) pathway. Such applicants may be able to rely on XHANCE or other approved drug products or published literature to develop drug products that are similar to ours. The introduction of a drug product similar to our products or product candidates could expose us to increased competition, leading to a decrease in sales of XHANCE. Competition that we may face from generic or similar versions of XHANCE could materially and adversely impact our future revenue, profitability, and cash flows.

**Even though we have obtained regulatory approval for XHANCE, we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.**

Even though we have obtained regulatory approval in the United States for XHANCE, the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of XHANCE, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. For example, as part of its approval of XHANCE for the treatment of nasal polyps in adults, the FDA required that we conduct a randomized, double-blind, placebo controlled clinical study in children and adolescents with nasal polyposis to assess the safety, efficacy, and pharmacokinetics of XHANCE in this population. The FDA originally indicated the study was to be conducted in children and adolescents 6 to 17 years of age. On October 30, 2017, the FDA notified us that in response to our request it had modified the required age range to 12 to 17 years of age. We submitted our final protocol to the FDA with respect to the pediatric study by January 2018 as required, and we are required to complete the study by January 2022 and to submit a final report with respect to the study by July 2022. Because the Optinose EDS for XHANCE was designed for use in adult patients, we may discover that the dimensions of this EDS make it unsuitable for use in pediatric patient populations. As such, this pediatric study may also require us to undergo a costly and time-consuming development process to design and manufacture as appropriate a modified EDS to conduct these studies.

We are also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the United States grant similar powers to the competent authorities and impose similar obligations on companies.



In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or cGMP, regulations and adherence to commitments made in the NDA. Since XHANCE is a combination product, we will also need to comply with some of the FDA's manufacturing regulations for devices. In addition to cGMP, the FDA requires that our drug-device combination product comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with XHANCE, such as AEs, of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to XHANCE or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities.

If we fail to comply with applicable regulatory requirements following approval of XHANCE, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

**Our relationships with physicians, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.**

Our current and future operations with respect to the commercialization of XHANCE are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide XHANCE, and other parties through which we market, sell and distribute XHANCE. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws are described in greater detail in the previous section under "Business — Government Regulation — Healthcare Fraud and Abuse Laws," and include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or

covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize XHANCE and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

**If we are able to successfully commercialize XHANCE and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.**

We participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, and therefore we will be obligated to pay certain specified rebates and report pricing information with respect to XHANCE. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by the Centers for Medicare & Medicaid Services, or CMS, to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price, or AMP, and best price for the quarter.

If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the Public Health Service's 340B drug pricing program, or the 340B program, and under other similar government pricing programs. These programs are described in greater detail in the previous section under "Business — Government Regulation — Coverage and Reimbursement."

We will also be liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, or best price information to the government, we may be liable for civil monetary penalties in the amount of \$181,071 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be liable for civil monetary penalties of up to \$13,066 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of \$18,107 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid for XHANCE. On January 5, 2017, the U.S. Health Resources and Services Administration (HRSA), an agency of the HHS that administers the 340B drug pricing program issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways that we cannot presently anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program to be eligible to have its products paid for with federal funds. As part of this program, we would be obligated to make XHANCE available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

**Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.**

Our promotional materials, statements and training methods must comply with applicable laws and regulations, including FDA's prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. As healthcare professionals frequently prescribe corticosteroids for the treatment of chronic nasal inflammatory diseases, such as chronic rhinosinusitis, doctors could prescribe XHANCE for the treatment of chronic sinusitis and other chronic nasal inflammatory diseases, even though the FDA has granted approval of XHANCE only for the treatment of nasal polyps. If the FDA determines that our promotional materials, statements or activities constitute promotion of an off-label use, we could be required to modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the U.S. civil False Claims Act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional, materials or activities to constitute promotion of an off-

label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and market adoption of XHANCE could be impaired.

**Even though we have obtained FDA approval for XHANCE in the United States, we may never obtain approval for or successfully commercialize it outside of the United States, which would limit our ability to realize its full market potential.**

In order to market XHANCE outside of the United States, we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of XHANCE in those countries. While our management team has experience in obtaining foreign regulatory approvals at other companies, we do not have any product candidates approved for sale in any foreign jurisdiction, and we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market for XHANCE will be reduced and we would not be able to realize the full market potential of XHANCE.

**The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize XHANCE and affect the prices we may obtain.**

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities and affect our ability to profitably sell XHANCE. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These intended reforms are described in greater detail in the previous section under "Business — Government Regulation — U.S. Healthcare Reform."

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of XHANCE are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. In addition, the Bipartisan Budget Act of 2018 increased the Affordable Care Act required manufacturer point-of-sale discount from 50% to 70% off the negotiated price for Medicare Part D beneficiaries during their coverage gap period beginning in 2019. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of XHANCE or to successfully commercialize XHANCE.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for XHANCE and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize XHANCE.

**Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of XHANCE and any other product candidates that we may develop.**

We currently face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and this risk will increase significantly as we commercialize XHANCE and other product candidates that we may develop. We may face product liability claims, regardless of FDA approval for commercial manufacturing and sale as product liability claims may be brought against us by patients who have used XHANCE in any of our clinical trials, future patients, healthcare providers or others using, administering or selling our products, if and when approved. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for XHANCE;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs that we conduct in the future relating to XHANCE or our other product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to XHANCE or our other product candidates;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and

- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

We currently carry product liability insurance with coverage up to \$10.0 million in the aggregate, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. Further, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of XHANCE or the development of our other product candidates.

Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of XHANCE or any of our other product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnifications obligations may exceed the coverage under our product liability insurance policy. For example, the AVP-825 License Agreement provides for reciprocal indemnification obligations for each of the parties in the event that a product liability claim arises from, among other things, one party's development, manufacture, sale or commercialization activities for AVP-825.

### **Risks Related to Clinical Development and Regulatory Approval of XHANCE for the Treatment of Chronic Sinusitis and Our Other Product Candidates**

#### **The design and execution of clinical trials to support FDA-approval of XHANCE for the treatment of chronic sinusitis is subject to substantial risk and uncertainty.**

We intend to initiate a clinical program to support a follow-on indication of XHANCE for the treatment of chronic sinusitis. Similar to our NDA for XHANCE for the treatment of nasal polyps, we believe we may also be able to use the Section 505(b)(2) pathway for potential U.S. approval for XHANCE for the treatment of chronic sinusitis. Because there is no FDA-approved product for the treatment of chronic sinusitis, we believe there is substantial risk and uncertainty in planning and conducting adequate clinical trials to meet FDA requirements to support approval for this indication. If the clinical program required by the FDA is more costly or time-consuming than anticipated, we may decide to not pursue this follow-on indication. Additionally, if we do conduct clinical trials for this indication, XHANCE may not demonstrate sufficient efficacy or safety to support FDA approval. If we do not obtain a follow-on indication for the treatment of chronic sinusitis, our promotion of XHANCE will be limited to nasal polyps, which would limit our potential sales of XHANCE.

#### **The regulatory approval processes of the FDA are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.**

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory agency. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may not accept our NDA filing;
- the FDA may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA;



- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may change in a manner rendering our clinical data insufficient for approval.

With the exception of our NDA submission for XHANCE, we have not previously submitted an NDA or any similar drug approval filing to the FDA for any product candidate, and we cannot be certain that any of our current product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

**Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.**

Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our clinical trials for the follow-on indication of XHANCE for the treatment of chronic sinusitis or our other product candidates may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for these product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA may not approve that product candidate and we would not be able to commercialize it, which could impair our ability to gain or maintain profitability.

**Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.**

We may experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- inability to raise funding necessary to initiate or continue a clinical trial;
- delays in obtaining regulatory approval to commence a clinical trial;
- delays in reaching agreement with the FDA or foreign regulatory authorities on final trial design or the scope of the development program;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval;
- delays in recruiting suitable patients to participate in a clinical trial;
- patients' delays or failure to complete participation in a clinical trial or return for post-treatment follow-up;
- clinical sites dropping out of a clinical trial;
- time required to add new clinical sites; or
- delays by our contract manufacturing organizations, or CMOs, to produce and deliver a sufficient supply of clinical trial materials.

If clinical trials for our product candidates are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed.

**We will need to identify proprietary names for our product candidates that are acceptable to FDA, and any delay associated with doing so may adversely impact our business.**

Any proprietary name we propose to use with our product candidates in the United States must be reviewed and accepted by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA.

**Our product candidates, if approved, may require REMS, which may significantly increase our costs.**

Our product candidates, if approved, may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to healthcare professionals and restrictions on distribution and use. We cannot predict the specific scope or magnitude of REMS that may be required as part of the FDA's approval of our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize our product candidates may increase significantly and distribution restrictions could limit sales. Similar requirements may arise in countries outside of the United States.

**Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.**

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of any of our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

#### **Risks Related to Our Reliance on Third Parties**

**If we encounter difficulties in maintaining commercial manufacturing and supply agreements with our third-party manufacturers and suppliers of XHANCE, our ability to commercialize XHANCE would be impaired.**

We do not own any manufacturing facilities. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources to manufacture and test, on a commercial scale, the technical performance of XHANCE and our other product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and CMOs and suppliers who assist in the production, assembly, test, supply, storage and distribution of XHANCE and its components in our clinical trials and FDA registration, and we control only some of the aspects of their activities. We may not be able to maintain terms that are favorable to us. We may not be able to enter into commercial manufacturing and supply agreements with any necessary third parties, should such additional agreements become necessary. If we are unable to enter into such agreements or maintain existing agreements, each on commercially reasonable terms, our ability to commercialize XHANCE would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

**If we encounter issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply XHANCE.**

We currently depend on contract manufacturers and suppliers for XHANCE and its components. Although we could obtain each of these components from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for each such component, which could be costly and cause significant delays. Each of our current commercial manufacturing and supply agreements include limitations on our ability to utilize alternative manufacturers or suppliers for these components above certain specified thresholds during the terms of the agreements, which impairs our ability to fully implement any future manufacturing strategies to prevent supply shortages or quality issues.

In addition, some of our suppliers, including our active pharmaceutical ingredient, or API, supplier and our contract manufacturers, conduct their manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require one of these manufacturers or suppliers to discontinue production at their respective facility, or if the equipment used for the production of XHANCE in these facilities is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer or supplier to provide components or API needed for XHANCE, or to manufacture XHANCE may be significantly impaired. In the event that these parties suffer a temporary or protracted loss of its facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the respective component before any components manufactured by such manufacturer or by such supplier could be sold or used.

Any production shortfall that impairs the supply of XHANCE or any of these components could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for XHANCE, which could adversely affect our product sales and operating results materially.

**If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to XHANCE or their performance is substandard, our product supply may be impacted.**

Our reliance on a limited number of manufacturers, wholesalers and distributors exposes us to the following risks, any of which could limit commercial supply of our products, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver XHANCE for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could default on their agreements with us to meet our requirements for commercial supply of XHANCE;
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute our products and we may incur additional cost; and
- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay our commercial programs.

Our reliance on third parties reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates or supply our commercial volume of XHANCE. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action,

including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

**Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.**

As we further scale up manufacturing of XHANCE and conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to continue with commercial marketing of XHANCE. In addition, quality issues may arise during scale-up and of commercial manufacturing processes. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for our products.

**We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to obtain regulatory approval for or commercialize our product candidates.**

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our prospective preclinical and clinical programs. We rely on these parties for execution of our clinical trials, and we control only some of the aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors. GCPs are enforced by the FDA and foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat preclinical studies and clinical trials, which would increase our operating expenses and delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons or if we receive additional FDA notices that do require corrective action, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to

disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

## **Risks Related to Our Business Operations and Industry**

### **Our future success depends on our ability to retain and have the full attention of our key executives and to attract, retain and motivate other qualified personnel.**

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive team and, in particular, the services of Peter K. Miller, our Chief Executive Officer, and Ramy A. Mahmoud, our President and Chief Operating Officer. Each of Mr. Miller and Dr. Mahmoud is employed by us at will and is permitted to terminate his employment with us at any time. We entered into employment agreements with Mr. Miller and Dr. Mahmoud in October 2017, but Mr. Miller and Dr. Mahmoud continue to be employed at will. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Miller or Dr. Mahmoud could impede the achievement of our development and commercialization objectives.

Recruiting and retaining qualified employees for our business, including scientific, technical and sales and marketing personnel, will also be critical to our success. Competition for skilled personnel in our industry is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in our commercialization efforts or in the performance of any future clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our research, development and commercialization objectives.

### **We will need to grow the size of our organization, and we may experience difficulties in managing this growth.**

Implementation of our development and commercialization strategies will require additional managerial, operational, sales, marketing, financial and other resources. Our current management, personnel and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization XHANCE and any other products for which we obtain marketing approval;
- overseeing our preclinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of any approved product;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and
- improving our managerial, development, operational and financial systems and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

**We are subject to intense competition and, if we are unable to compete effectively, our product candidates, if approved, may not reach their commercial potential.**

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We face competition with respect to XHANCE from INS, oral steroids and other medical management products, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from many different sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies.

The key competitive factors that we expect to impact the commercial success of XHANCE and any other product candidates we may develop are likely to be their efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement. Nasonex, marketed by Merck, is currently the only other branded drug therapy approved by the FDA for the treatment of nasal polyps, which is our initial indication for XHANCE. A generic version of Nasonex, mometasone furoate monohydrate, was approved by the FDA for, among other indications, the treatment of nasal polyps and launched in 2016. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. We are not aware of any drug therapy approved by the FDA or foreign regulatory agencies for the treatment of chronic sinusitis.

Even though they have not been approved for the treatment of such indications, published clinical practice guidelines do recommend the use of INS products for the treatment of chronic rhinosinusitis and nasal polyps in an effort to maximize medical therapy prior to surgical intervention. Currently approved branded INS products include Rhinocort, marketed by AstraZeneca, Nasacort AQ, marketed by sanofi-aventis, Beconase AQ, Flonase, and Veramyst, each marketed by GlaxoSmithKline, Qnasl, marketed by Teva Pharmaceuticals, and Omnaris and Zetonna, each marketed by Sunovion Pharmaceuticals. Due to the limitations of current treatments, several companies are investigating the treatment of nasal polyps with biologic monoclonal antibodies. To date, four biologic monoclonal antibodies have been studied in nasal polyps: omalizumab, reslizumab, mepolizumab and dupilumab. Most of these INS and biologics companies, as well as other potential competitors, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs, or drugs they may develop in the future, may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render XHANCE or any of our other product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing XHANCE or any of our other product candidates. Our competitors may also obtain FDA or other regulatory approval of products more rapidly than expected or may obtain better or preferred market access by offering large rebates to payors or by other means. We may not have accurately or completely predicted the development of new and improved or low-cost surgical interventions, alternative medical therapies or other market-disrupting events. If we are unable to manufacture, distribute, stimulate demand reaching the predicted market share, overcome barriers to access or otherwise effectively commercialize the product, all of which factors may be influenced by current or future competition, then our opportunity to generate revenue from the sale of XHANCE or any of our other product candidates, if approved, will be compromised.

**Our long-term growth depends on our ability to develop and commercialize additional ENT products.**

It is important to our business that we continue to build a more complete product offering within the ENT and allergy markets. We are evaluating the use of our proprietary EDS technology to develop new product candidates for the ENT and allergy markets. Developing additional product candidates is expensive and time-consuming and could divert management's attention away from the commercialization of XHANCE. Even if we are successful in developing additional product candidates, the success of any new product candidates or enhancement to any existing product candidates will depend on several factors, including our ability to:

- properly identify and anticipate ENT and allergy physician and patient needs;
- develop, obtain necessary regulatory clearances or approvals, and introduce new product candidates or product enhancements in a timely manner;



- demonstrate, if required, the safety and efficacy of new product candidates with data from preclinical studies and clinical trials;
- avoid infringing upon the intellectual property rights of third parties;
- comply with all regulations relating to the marketing of new product candidates, including any new or modified EDS technologies; and
- provide adequate training to potential users of our product candidates.

If we are unsuccessful in developing and commercializing additional product candidates in other areas of the ENT and allergy markets, our ability to gain and maintain profitability may be impaired.

**We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could negatively impact our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.**

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial-stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to complete technology transfers and integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities as part of the transaction. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

**Our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.**

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

In October 2017, we adopted a Code of Business Conduct and Ethics to govern and deter such behaviors, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

**The security of our information technology systems may be compromised, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.**

Our information technology systems may be vulnerable to physical or electronic intrusions, computer viruses or other attacks. As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients, our employees and business partners. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, however, there can be no assurance that such use or disclosure will not occur.

**If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.**

We may be subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Certain of these laws and regulations are described in greater detail in the previous section under "Business — Government Regulation — Healthcare Privacy Laws." Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

**Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.**

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential, proprietary or personal information, we could incur material legal claims and liability and damage to our reputation and the development and commercialization of our product candidates could be delayed.

**If we fail to successfully manage the implementation of our new global enterprise resource planning system, it could adversely affect our operations and operating results.**

We are in the process of implementing a new global enterprise resource planning (ERP) system. This system will replace many of our existing operating and financial systems. Such an implementation is a major undertaking, both financially and from a management and personnel perspective. Any disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process financial transactions, fulfill contractual obligations or otherwise operate our business.

**We are subject to risks inherent in foreign operations.**

We currently operate portions of our business through our foreign subsidiaries, including through our Norwegian subsidiary, OptiNose AS, which currently owns a substantial portion of our intellectual property and conducts development activities, and our United Kingdom subsidiary OptiNose UK Ltd., which performs research and development for the Optinose EDS technology as well as other services. We have committed, and intend to continue to commit, resources to our international operations. We are subject to a number of risks associated with our international business operations and activities that may increase liability, costs, and require significant management attention. These risks include:

- compliance with the laws of the United States, the United Kingdom, Norway, and other countries that apply to our international operations, including import and export legislation;
- compliance with foreign data protection laws and regulations in the United Kingdom, Norway and other countries that apply to our international operations;
- the complexities and expenses of administering a business abroad;
- complications in compliance with, and unexpected changes in, tariffs, trade barriers, price and exchange controls and other foreign regulatory requirements, including potential trade conflicts, changes to trade agreements/treaties, and the implementation of trade restrictions;
- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- uncertainties of laws and enforcement relating to the protection of intellectual property or secured technology;
- litigation in foreign court systems;
- language barriers;
- changes in tax laws and regulations in the jurisdictions in which we operate;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- difficulties staffing and managing foreign operations; and
- workforce uncertainty in countries where labor unrest is more common than in the United States;

There can be no assurance that the policies and procedures we implement to address or mitigate these risks will be successful, that our personnel will comply with them or that we will not experience these factors in the future or that they will not have a material adverse effect on our business, results of operations and financial condition.

**Our corporate structure and foreign operations may have adverse tax consequences and expose us to additional tax liabilities.**

A substantial portion of our intellectual property, including rights to XHANCE and rights under the AVP-825 License Agreement, are owned by OptiNose AS, our Norwegian subsidiary. In addition, as we plan for the commercial launch of XHANCE, commercial functions may be conducted by a current or potential future foreign subsidiary.

We operate pursuant to written intercompany service and related agreements, or transfer pricing agreements. These transfer pricing agreements establish transfer prices for intellectual property licenses, production, marketing, management, technology development and other services performed by our group companies for other group companies. Transfer prices are prices that one company in a group of related companies charge to another member of the group for goods, services or the use of property. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be consistent with those between unrelated companies dealing at arm's length. Our transfer pricing arrangements are not binding on applicable tax authorities, and, if tax authorities in any country were successful in challenging our transfer prices as not representing arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income. A reallocation of taxable income from one tax jurisdiction to another tax jurisdiction could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation.

If we generate sales of XHANCE in the United States or otherwise generate any other sales or revenues, a portion of the income we generate may be allocated to one or more of our current or future foreign subsidiaries and repatriation of any cash from our foreign subsidiaries to the United States may trigger significant adverse tax consequences. If we generate cash through our foreign operations or if the cash generated by our U.S. operations is not sufficient to fund our U.S. operations, we may face challenges applying any such cash held by our foreign subsidiaries to support the growth of our U.S. operations and any strategic opportunities in the United States. If we are forced to repatriate any foreign-held cash, we could incur a significant tax charge, and our business, operating results or financial condition could be adversely impacted.

Income earned by our foreign subsidiaries may give rise to United States corporate income tax, even if there are no distributions to the United States, to the extent that our foreign subsidiaries generate income that is subject to Subpart F or similar provisions of the U.S. Internal Revenue Code, such as the new global intangible low-taxed income provisions, generally referred to in this paragraph as Subpart F. Subpart F income includes, for example, certain "passive" income, certain income from intercompany transactions involving our foreign subsidiaries, foreign subsidiary income over a legislative threshold, and certain income of any foreign subsidiary which makes an "investment in U.S. property", such as holding the stock in, or making a loan to, a U.S. corporation. Any income taxable under Subpart F is currently taxable in the United States at federal corporate income tax rates of up to 21.0%, even if it is not distributed to us. We have not treated any of our foreign subsidiaries' income as being Subpart F income pursuant to available exemptions for which we believe we qualify. We may, however, be required to do so and pay taxes on the prior and future income of our foreign subsidiaries if we do not qualify for an available exemption.

**Comprehensive tax reform legislation could adversely affect our business and financial condition.**

On December 22, 2017, the US government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act introduced significant changes to the US tax laws. The Tax Act, among other things, contains significant changes to corporate taxation, including but not limited to the reduction of the corporate tax rate from a top rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of losses arising in taxable years beginning after 2017 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). Any federal net operating loss carryovers for taxable years beginning after 2017 will be carried forward indefinitely pursuant to the Tax Act. The Tax Act also limits deductions for compensation in excess of \$1 million, which could impact our ability to deduct such corporate expenses. We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the federal corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

**We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act and other U.S. and foreign anti-corruption anti-money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business.**

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. We are also subject to the U.S. Foreign Corrupt

Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti-bribery and anti-money laundering laws in countries outside of the United States in which we conduct our activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize XHANCE and any other product candidates that we may develop, we may engage with third-party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be subject to our control. It is our policy to implement safeguards to discourage these practices by our employees, consultants, sales agents and distributors. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption, anti-money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In addition, the U.S. government may seek to hold us liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.

### **Risks Related to Our Intellectual Property**

**If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, XHANCE or our other product candidates, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed.**

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our strategy is to seek patent protection for XHANCE, our other product candidates and their compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

As of December 31, 2017, we owned a total of 43 U.S. patents and 43 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2030. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

**We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.**

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a



federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of the Optinose EDS technology. Such a loss of patent protection could compromise our ability to pursue our business strategy.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

**We may not be able to protect our intellectual property rights throughout the world.**

Filing, prosecuting and defending patents on XHANCE, our other product candidates and the Optinose EDS technology throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Furthermore, the prevalence of counterfeit medicines, which is one that has been deliberately and fraudulently mislabeled as to its identity and source, is a significant and growing industry-wide issue that could impact our revenue and our reputation for which we may have limited or no recourse. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

**Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.**

Our commercial success depends upon our ability to develop, manufacture, market and sell XHANCE and our other product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As XHANCE and our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. For instance, our use of the Section 505(b)(2) regulatory pathway for the follow-on indication of chronic sinusitis or any of our other product candidates will require us to provide a Paragraph IV certification to the NDA and patent holders of the RLD pursuant to the Hatch-Waxman Act if the RLD is covered by Orange Book-listed patents. If the NDA or patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patents, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our product candidates do not infringe other parties' patents or other proprietary rights and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and

development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

**Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.**

Our competitors may seek to market generic versions of any of our approved products by submitting ANDAs to the FDA or new products that use our approved products as the RLD, in each case where our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with XHANCE and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

**Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.**

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in United States federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

**We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.**

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property

rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

**Intellectual property rights do not prevent all potential threats to competitive advantages we may have.**

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- Others may be able to make drug and device components that are the same as or similar to XHANCE and our other product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- The prosecution of our pending patent applications may not result in granted patents;
- Granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;
- With respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- We may not develop additional proprietary technologies that are patentable;
- The patents of others may have an adverse effect on our business; and
- We may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

**If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.**

In addition to seeking patent protection for certain aspects of our product candidates and delivery technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily

entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

**If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.**

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. OPTINOSE®, XHANCE™ and Breath Powered® are trademarks or registered trademarks of ours in the United States. Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

## **Risks Related to Ownership of Our Common Stock and Our Status as a Public Company**

### **An active market for our common stock may not develop.**

We completed our initial public offering in October 2017, but prior to that offering there was no market for our shares of common stock. Although our common stock is listed on Nasdaq, an active market for our common stock may not develop. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

### **The price of our common stock may be volatile and you may lose all or part of your investment.**

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this 10-K, these factors include:

- our ability to successfully commercialize XHANCE;
- any delay in our regulatory approval or filings for XHANCE for a follow-on indication for the treatment of chronic sinusitis or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter, a request for additional information, or a CRL;
- the success of competitive products or technologies;
- adverse regulatory actions with respect to our product candidates, including the failure to receive regulatory approval, or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions or divestitures, strategic collaborations, joint ventures, collaborations or capital commitments;

- the commencement, enrollment or results of planned clinical trials of our product candidates or any future clinical trials we may conduct, or any changes generally in the development status of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- the outcome of any investigations or regulatory scrutiny of our operations or litigation that may be brought against us;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated variations in our quarterly operating results;
- the number and characteristics of our efforts to in-license or acquire additional product candidates or products;
- introduction of new products or services by us or our competitors;
- failure to meet the estimates and projections of the investment community or financial guidance that we may otherwise provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated changes in estimates as to development timelines that we may provide to the public;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general political, economic, industry and market conditions;
- investors' general perception of our company and our business;
- publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks stated above could have a material adverse effect on the market price of our common stock.

**A significant portion of our total outstanding shares are restricted from resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.**

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that the holders of a large number of shares intend to sell, substantial



amounts of our common stock in the public market, the market price of our common stock could decline significantly.

As of March 1, 2018, there were 37,865,740 outstanding shares of our common stock. Various shareholders who held shares of our common stock before our October 2017 initial public offering are currently restricted from selling their shares for a 180-day period, which is until the close of the market on April 9, 2018, pursuant to a contractual lock-up agreements with the underwriters and/or pursuant to the terms of our Second Amended and Restated Shareholders' Agreement. The representatives of the underwriters may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. Holders of an aggregate of 30,482,155 shares of our common stock have rights, subject to specified conditions, that require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. Additionally, these shares are also eligible for sale without registration under Rule 144, subject to volume limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

**Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.**

We expect that we may require additional capital in the future to execute our business plan. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options, warrants and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

**Our principal stockholders and management own a majority of our stock and are able to exert significant control over matters subject to stockholder approval, which could prevent new investors from influencing significant corporate decisions.**

Our executive officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates, in the aggregate, beneficially own approximately 82.2% of our outstanding common stock as of March 1, 2018. Entities associated with Avista Capital Partners II, L.P., or Avista, our largest stockholder, collectively hold as a group approximately 48.6% of our outstanding common stock as of March 1, 2018. As a result, Avista can significantly influence the outcome of matters requiring stockholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of Avista may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. For instance, under the terms of our fourth amended and restated certificate of incorporation, neither Avista nor any of its respective representatives on our board of directors are required to offer us any transaction opportunity of which they become aware, and they could take any such opportunity for themselves or offer it to other companies in which they have an investment, unless that opportunity is expressly offered to a person serving on our board of directors solely in his or her capacity as one of our directors. These actions might affect the prevailing market price for our common stock. In addition, because Avista and certain of our other principal stockholders have held their shares for several years, they may be more interested in selling our company to an acquiror than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. Such concentration of ownership control may also:

- delay, defer or prevent a change in control;
- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We may also take actions that our other stockholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause the value of your investment to decline.

**Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.**

Provisions in our fourth amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that :

- permit our board of directors to issue up to five million shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders;
- provide that our board of directors will be classified into three classes with staggered, three-year terms and that, subject to the rights of Avista to remove its respective director nominees with or without cause, directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the voting power of outstanding shares of our capital stock;
- subject to any director nomination rights afforded Avista, provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- following the date that Avista ceases to hold a majority of the outstanding shares of our common stock, require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that, with the exception of director nominees submitted by Avista pursuant to our Stockholders Agreement, dated October 2, 2017 with Avista, stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- require that the amendment of certain provisions of our certificate of incorporation relating to anti-takeover measures may only be approved by a vote of 66 $\frac{2}{3}$ % of our outstanding common stock;
- require that the amendment of our bylaws be approved by the affirmative vote of a majority of directors then in office or 66 $\frac{2}{3}$ % of our outstanding common stock entitled to vote thereon;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the chairman or vice chairman of our board of directors, our chief executive officer, a majority of our board of directors or, for so long as Avista holds a controlling ownership interest in our common stock, by the holders of a majority of our outstanding common stock.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Under our fourth amended and restated certificate of incorporation, we have elected not to be governed by Section 203 of the Delaware General Corporation Law until such time that Avista ceases to own 15% or more of our capital stock. Our fourth amended and restated certificate of incorporation does, however, contain a provision that generally mirrors Section 203 of the Delaware General Corporation Law, except that it excludes Avista and its affiliates from the definition of "interested stockholder." At such time that Avista ceases to own 15% or more of our capital stock, we will be governed by the provisions of Section 203 of the Delaware General Corporation Law. These provisions may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, prior to the time the stockholder has become an interested stockholder, the board of directors has approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder.

These provisions of our fourth amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law could have the effect of discouraging potential acquisition proposals and delaying or preventing a

change in control. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests or provide an opportunity for our stockholders to receive a premium for their shares of our common stock. These provisions could also affect the price that some investors are willing to pay for our common stock.

**Our certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.**

Our fourth amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our fourth amended and restated certificate of incorporation also provides that the United States District Court for the District of Delaware and any appellate courts thereof will be the exclusive forum for resolving any such complaint for which subject matter jurisdiction of such claim is vested exclusively in the federal courts of the United States of America. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

**We may fail to qualify for continued listing on Nasdaq which could make it more difficult for investors to sell their shares.**

We list our common stock on The Nasdaq Global Market. We will need to satisfy the continued listing requirements of The Nasdaq Stock Market, LLC, or Nasdaq, for inclusion on The Nasdaq Global Market to maintain such listing, including, among other things, the maintenance of a minimum bid price of \$1.00 per share and stockholders' equity of at least \$10.0 million. There can be no assurance that we will be able to maintain compliance with the continued listing requirements or that our common stock will not be delisted from Nasdaq in the future. If our common stock is delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares are a "penny stock," which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

**If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.**

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain and you may never receive a return on your investment.**

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to

finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of the Note Purchase Agreement precludes us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**We may be subject to securities litigation, which is expensive and could divert our management's attention.**

As we operate in the pharmaceutical industry, we may be especially vulnerable to volatility in the market price of our common stock, especially to the extent that various factors affect the common stock of companies in our industry. In the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

**We are an "emerging growth company" and intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we are eligible to and intend to take advantage of some of the exemptions from reporting requirements applicable to other public companies, but not to emerging growth companies, including, but not limited to, an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, reduced disclosure about executive compensation arrangements pursuant to the rules applicable to smaller reporting companies and no requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. We will remain an emerging growth company until the earliest of (1) the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2023, (2) the beginning of the first fiscal year after our annual gross revenue is \$1.07 billion or more, (3) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities and (4) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the end of the second quarter of that fiscal year.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive as a result of our taking advantage of these exemptions. If some investors find our common stock less attractive as a result of our choices, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to timely and accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.**

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, as well as the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we will be required, under Section 404 of the Sarbanes-Oxley Act, to include in our Form 10-K filing for that year a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the

effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of an exemption from the independent registered public accounting firm attestation requirement.

Our compliance with Section 404's requirement to furnish a report by management requires that we incur substantial accounting expense and expend significant management efforts. Prior to our initial public offering in October 2017, we were never required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. We currently do not have an internal audit function. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the Securities and Exchange Commission, or the SEC, or other regulatory authorities.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to timely and accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting once that firm begins the testing procedures over internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

**Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.**

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

**We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.**

Prior to the consummation of our initial public offering in October 2017, we were not subject to public company reporting obligations. We now incur significant additional legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act, the Dodd-Frank Act of 2010, the Exchange Act, as well as rules of the SEC and Nasdaq, for example, resulted in, and will result in further, significant initial costs to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by Nasdaq and the SEC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may

evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, failure to comply with these rules and regulations might make it more difficult and more expensive for us to obtain director and officer liability insurance, or we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to maintain the same or similar coverage.



**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our principal office is located in Yardley, Pennsylvania, where we lease approximately 30,000 square feet of office space pursuant to a lease that expires in May 2021. We also lease facilities in Ewing, New Jersey, Oslo, Norway and Swindon, England. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

We are not currently a party to any legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

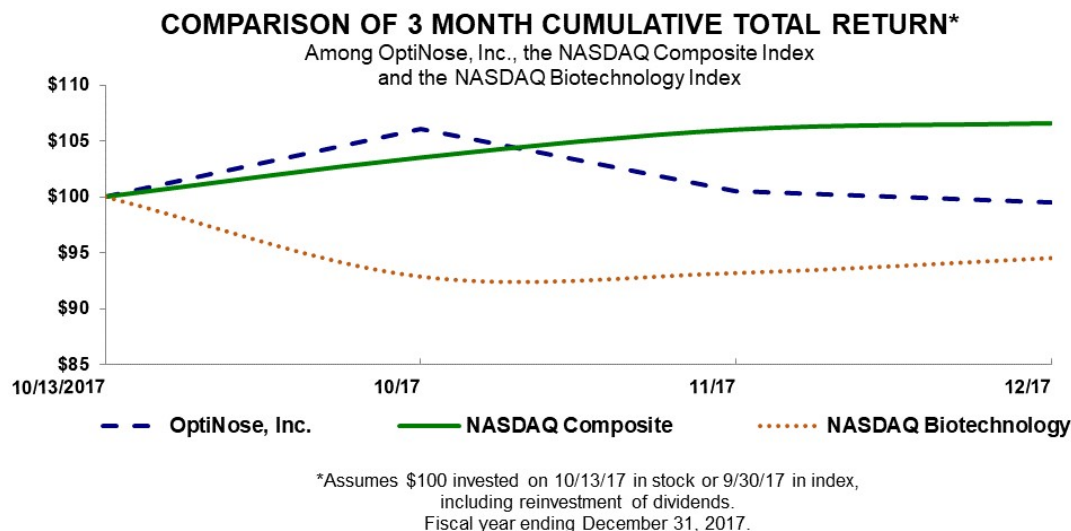
Our common stock has been publicly traded on The Nasdaq Global Select Market under the symbol "OPTN" since October 13, 2017. Prior to that time, there was no public market for our common stock. Shares sold in our initial public offering on October 12, 2017 were priced at \$16.00 per share. The following table sets forth the high and low sales price of our common stock, as reported by the Nasdaq Global Select Market for the periods indicated:

|   | High     | Low      |
|---|----------|----------|
| Year Ended December 31, 2017                |          |          |
| Fourth Quarter (beginning October 13, 2017) | \$ 21.46 | \$ 15.01 |

The last reported sale price of shares of our common stock on March 12, 2018 was \$17.36 per share.

**Stock Performance Graph**

The graph set forth below compares the cumulative total stockholder return on our common stock between October 13, 2017 (the first date that shares of our common stock were publicly traded) and December 31, 2017, with the cumulative total return of (a) the Nasdaq Biotechnology Index and (b) the Nasdaq Composite Index, over the same period. This graph assumes the investment of \$100 after the market closed on October 13, 2017 in each of our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index. The graph assumes our closing sales price on October 13, 2017 of \$19.00 per share as the initial value of our common stock and not the initial offering price to the public in our initial public offering of \$16.00 per share.



### Holders of Record

As of March 1, 2018, there were 37,865,740 shares of our common stock outstanding. There were approximately 40 stockholders of record at March 1, 2018. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

### Dividends

We have never declared or paid any cash dividend on our common stock and our board of directors does not intend to do so in the foreseeable future. In addition, the Note Purchase Agreement precludes us from paying dividends. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the board of directors in light of conditions then existing, including earnings, financial condition, capital requirements and other factors.

### Securities Authorized for Issuance under Equity Compensation Plans

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

### Recent Sales of Unregistered Securities

Set forth below is information regarding securities issued by us during the year ended December 31, 2017 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such securities, and information relating to the section of the Securities Act, or the rule of the SEC, under which exemption from registration was claimed:

#### (a) Issuances of Capital Stock.

1. In March 2017, we issued and sold an aggregate of 1,065,451 shares of our Series D Preferred Stock to certain new and existing investors at a purchase price of \$32.85 per share, for aggregate consideration of \$35.0 million.
2. In April 2017 and May 2017, we issued and sold to certain of our existing stockholders an additional 52,127 shares of Series D Preferred Stock at a purchase price of \$32.85 per share, for aggregate consideration of \$1.7 million.

#### (b) Convertible Notes

1. In September 2015, we issued and sold convertible notes in the aggregate principal amount of \$15.0 million. In March 2017, concurrently with our Series D Preferred Stock financing, the notes were converted

into an aggregate of 687,474 shares of our Series C-2 Preferred Stock at a conversion price of approximately \$28.40 per share.

(c) Stock Option Grants

1. On January 23, 2017, we granted a stock option to purchase a total of 158,834 shares of common stock at an exercise price of \$5.14 per share to one executive officer pursuant to our 2010 Stock Incentive Plan.
2. On January 30, 2017, we granted stock options to purchase a total of 144,395 shares of common stock at an exercise price of \$5.14 per share to one executive officer pursuant to our 2010 Stock Incentive Plan.
3. On February 13, 2017, we granted stock options to purchase a total of 20,214 shares of common stock at an exercise price of \$5.14 per share to two employees pursuant to our 2010 Stock Incentive Plan.
4. On February 20, 2017, we granted a stock option to purchase 5,775 shares of common stock at an exercise price of \$5.14 per share to one employee pursuant to our 2010 Stock Incentive Plan.
5. On February 27, 2017, we granted a stock option to purchase 5,775 shares of common stock at an exercise price of \$5.14 per share to one employee pursuant to our 2010 Stock Incentive Plan.

The offers, sales and issuances of the securities described in paragraphs (a) and (b) above were exempt from registration under the Securities Act in reliance on Regulation D of the Securities Act.

With respect to the shares of Series C-2 Preferred Stock issued upon conversion of the convertible notes in March 2017 described in paragraph (b), the issuance of such shares was exempt from registration under Section 3(a)(9) of the Securities Act.

The grants of stock options described in paragraph (c) above to our executive officers and directors were exempt from registration under Section 4(a)(2) of the Securities Act as transactions not involving any public offering. The remaining grants of stock options described in paragraph (c) above were exempt from registration under the Securities Act in reliance on Rule 701 as offers and sales of securities under written compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All purchasers of securities in transactions exempt from registration pursuant to Regulation D described above represented to us in connection with their purchase that they were accredited investors, as defined in Rule 501 under the Securities Act, and were acquiring the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from the registration requirements of the Securities Act.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The certificates representing the issued securities described in this Item 5 included appropriate legends setting forth that the applicable securities have not been registered and reciting the applicable restrictions on transfer. There were no underwriters employed in connection with any of the transactions set forth in this Item 5. Except as set forth above, we did not sell any shares of our common stock or our preferred stock, or grant any stock options or restricted stock awards, during the year ended December 31, 2017 that were not registered under the Securities Act of 1933, as amended, or the Securities Act, and that have not otherwise been described in a Quarterly Report on Form 10-Q.

**Issuer Purchases of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

**Use of Proceeds from Registered Securities**

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-220515) that was declared effective by the SEC on October 12, 2017. On October 17, 2017, 8,625,000 shares of our common stock were sold at a price to the public of \$16.00 per share, for aggregate gross proceeds of \$138.0 million. As of the date of filing this report, the offering has terminated, and all of the securities registered pursuant to the offering were sold prior to termination. Jefferies and Piper Jaffray acted as lead joint book-running managers in the IPO, and BMO Capital Markets and RBC Capital Markets acted as joint book-running managers in the IPO.

On October 17, 2017 we received proceeds from the IPO of \$128.3 million, which was net of underwriting discounts and commissions of approximately \$9.7 million. Of this amount, we paid offering expenses of approximately \$2.8 million. The balance of the funds totaling approximately \$125.5 million shall be used in a manner consistent with the use of proceeds described in the final prospectus for the IPO filed with the SEC on October 12, 2017 (the "Final Prospectus").

The foregoing expenses are a reasonable estimate of the expenses incurred by us in the offering and do not represent the exact amount of expenses incurred. All of the foregoing expenses were direct or indirect payments to persons other than (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

There has been no material change in the use of proceeds from the IPO as described in the Final Prospectus. During the period from the closing of our IPO to December 31, 2017, we used \$13.8 million of the proceeds as follows:

- approximately \$7.7 million to support the planned launch of XHANCE, including investments in marketing and sales, inventory and our commercial infrastructure;
- approximately \$1.7 million to fund further development efforts for XHANCE; and
- approximately \$4.4 million to fund other working capital and general corporate purposes, including costs of operating as a public company.

The foregoing amounts represent the Company's reasonable estimate of the amount of net offering proceeds applied to such activities instead of the actual amount of net offering proceeds used.

## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. This section should be read together with our consolidated financial statements and accompanying notes and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Form 10-K. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future.

| (in thousands, except share and per share data)       | Years Ended December 31, |           |             |
|---|--------------------------|-----------|-------------|
|   | 2017                     | 2016      | 2015        |
| <b>Consolidated Statement of Operations Data:</b>     |                          |           |             |
| Licensing revenues                                    | \$ —                     | \$ 47,500 | \$ 85       |
| Operating expenses:                                   |                          |           |             |
| Research and development                              | 16,832                   | 15,311    | 22,156      |
| Selling, general and administrative                   | 31,698                   | 6,869     | 6,006       |
| Total operating expenses                              | 48,530                   | 22,180    | 28,162      |
| (Loss) income from operations                         | (48,530)                 | 25,320    | (28,077)    |
| Other (income) expense, net:                          |                          |           |             |
| Interest (income) expense                             | 607                      | 3,374     | 791         |
| Other (income) expense                                | (235)                    | (667)     | (554)       |
| Total other (income) expense, net                     | 372                      | 2,707     | 237         |
| Net (loss) income                                     | (48,902)                 | 22,613    | (28,314)    |
| Accretion of redeemable convertible preferred stock   | (13,065)                 | (13,114)  | (12,061)    |
| Net (loss) income attributable to common stockholders | \$ (61,967)              | \$ 9,499  | \$ (40,375) |
| Net (loss) income per share of common stock,          |                          |           |             |
| basic   | \$ (5.63)                | \$ 0.40   | \$ (9.97)   |
| diluted   | \$ (5.63)                | \$ 0.32   | \$ (9.97)   |
| Weighted average common shares outstanding,           |                          |           |             |
| basic   | 10,999,121               | 4,054,316 | 4,049,668   |
| diluted   | 10,999,121               | 4,980,181 | 4,049,668   |

| (in thousands)                          | As of December 31, |           |           |
|---|--------------------|-----------|-----------|
|   | 2017               | 2016      | 2015      |
| <b>Consolidated Balance Sheet Data:</b> |                    |           |           |
| Cash and cash equivalents               | \$ 234,854         | \$ 36,797 | \$ 15,198 |
| Working capital <sup>(1)</sup>          | 223,390            | 34,765    | 8,624     |
| Total assets                            | 241,136            | 41,551    | 16,009    |
| Convertible notes                       | —                  | 15,256    | 14,480    |
| Long term debt, net                     | 71,863             | —         | —         |
| Redeemable convertible preferred stock  | —                  | 168,173   | 155,059   |
| Accumulated deficit                     | (211,269)          | (151,102) | (161,255) |
| Total stockholders' deficit             | 154,496            | (151,197) | (161,392) |

<sup>(1)</sup> Working capital is calculated as current assets minus current liabilities.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our historical consolidated financial statements and the related notes thereto appearing in this Annual Report. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat, or ENT, and allergy specialists. Our lead product, XHANCE™ (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System, or EDS, that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids, or INS, that have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS. We also believe that payors will respond favorably to XHANCE's clinical, cost, and quality-of-care profile, as compared to current and potential future costly drug therapy and surgical treatment options.

On September 18, 2017, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, for XHANCE for the treatment of nasal polyps in patients 18 years of age or older. Based upon our research of over 300 launches between 2010 and 2016, we believe the evidence suggests that the success of a launch is highly dependent upon four critical factors: level of unmet need that exists within the market, level of clinical differentiation of a brand, market access and brand awareness. Therefore, rather than rushing our product to the market immediately following approval, our Company employed a different, purposeful launch model that would enable our commercial team to build market access for XHANCE and achieve critical levels of customer awareness to facilitate adoption upon making XHANCE available in the market.

Since the FDA approved of our NDA for XHANCE, we have been focused on executing our integrated launch plan with the objective of making XHANCE widely available through retail pharmacies in the second quarter of 2018; we now believe XHANCE will be available in retail pharmacies in early April 2018. The key strategies in our integrated launch plan include: (i) build a robust supply chain network and quality management system, (ii) drive awareness and appreciation of the clinical differentiation of XHANCE, (iii) design and deploy our customer facing model, (iv) engage commercial payors with the objective of securing tier 3 coverage, and (v) develop our internal capabilities (Finance, HR, IT, Data Analytics and Compliance) to support a commercial stage company. We have made progress in each of these key strategic areas:

- **Commercial Supply Chain.** We have entered into commercial supply agreements with our key suppliers, spent significant time with our suppliers to oversee product production and quality management, and

manufactured our initial commercial supply of XHANCE. We have contracted with a third-party logistics partner and are in the process of finalizing agreements with our distribution partners.

- **Brand Awareness.** We have executed a broad, multi-channel awareness campaign leveraging digital, non- personal promotion and journal advertising and have already reached over 10,000 ENT physicians and allergists with disease state and branded messages. In November 2017, we launched a nurse educator team of approximately 85 nurse professionals who have since called on approximately 5,000 ENT physicians and allergists and delivered over 10,000 presentations. The focus of their interactions with healthcare professionals include: (i) introducing Optinose and highlighting the unmet medical need and limitations of current treatments, (ii) increasing awareness about XHANCE along with differentiating the Optinose EDS, and (iii) familiarizing healthcare professionals with the proper administration of XHANCE. Initial reaction to core brand messages among target physicians has been positive.
- **Customer Model.** We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENT physicians, allergists and “specialty like” primary care physicians and are deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target customer universe. We have prioritized approximately 80 territories within our sales force footprint to deploy at launch based upon an expectation that we will achieve an estimated 65% commercial market access within each of those territories during launch. Most of the initial 80 territory managers have completed training and are already engaging approximately 8,000 ENTs, allergists and primary care physician targets to promote XHANCE for the treatment of nasal polyps. Additionally, in March 2018, we introduced the XHANCE Xperience program to offer select physicians and their patients an opportunity to gain initial experience with XHANCE. Physicians can enroll a limited number of eligible patients in this program. Patients will receive up to two XHANCE prescriptions at no cost to them (\$0 co-pay), and physicians will receive an opportunity for feedback on patient experience. We believe the positive experience that physicians and patients have with XHANCE in this program will help drive demand for XHANCE during the retail launch, starting in early April 2018.
- **Market Access.** We have been engaging payors with the goal of securing tier 3 commercial coverage, primarily with a single step edit and no prior authorization. We have engaged with approximately 40 plans representing approximately 85% of commercial lives. In meeting with potential payors, we have shared what we believe is our compelling economic value proposition. Our analyses show that XHANCE will have a comparatively low pharmacy budget impact and our clinical trial data suggest that XHANCE may produce an offsetting benefit by helping reduce the rate of surgery with its related costs. For an insurance plan, this could represent a potential overall cost reduction for the population of patients with nasal polyps, as the overall cost of XHANCE could be less than the offsetting costs related to the reduction in surgeries. During clinical studies, XHANCE was also associated with an improvement in reported work productivity in treated patients, which should be valued by employers and patients. Further, we believe the cost of XHANCE to insurance plans will likely be significantly less than the projected costs of monoclonal antibodies that are currently in development for the treatment of nasal polyps. We expect to achieve approximately 65% coverage of commercial lives during the retail launch of XHANCE, and will seek to increase the number of covered lives during the first year. We have contracted with the Centers for Medicare and Medicaid Services regarding certain government covered lives. Further, we plan to introduce a co-pay assistance program and other patient affordability programs to appropriately support patient access to XHANCE.
- **Infrastructure.** We continue to develop our internal capabilities and grew from 21 employees as of January 1, 2017 to 82 employees as of March 1, 2018 to support a commercial stage company. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have implemented a robust healthcare compliance program to guide our staff’s and our partners’ compliance with rules and regulations regarding pharmaceutical sales. In managing our growth, we have remained focused on fostering our One Mission culture.

In addition to XHANCE’s existing indication for nasal polyps, we plan to initiate additional clinical trials in the fourth quarter of 2018 to seek a follow-on indication for the treatment of chronic sinusitis in order to broaden our market opportunity. XHANCE is the second commercial product that we have developed utilizing an Optinose EDS. Our first commercial product, indicated for the acute treatment of migraines in adults, was licensed in 2013 to Avanir Pharmaceuticals, Inc., or Avanir, and was approved by the FDA in January 2016.



## Financial Operations Overview

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

### *Licensing revenues*

To date, we have not generated any revenues from product sales. Substantially all of our revenue to date has been derived from the AVP-825 License Agreement. We do not expect to generate significant product revenue until we commercialize XHANCE and our other product candidates.

In July 2013, we, through our wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement under which we granted an exclusive license to Avanir to further develop and commercialize AVP-825 (now marketed as Onzetra Xsail). Under the terms of the AVP-825 License Agreement, we have received \$70.0 million in aggregate licensing revenues to date in connection with the initial signing and the achievement of development milestones, including a \$47.5 million payment upon FDA approval of AVP-825 in the first quarter of 2016. We are eligible to receive up to an additional \$50.0 million upon the achievement of annual sales milestones and tiered low double-digit royalty payments once and if net sales of the product exceed a specified cumulative threshold. We do not expect to generate any additional revenue from the AVP-825 License Agreement in the near term.

### *Research and development expense*

Research and development expense consists substantially of costs incurred in connection with the development and pursuit of regulatory approval for XHANCE for the treatment of nasal polyps. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding research performed by third parties, including pursuant to agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations, or CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA;
- costs incurred to maintain, expand and protect our patent portfolio as it relates to product candidates in development; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

Certain regulatory, patent and pre-commercialization expenses classified as research and development expenses prior to the FDA approval of XHANCE in September 2017 have been classified as selling, general and administrative expenses if incurred post approval of XHANCE to the extent that these expenses support the commercialization of XHANCE.

We typically use our employee, consultant and infrastructure resources across our research and development programs. Although we track certain outsourced development costs by product candidate, we do not allocate personnel costs or other internal costs to specific product candidates.

We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of XHANCE for a follow-on indication for the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, and given the preliminary nature of our clinical trial design for XHANCE for a follow-on indication for the treatment of chronic sinusitis and the FDA-mandated pediatric studies for XHANCE, and the early stage of our other product candidates, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development efforts.

### ***Selling, general and administrative expense***

Selling, general and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as regulatory fees and professional fees for legal, patent, accounting and other consulting services.

We anticipate that our general and administrative expenses will increase in 2018 as compared to 2017 as a result of an expanded infrastructure and an increased headcount to support the commercialization of XHANCE. We also anticipate higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting and investor relations expenses, as well as increased director and officer insurance premiums, associated with operating as a public company.

Sales and marketing related expenses consist of market research and other market preparation and pre-commercial activities ahead of making XHANCE available through retail pharmacies, expected to occur in early April 2018, as well as salaries and related benefits for employees focused on such efforts. We anticipate that our sales and marketing and related expenses will increase in 2018 as compared to 2017 as a result of an increase in headcount and the commercial launch of XHANCE in the United States, including the engagement of a dedicated contract sales organization.

### ***Interest (income) expense***

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense related to our long-term debt and amounts amortized and accrued under our convertible notes that were converted into preferred stock in March 2017.

### ***Other (income) expense***

Other (income) expense consists primarily of grant and other income as a result of government cost reimbursements for research and development activities over a contractually defined period, as well as foreign currency (income) losses due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

### ***Critical accounting policies***

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this report, we believe that the following accounting policies are those most critical to the preparation of our consolidated financial statements.

### ***Revenue recognition***

We have generated revenue primarily through licensing arrangements, which generally contain multiple elements, or deliverables, including licenses and research and development activities we perform on behalf of the licensee. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Currently, our only source of revenue is the AVP-825 License Agreement. The AVP-825 License Agreement includes licensed rights to patented technology, non-refundable up-front license fees, research services, and regulatory and sales milestones as well as royalty payments.

For arrangements with multiple elements, we recognize revenue in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which provides guidance for separating and allocating consideration in a multiple element arrangement. The selling prices of deliverables under an arrangement may be derived using third-party evidence, or TPE, or a best estimate of selling price, or BESP, if vendor-specific objective evidence of selling price, or VSOE, is not available. The objective of BESP is to determine the price at which we would transact a sale if each element within the AVP-825 License Agreement was sold on a standalone basis. Deliverables under the arrangement are separate units of accounting if the delivered item has value to the customer on a standalone basis and if the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially within our control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting for our licensing arrangements, we evaluate whether the license has standalone value to the licensee based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the licensee and the availability of relevant research expertise in the marketplace. In addition, we consider whether or not the licensee could use the license for its intended purpose without the receipt of the remaining deliverables, the value of the license was dependent on the undelivered items and the licensee or other vendors could provide the undelivered items.

Whenever we determine that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

Development milestones may be triggered either by the results of our research efforts or by events external to it, such as regulatory approval to market a product. Consideration that is contingent upon achievement of a development milestone is recognized in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must be commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, relate solely to past performance and be reasonable relative to all deliverables and payment terms in the collaboration agreement. As of December 31, 2016, all development milestones have been achieved under the AVP-825 License Agreement.

Royalties and sales milestones are recorded as earned in accordance with the contract terms when third party sales can be reliably measured and collectability is reasonably assured.

### ***Research and development expenses***

Research and development expense consists primarily of costs incurred in connection with development and regulatory approval of XHANCE, as well as costs associated with developing commercial manufacturing capabilities for XHANCE. We expense research and development costs as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expenses relating to these costs. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

### ***Stock-based compensation***

We account for stock-based compensation awards in accordance with the FASB Accounting Standards Codification, or ASC, Topic 718, *Compensation — Stock Compensation*, or ASC 718. ASC 718 requires all stock-based compensation awards to employees to be recognized as expense based on their grant date fair values. We

use the Black-Scholes option pricing model to value our stock option awards and we account for forfeitures of stock option awards as they occur. For awards issued to employees, we recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock-based awards issued to nonemployees are revalued at each reporting period until the award vests in accordance with ASC Topic 505, *Equity*. The resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered. Expense for awards with performance conditions is estimated and adjusted on a quarterly basis based upon our assessment of the probability that the performance condition will be met. We have not issued awards where vesting is subject to market conditions; however, if we were to grant such awards in the future, recognition would be based on the derived service period.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term.* Due to the lack of a public market for the trading of our common stock and the lack of sufficient company-specific historical data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin, or SAB, No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of nonemployee options is equal to the contractual term.
- *Expected Volatility.* The expected volatility is based on historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB No. 107.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- *Expected Dividends.* The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.

The following table reflects the weighted average assumptions used to estimate the fair value of options granted during the periods presented.

|                            | December 31, |         |
|----------------------------|--------------|---------|
|                            | 2017         | 2016    |
| Expected term (in years)   | 6.06         | 6.08    |
| Expected volatility        | 78.67%       | 74.29%  |
| Risk free interest rate    | 2.06%        | 2.22%   |
| Expected dividend yield    | 0.00%        | 0.00%   |
| Fair value of common stock | \$ 9.68      | \$ 5.14 |

No awards were granted during the year ended December 31, 2015.

For information about our employee stock purchase plan, see Note 13 to the Consolidated Financial Statements.

### ***Inventory***

Prior to receiving FDA approval for XHANCE in September 2017, inventory purchases were expensed as incurred and recorded as a component of research and development expense. Subsequent to receiving FDA approval, inventories are stated at the lower of cost or net realizable value, net of reserves for excess and obsolete inventory. Cost is computed using standard cost (which approximates actual cost) on a first-in, first-out basis. At December 31, 2017, inventory consisted of raw materials and sub-assemblies.

### **Recent Accounting Pronouncements**

See Note 3 of our audited consolidated financial statement beginning on page F-1 of this Annual Report on Form

10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

### **JOBS Act**

The JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

### **Consolidated Results of Operations**

#### **Comparison of the years ended December 31, 2017 and 2016**

The following table sets forth our selected consolidated statements of operations data for the periods indicated (in thousands):

|                                     | Year Ended December 31, |           |
|-------------------------------------|-------------------------|-----------|
|                                     | 2017                    | 2016      |
| Licensing revenues                  | \$ —                    | \$ 47,500 |
| Operating expenses:                 |                         |           |
| Research and development            | 16,832                  | 15,311    |
| Selling, general and administrative | 31,698                  | 6,869     |
| Total operating expenses            | 48,530                  | 22,180    |
| (Loss) income from operations       | (48,530)                | 25,320    |
| Other (income) expense:             |                         |           |
| Interest (income) expense           | 607                     | 3,374     |
| Other (income) expense              | (235)                   | (667)     |
| Total other (income) expense        | 372                     | 2,707     |
| Net (loss) income                   | \$ (48,902)             | \$ 22,613 |

#### *Licensing Revenues*

Licensing revenues were \$47.5 million for the year ended December 31, 2016 and were attributable to the achievement of a development milestone under the terms of the AVP-825 License Agreement as a result of FDA approval of Onzetra Xsail in January 2016. There were no licensing revenues during the year ended December 31, 2017.

#### *Research and development expense*

Research and development expenses were \$16.8 million and \$15.3 million for the years ended December 31, 2017 and 2016, respectively. The \$1.5 million increase was attributable primarily to:

- a \$1.2 million increase related to the preparation of contract manufacturing capabilities prior to the receipt of FDA approval of XHANCE in September of 2017 in anticipation of the expected commercial launch of XHANCE in the U.S. for the treatment of nasal polyps;
- a \$1.3 million increase in personnel and bonus expenses, including non-cash stock-based compensation, due to increases in headcount, as well as increases in bonus expense as a result of the achievement of Company performance targets; and
- a \$1.1 million increase in medical affairs spending in connection with the conduct, reporting and planning for current and future research programs and to prepare for our planned clinical trials for a follow-on indication for XHANCE for the treatment of chronic sinusitis.

These increases were offset primarily by:

- a \$1.3 million decrease in regulatory expenses as a result of the substantial completion in 2016 of our NDA submission activities for XHANCE for the treatment of nasal polyps; and
- a \$0.7 million decrease in expenses as a result of the completion of an anthropometric study in preparation for the FDA mandated pediatric studies as well as the completion of other early research projects.

### *Selling general and administrative expense*

Selling, general and administrative expenses were \$31.7 million and \$6.9 million for the years ended December 31, 2017 and 2016, respectively. The \$24.8 million increase was due primarily to:

- a \$9.7 million increase in sales and marketing expenses related to our preparation for the expected commercial launch of XHANCE in the U.S. for the treatment of nasal polyps;
- a \$9.1 million increase in personnel and bonus expenses, including non-cash stock-based compensation, due to increases in headcount, as well as increases in bonus expense as a result of the achievement of Company performance targets;
- a \$4.4 million increase in professional fees and consultant expenses related to the completion of our IPO, the support of our expanding infrastructure to prepare for the expected commercial launch of XHANCE and as a result of operating as a public company; and
- \$1.7 million increase in facilities and administrative expenses to support expanding business operations.

### *Interest (income) expense, net*

Interest expense, net, was \$0.6 million and \$3.4 million for the years ended December 31, 2017 and 2016, respectively. The \$2.8 million decrease was due primarily to the conversion of convertible notes to shares of preferred stock in March 2017.

### *Other (income) expense, net*

Other income, net, was \$0.2 million and \$0.7 million for the years ended December 31, 2017 and 2016, respectively. The income in both periods was attributable primarily to grant eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

### **Comparison of the years ended December 31, 2016 and 2015**

The following table sets forth our selected consolidated statements of operations data for the periods indicated (in thousands):

|                                     | Year Ended December 31, |             |
|-------------------------------------|-------------------------|-------------|
|                                     | 2016                    | 2015        |
| Licensing revenues                  | \$ 47,500               | \$ 85       |
| Operating expenses:                 |                         |             |
| Research and development            | 15,311                  | 22,156      |
| Selling, general and administrative | 6,869                   | 6,006       |
| Total operating expenses            | 22,180                  | 28,162      |
| Income (loss) from operations       | 25,320                  | (28,077)    |
| Other (income) expense:             |                         |             |
| Interest (income) expense           | 3,374                   | 791         |
| Other (income) expense              | (667)                   | (554)       |
| Total other (income) expense        | 2,707                   | 237         |
| Net income (loss)                   | \$ 22,613               | \$ (28,314) |

### *Licensing Revenues*

Licensing revenues were \$47.5 million and \$0.1 million for the years ended December 31, 2016 and 2015, respectively. Licensing revenues earned during the year ended December 31, 2016 were attributable to the achievement of a development milestone under the terms of the AVP-825 License Agreement as a result of FDA approval of Onzetra Xsail in January 2016. Licensing revenues earned during the year ended December 31, 2015 were attributable to research and development services provided in connection with the AVP-825 License Agreement.

### *Research and development expense*

Research and development expenses were \$15.3 million and \$22.2 million for the years ended December 31, 2016 and 2015, respectively. The \$6.9 million decrease was attributable primarily to the \$10.0 million decrease in clinical



development and chemistry, manufacturing and controls expenses in connection with the substantial completion of our Phase 3 clinical trial development program of XHANCE for the treatment of nasal polyps in 2015.

This decrease was offset primarily by:

- a \$2.2 million increase in personnel and bonus expense;
- a \$0.8 million increase in regulatory and intellectual property maintenance costs in connection with the submission of our NDA for XHANCE for the treatment of nasal polyps; and
- a \$0.1 million increase in rent and other operating expenses in connection our new corporate office lease.

*Selling, general and administrative expense*

Selling, general and administrative expenses were \$6.9 million and \$6.0 million for the years ended December 31, 2016 and 2015, respectively. The \$0.9 million increase was due primarily to:

- a \$1.5 million increase in personnel and bonus expense;
- a \$0.6 million increase in professional service expenses as a result of our preparations to become a public company and for the expected commercial launch of XHANCE for the treatment of nasal polyps; and
- a \$0.1 million increase in rent and other operating expenses in connection with our new corporate office lease.

These increases were offset by a \$1.3 million decrease in marketing-related expenses incurred in connection with market research and commercial feasibility studies that we commissioned for XHANCE in 2015.

*Interest (income) expense, net*

Interest expense, net, was \$3.4 million and \$0.8 million for the years ended December 31, 2016 and 2015, respectively. The \$2.6 million increase was attributable primarily to the September 2015 issuance of \$15.0 million in convertible notes.

*Other (income) expense, net*

Other income, net, was \$0.7 million and \$0.6 million for the years ended December 31, 2016 and 2015, respectively. The \$0.1 million increase was due primarily to an increase in grant eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

**Liquidity and Capital Resources**

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We had net income of \$22.6 million for the year ended December 31, 2016 due primarily to the achievement of a milestone under the AVP-825 License Agreement. However, we incurred net losses of \$48.9 million for the year ended December 31, 2017. As of December 31, 2017, we had an accumulated deficit of \$211.3 million.

We have funded our operations primarily through the sale of stock and the issuance of debt, as well as through licensing revenues received under the terms of the AVP-825 License Agreement. As of December 31, 2017, we had \$234.9 million in cash and cash equivalents.

In October 2017, we completed our initial public offering, or IPO, selling 8,625,000 shares of our common stock at a price of \$16.00 per share. As a result of the IPO, we received approximately \$125.5 million in net proceeds, after deducting underwriting discounts and commissions of approximately \$9.7 million and offering expenses of approximately \$2.9 million payable by us.

In December 2017, we entered into a Note Purchase Agreement with Athyrium Opportunities III Acquisition LP, as collateral agent, or the Collateral Agent, and the purchasers party thereto, or the Purchasers, that provides for the issuance of up to \$100.0 million of senior secured notes, or the Notes, of which \$75.0 million of the Notes were issued on December 29, 2017, of which \$50.0 million were issued by OptiNose AS and \$25 million were issued by

OptiNose US, Inc., or the Issuers. The remaining \$25.0 million of Notes, or the Delayed Draw Notes, may be issued by OptiNose US, Inc. and sold to the Purchasers between April 1, 2019 and August 14, 2019, subject to achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Note Purchase Agreement) of \$15.0 million and a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00, and certain other conditions.

The unpaid principal amount under the Notes is due and payable on June 29, 2023, or the Maturity Date. The Notes bear interest at a per annum rate of three-month LIBOR rate (subject to a 1.0% floor) plus 9.0%. The Issuers are required to make quarterly interest-only payments until the Maturity Date. In addition, the Issuers paid an upfront fee of 1% of the aggregate principal amount of the Notes on the Closing Date. We are also required to pay an exit fee of 2% of any principal payments (whether mandatory, voluntary or at maturity) made throughout the term of the Note Purchase Agreement. Subject to certain exceptions, the Issuers are required to make mandatory prepayments of the Notes, with the proceeds of assets sales extraordinary receipts and prohibited debt issuances and upon the occurrence of a change of control. In addition, the Issuers may make voluntary prepayments of the Notes, in whole or in part. All mandatory and voluntary prepayments of the Notes are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the second anniversary of the applicable date of issuance, an amount equal to the amount by which (a) the present value of 102% of the principal prepaid plus all interest that would have accrued on such principal through such second anniversary exceeds (b) the amount of principal prepaid, (ii) if prepayment occurs on or after the second anniversary of the applicable date of issuance but prior to the third anniversary of such issuance, an amount equal to 2% of the principal prepaid, and (iii) if prepayment occurs on or after the third anniversary of the applicable date of issuance but prior to the fourth anniversary of such issuance, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid after the fourth anniversary of the applicable date of issuance of any Notes.

The Note Purchase Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, grant certain license rights to our products, technology and other intellectual property rights, pay dividends and distributions, repay junior indebtedness and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Note Purchase Agreement contains financial covenants requiring us to maintain at all times (i) at least \$10 million of cash and cash equivalents and (ii) following the issuance of the Delayed Draw Notes or upon entering into certain exclusive licenses of XHANCE, a total debt to trailing four quarter XHANCE net revenue ratio of not more than 6.50 to 1.00 initially, and thereafter declining quarterly by equal half-steps to a ratio of not more than 3.00 to 1.00.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

|  | Year Ended<br>December 31, |                  |                   |
|--|----------------------------|------------------|-------------------|
|  | 2017                       | 2016             | 2015              |
| Net cash (used in) provided by operating activities    | \$ (35,651)                | \$ 21,720        | \$ (28,714)       |
| Net cash used in investing activities                  | (2,406)                    | (215)            | (80)              |
| Net cash provided by financing activities              | 236,125                    | 55               | 19,123            |
| Effects of exchange rates on cash and cash equivalents | (11)                       | 39               | (14)              |
| Net increase (decrease) in cash and cash equivalents   | <u>\$ 198,057</u>          | <u>\$ 21,599</u> | <u>\$ (9,685)</u> |

*Operating activities*

Cash provided by (used in) operating activities decreased by \$57.4 million, from \$21.7 million for the year ended December 31, 2016 to \$(35.7) million for the year ended December 31, 2017. The decrease in cash provided by operating activities was attributable primarily to the net income generated from the \$47.5 million of licensing revenue earned in connection with the achievement of a development milestone under the terms of the AVP-825 License Agreement resulting from FDA approval of Onzetra Xsail in January 2016. No revenue was generated from the AVP-825 License Agreement during the year ended December 31, 2017.

Cash provided by (used in) operating activities increased by \$50.4 million, from \$(28.7) million for the year ended December 31, 2015 to \$21.7 million for the year ended December 31, 2016. The \$50.4 million increase in cash provided by operating activities was attributable primarily to the net income generated from the \$47.5 million of

licensing revenue earned in connection with the achievement of a development milestone under the terms of the AVP-825 License Agreement resulting from FDA approval of Onzetra Xsail in January 2016.

#### *Investing activities*

Cash used in investing activities increased \$2.2 million from \$0.2 million for the year ended December 31, 2016 to \$2.4 million for the year ended December 31, 2017. The increase was related to purchases of equipment in connection with our preparation for the commercial launch of XHANCE.

Cash used in investing activities increased \$0.1 million from \$0.1 million for the year ended December 31, 2015 to \$0.2 million for the year ended December 31, 2016. The \$0.1 million increase was related to increased purchases of equipment.

#### *Financing activities*

Cash provided by financing activities increased to \$236.1 million for the year ended December 31, 2017 from \$0.1 million for the year ended December 31, 2016. During 2017, we received \$36.4 million in net proceeds from the sale of our Series D Preferred Stock, \$125.5 million in net proceeds from our IPO and \$71.9 million in net proceeds from the issuance of the Notes.

Cash provided by financing activities decreased \$19.0 million from \$19.1 million for the year ended December 31, 2015 to \$0.1 million for the year ended December 31, 2016. During 2015, we received \$4.8 million in net proceeds from the sale of our Series C-1 Preferred Stock and \$14.3 million in net proceeds from the sale and issuance of our convertible promissory notes that were subsequently converted to Series C-2 Preferred Stock in March 2017. During 2016, we received \$0.1 million in cash from stock option exercises.

#### *Future funding requirements*

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we:

- deploy a contract specialty sales force, which initially consists of approximately 80 territory managers, to market XHANCE for the treatment of nasal polyps and build commercial infrastructure to support sales and marketing for XHANCE;
- initiate advertising and other promotional activities to support the commercialization of XHANCE;
- continue clinical development activities for XHANCE, including FDA-mandated pediatric studies and clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- hire additional staff and add operational, financial and information systems to execute our business plan;
- maintain, expand and protect our patent portfolio;
- contract to manufacture XHANCE and our other product candidates;
- service our debt obligations under the Notes issued in December 2017;
- continue research and development activities for our other product candidates; and
- operate as a public company.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the success of our commercialization of XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to obtain adequate coverage and reimbursement for XHANCE;
- the cost and timing of commercialization activities for XHANCE, including product manufacturing, marketing, sales and distribution;
- revenue received from commercial sales of XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the follow-on indication for the treatment of chronic sinusitis;

- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- potential future licensing revenue from the AVP-825 License Agreement;
- fluctuations in the three-month LIBOR-based floating interest rate of our Notes;
- the initiation, progress, timing, costs and results of clinical trials for our other product candidates; and
- the extent to which we in-license or acquire other products, product candidates or technologies.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents will enable us to fund our operations as well as our debt service obligations through the end of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will need to raise additional capital in the future to further the commercialization of XHANCE for the treatment of nasal polyps, to complete the clinical development of XHANCE for a follow-on indication for the treatment of chronic sinusitis, and to support the development of our other product candidates. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received. Additionally, we may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

### Contractual obligations and commitments

The following table summarizes our contractual obligations at December 31, 2017:

|                                     | Total          | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
|-------------------------------------|----------------|------------------|-----------|-----------|-------------------|
|                                     | (in thousands) |                  |           |           |                   |
| Operating leases <sup>(1)</sup>     | \$ 187         | \$ 187           | \$ —      | \$ —      | \$ —              |
| Long-term debt <sup>(2)</sup>       | 121,494        | 7,928            | 16,327    | 16,349    | 80,890            |
| Purchase obligations <sup>(3)</sup> | 16,354         | 14,019           | 2,335     | —         | —                 |
| Total                               | \$ 138,035     | \$ 22,134        | \$ 18,662 | \$ 16,349 | \$ 80,890         |

<sup>(1)</sup> Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England. In January 2018, we amended our existing office lease agreement for our headquarters in Yardley, PA, or the Lease Amendment. Under the terms of the Lease Amendment, our leased office space was increased from approximately 20,050 square feet to approximately 30,000 square feet and the term of the lease was extended from March 31, 2018 to May 31, 2021, or the Extended Term. The rent payments during the Extended Term will be approximately \$2.8 million in the aggregate and we will also be required to pay our proportionate share of certain operating costs and property taxes applicable to the leased premises. Because the Lease Amendment was executed after December 31, 2017, obligations under the Lease Amendment are not included in the table above.

<sup>(2)</sup> Reflects principal, interest obligations and exit fees pursuant to the Note Purchase Agreement entered into on December 29, 2017. The Notes bear interest at 9.0% plus the three-month LIBOR rate, subject to a 1.0% floor. The Company is required to make quarterly, interest only payments until the maturity date. Interest amounts included above are calculated at the quarterly rate as of December 31, 2017.

<sup>(3)</sup> Reflects non-cancellable services under an agreement we entered into in November 2017 with a contract sales organization for the recruitment, deployment and management of a contract sales force to market XHANCE in the United States. Subject to certain limited exceptions, we may not terminate this agreement until after the first anniversary of the deployment of the sales force (which occurred in March 2018). We estimate the expenses related to the non-cancellable services during this period to be approximately \$16.4 million. Thereafter, we may terminate the agreement subject to potential early termination fees ranging from \$0.1 million to \$0.7 million.

### **Off-balance sheet arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

## **ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

Through the operation of our subsidiaries based in the United Kingdom and Norway, we are exposed to foreign exchange rate risks. In addition to the operations of our foreign subsidiaries, we also contract with vendors that are located outside the United States, and in some cases make payment of invoices denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2017, we had minimal liabilities denominated in foreign currencies.

As of December 31, 2017, we had cash and cash equivalents of \$234.9 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

The interest rate on our senior secured notes under the Note Purchase Agreement is variable based on the three-month London Interbank Offered Rate (LIBOR) and, therefore, is affected by changes in market interest rates. As of December 31, 2017, we had \$75.0 million of aggregate principal amount of senior secured notes outstanding under the Note Purchase Agreement. As of December 31, 2017, the three-month LIBOR was 1.75%. A hypothetical 1% increase the the three-month LIBOR would result in \$0.8 million in incremental annual interest expense under the outstanding senior secured notes.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by Item 8 including the financial statements and notes thereto, and report of the independent registered public accounting firm thereon, are included in this Form 10-K as set forth in the "Index to Consolidated Financial Statements" on page F-1.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will

succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our Chief Executive Officer and our Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2017.

#### **Management's Report on Internal Control over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

#### **Attestation Report of the Registered Public Accounting Firm**

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during our the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

None.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Our Board has adopted a written Code Conduct applicable to all officers, directors and employees, which is available on our website ([www.optinose.com](http://www.optinose.com)) under "Corporate Governance" within the "Investors" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.



**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

## (a) (1) Consolidated Financial Statements.

The Consolidated Financial Statements are filed as part of this report. See the Index to the Consolidated Financial Statements on page F-1.

## (2) Consolidated Financial Statement Schedule.

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the Consolidated Financial Statements and Notes thereto.

## (3) The exhibits listed under Item 15(b), which are incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

## (b) Exhibits.

| Exhibit Number | Exhibit Description   | Incorporated by Reference |          |        | Filed Herewith |
|----------------|---|---------------------------|----------|--------|----------------|
|                |   | Form                      | Date     | Number |                |
| 2.1            | <a href="#">Exchange Agreement, dated as of June 7, 2010, by and among the Registrant, OptiNose AS and the other signatories thereto (the Registrant hereby agrees to furnish supplementally a copy of any omitted schedules to the SEC upon request)</a> | S-1                       | 9/18/17  | 2.1    |                |
| 3.1            | <a href="#">Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc.</a>  | 8-K                       | 10/18/17 | 3.1    |                |
| 3.2            | <a href="#">Amended and Restated Bylaws of OptiNose, Inc.</a>   | 8-K                       | 10/18/17 | 3.2    |                |
| 4.1            | <a href="#">Form of Common Stock Certificate.</a>   | S-1/A                     | 10/3/17  | 4.1    |                |
| 4.2            | <a href="#">Second Amended and Restated Registration Rights Agreement, dated March 24, 2017, by and among the Registrant and certain of its stockholders.</a>   | S-1                       | 9/18/17  | 4.2    |                |
| 4.3            | <a href="#">Second Amended and Restated Shareholders' Agreement, dated March 24, 2017, by and among the Registrant and certain of its stockholders.</a>   | S-1                       | 9/18/17  | 4.3    |                |
| 4.4            | <a href="#">Form of Warrant issued by the Registrant on June 7, 2010.</a>   | S-1                       | 9/18/17  | 4.4    |                |
| 10.1           | <a href="#">Form of Indemnification Agreement.</a> <sup>+</sup>   |                           |          |        | x              |
| 10.2           | <a href="#">Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Peter K. Miller.</a> <sup>+</sup>   | 8-K                       | 10/18/17 | 10.1   |                |
| 10.3           | <a href="#">Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Ramy A. Mahmoud.</a> <sup>+</sup>   | 8-K                       | 10/18/17 | 10.2   |                |
| 10.4           | <a href="#">Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Thomas E. Gibbs.</a> <sup>+</sup>   | 8-K                       | 10/18/17 | 10.3   |                |
| 10.5           | <a href="#">Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Keith A. Goldan.</a> <sup>+</sup>   | 8-K                       | 10/18/17 | 10.4   |                |
| 10.6           | <a href="#">Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Michael F. Marino.</a> <sup>+</sup>   | 8-K                       | 10/18/17 | 10.5   |                |
| 10.7           | <a href="#">Amended and Restated 2010 Stock Incentive Plan.</a> <sup>+</sup>  | S-1/A                     | 10/3/17  | 10.7   |                |
| 10.8           | <a href="#">Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Success Pool Grants).</a> <sup>+</sup>  | S-1/A                     | 10/3/17  | 10.8   |                |
| 10.9           | <a href="#">Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Option Pool Grants).</a> <sup>+</sup>   | S-1/A                     | 10/3/17  | 10.9   |                |

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|         |  |       |         |       |   |
|---------|--|-------|---------|-------|---|
| 10.10   | <a href="#">Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan.</a> <sup>+</sup>   | S-1/A | 10/3/17 | 10.10 |   |
| 10.11   | <a href="#">License Agreement, dated as of July 1, 2013, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.</a> <sup>†</sup>  | S-1   | 9/18/17 | 10.11 |   |
| 10.12   | <a href="#">First Amendment of License Agreement, dated as of April 25, 2014, by and between OptiNose US, Inc. and Avanir Pharmaceuticals, Inc.</a> <sup>†</sup>   | S-1   | 9/18/17 | 10.12 |   |
| 10.13   | <a href="#">Amendment to License Agreement, dated as of August 6, 2015, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.</a> <sup>†</sup>   | S-1   | 9/18/17 | 10.13 |   |
| 10.14   | <a href="#">Supply Agreement, dated July 1, 2017, by and between Hovione Inter Ltd and OptiNose US, Inc., OptiNose UK, Ltd and OptiNose AS.</a> <sup>†</sup>   | S-1   | 9/18/17 | 10.14 |   |
| 10.15   | <a href="#">Manufacture and Supply Agreement, dated as of August 18, 2017, by and among OptiNose US, Inc., OptiNose UK Ltd. and OptiNose AS and Contract Pharmaceuticals Limited Canada.</a> <sup>†</sup>  | S-1   | 9/18/17 | 10.15 |   |
| 10.16   | <a href="#">Manufacturing Services Agreement, dated as of August 31, 2017, by and among OptiNose US, Inc., OptiNose UK Ltd. and OptiNose AS and Ximedica, LLC.</a> <sup>†</sup>  | S-1   | 9/18/17 | 10.16 |   |
| 10.17   | <a href="#">Form of Non-Qualified Stock Option Agreement Under the Amended and Restated 2010 Stock Incentive Plan</a> <sup>+</sup>   | S-1/A | 10/3/17 | 10.17 |   |
| 10.18   | <a href="#">2017 Employee Stock Purchase Plan.</a> <sup>+</sup>  | S-1/A | 10/3/17 | 10.18 |   |
| 10.19   | <a href="#">Note Purchase Agreement dated December 29, 2017, among OptiNose AS and OptiNose US, Inc., as the Issuers, OptiNose, Inc. as Parent and a Guarantor, and Athyrium Opportunities III Acquisition LP, as Collateral Agent and a Purchaser</a> |       |         |       | x |
| 21.1    | <a href="#">List of Subsidiaries</a>   |       |         |       | x |
| 23.1    | <a href="#">Consent of Ernst &amp; Young LLP, independent registered public accounting firm.</a>   |       |         |       | x |
| 31.1    | <a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>   |       |         |       | x |
| 31.2    | <a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>   |       |         |       | x |
| 32.1    | <a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.</a>   |       |         |       | x |
| 32.2    | <a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.</a>   |       |         |       | x |
| 101.INS | XBRL Instance Document.  |       |         |       | x |
| 101.SCH | XBRL Taxonomy Extension Schema Document.   |       |         |       | x |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document.   |       |         |       | x |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document.  |       |         |       | x |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document.   |       |         |       | x |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document.  |       |         |       | x |

<sup>†</sup> Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment granted pursuant to Rule 406 under the Securities Act of 1933.

<sup>+</sup> Indicates management contract or compensatory plan.

## ITEM 16. FORM 10-K SUMMARY

Not applicable.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the capacities and on the date indicated.

Date: March 13, 2018

### OPTINOSE, INC.

By: /s/ PETER K. MILLER

Name: Peter K. Miller

Title: *Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| <u>Signature</u>  | <u>Title</u>   | <u>Date</u>    |
|---|--|----------------|
| <u>/s/ PETER K. MILLER</u><br>Peter K. Miller             | Chief Executive Officer and Director (Principal Executive Officer)                   | March 13, 2018 |
| <u>/s/ KEITH A. GOLDAN</u><br>Keith A. Goldan             | Chief Financial Officer (Principal Finance Officer and Principal Accounting Officer) | March 13, 2018 |
| <u>/s/ JOSEPH C. SCODARI</u><br>Joseph C. Scodari         | Chairman of the Board of Directors   | March 13, 2018 |
| <u>/s/ LARRY G. PICKERING</u><br>Larry G. Pickering       | Vice Chairman of the Board of Directors  | March 13, 2018 |
| <u>/s/ SRIRAM VENKATARAMAN</u><br>Sriram Venkataraman     | Director   | March 13, 2018 |
| <u>/s/ WILLIAM F. DOYLE</u><br>William F. Doyle           | Director   | March 13, 2018 |
| <u>/s/ JOSHUA A. TAMAROFF</u><br>Joshua A. Tamaroff       | Director   | March 13, 2018 |
| <u>/s/ WILHELMUS GROENHUYSEN</u><br>Wilhelmus Groenhuysen | Director   | March 13, 2018 |
| <u>/s/ SANDRA L. HELTON</u><br>Sandra L. Helton           | Director   | March 13, 2018 |

**OptiNose, Inc.**  
**Notes to Consolidated Financial Statements**  
**(in thousands, except share and per share data)**

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| <a href="#">Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015</a>   | <a href="#">F-4</a> |
| <a href="#">Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2017, 2016 and 2015</a>  | <a href="#">F-5</a> |
| <a href="#">Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2017, 2016 and 2015</a> | <a href="#">F-6</a> |
| <a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015</a>   | <a href="#">F-7</a> |
| <a href="#">Notes to Consolidated Financial Statements</a>   | <a href="#">F-8</a> |

**OptiNose, Inc.**  
**Notes to Consolidated Financial Statements**  
**(in thousands, except share and per share data)**

**Report of Independent Registered Public Accounting Firm**

To the Shareholders and Board of Directors and of OptiNose, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of OptiNose, Inc. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Philadelphia, Pennsylvania

March 13, 2018

**OptiNose, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

|   | December 31, |           |
|---|--------------|-----------|
|   | 2017         | 2016      |
| <b>Assets</b>   |              |           |
| Current assets:   |              |           |
| Cash and cash equivalents   | \$ 234,854   | \$ 36,797 |
| Grants and other receivables  | 46           | 384       |
| Inventory   | 2,013        | —         |
| Deposits and other current assets   | 1,254        | 3,494     |
| Total current assets  | 238,167      | 40,675    |
| Property and equipment, net   | 2,564        | 323       |
| Deposits and other assets — long-term   | 405          | 553       |
| Total assets  | \$ 241,136   | \$ 41,551 |
| <b>Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>   |              |           |
| Current liabilities:  |              |           |
| Accounts payable  | \$ 5,893     | \$ 3,369  |
| Accrued expenses  | 8,698        | 2,541     |
| Deferred other income   | 186          | —         |
| Total current liabilities   | 14,777       | 5,910     |
| Convertible notes payable, net  | —            | 15,256    |
| Long-term debt, net   | 71,863       | —         |
| Accrued interest  | —            | 3,409     |
| Total liabilities   | 86,640       | 24,575    |
| Commitments and contingencies (Note 11)   |              |           |
| Redeemable convertible preferred stock, \$0.001 par value:  |              |           |
| Series A, No shares authorized, issued and outstanding at December 31, 2017; 285,480 shares authorized, issued and outstanding at December 31, 2016   | —            | 5,381     |
| Series B-1, No shares authorized, issued and outstanding at December 31, 2017; 35,680 shares authorized, issued and outstanding at December 31, 2016  | —            | 673       |
| Series B-2, No shares authorized, issued and outstanding at December 31, 2017; 782,600 shares authorized, issued and outstanding at December 31, 2016   | —            | 14,760    |
| Series C, No shares authorized, issued and outstanding at December 31, 2017; 4,115,344 shares authorized, issued and outstanding at December 31, 2016   | —            | 105,738   |
| Series C-1, No shares authorized, issued and outstanding at December 31, 2017; 1,656,410 shares authorized, issued and outstanding at December 31, 2016   | —            | 41,621    |
| Total redeemable convertible preferred stock  | —            | 168,173   |
| Stockholders' equity (deficit):   |              |           |
| Common stock, \$0.001 par value; 200,000,000 and 10,624,486 shares authorized at December 31, 2017 and December 31, 2016, respectively; 37,802,556 and 4,067,717 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively | 38           | 4         |
| Additional paid-in capital  | 365,838      | —         |
| Accumulated deficit   | (211,269)    | (151,102) |
| Accumulated other comprehensive loss  | (111)        | (99)      |
| Total stockholders' equity (deficit)  | 154,496      | (151,197) |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)  | \$ 241,136   | \$ 41,551 |

See accompanying notes to consolidated financial statements



**OptiNose, Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

|   | Year Ended December 31, |           |             |
|---|-------------------------|-----------|-------------|
|   | 2017                    | 2016      | 2015        |
| Licensing revenues                                    | \$ —                    | \$ 47,500 | \$ 85       |
| Operating expenses:                                   |                         |           |             |
| Research and development                              | 16,832                  | 15,311    | 22,156      |
| Selling, general and administrative                   | 31,698                  | 6,869     | 6,006       |
| Total operating expenses                              | 48,530                  | 22,180    | 28,162      |
| (Loss) income from operations                         | (48,530)                | 25,320    | (28,077)    |
| Other (income) expense:                               |                         |           |             |
| Grant and other income                                | (162)                   | (727)     | (643)       |
| Interest income                                       | (303)                   | (143)     | (28)        |
| Interest expense                                      | 910                     | 3,517     | 819         |
| Foreign currency (gains) losses                       | (73)                    | 60        | 89          |
| Net (loss) income                                     | \$ (48,902)             | \$ 22,613 | \$ (28,314) |
| Deemed dividend                                       | 11,969                  | 11,005    | 9,992       |
| Accretion to redemption value                         | 1,096                   | 2,109     | 2,069       |
| Net (loss) income attributable to common stockholders | \$ (61,967)             | \$ 9,499  | \$ (40,375) |
| Net (loss) income per share of common stock,          |                         |           |             |
| basic   | \$ (5.63)               | \$ 0.40   | \$ (9.97)   |
| diluted   | \$ (5.63)               | \$ 0.32   | \$ (9.97)   |
| Weighted average common shares outstanding,           |                         |           |             |
| basic   | 10,999,121              | 4,054,316 | 4,049,668   |
| diluted   | 10,999,121              | 4,980,181 | 4,049,668   |

See accompanying notes to consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Comprehensive Income and Loss**  
**(in thousands)**

|   | Year Ended<br>December 31, |                  |                    |
|---|----------------------------|------------------|--------------------|
|   | 2017                       | 2016             | 2015               |
| Net (loss) income                       | \$ (48,902)                | \$ 22,613        | \$ (28,314)        |
| Other comprehensive (loss) income:      |                            |                  |                    |
| Foreign currency translation adjustment | (12)                       | 42               | (13)               |
| Comprehensive (loss) income             | <u>\$ (48,914)</u>         | <u>\$ 22,655</u> | <u>\$ (28,327)</u> |

See accompanying notes to consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and**  
**Stockholders' Equity (Deficit)**  
**(in thousands, except share data)**

|   | Redeemable Convertible Preferred Stock |            | Stockholders' Deficit |        |                            |                     |                                      |                             |
|---|--|------------|-----------------------|--------|----------------------------|---------------------|--------------------------------------|-----------------------------|
|   |  |            | Common Stock          |        | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Deficit |
|   | Shares                                 | Amount     | Shares                | Amount |                            |                     |                                      |                             |
| Balance at January 1, 2015  | 6,638,885                              | \$ 138,160 | 4,049,668             | \$ 4   | \$ —                       | \$ (121,468)        | \$ (128)                             | \$ (121,592)                |
| Stock compensation expense  | —                                      | —          | —                     | —      | 588                        | —                   | —                                    | 588                         |
| Balance at Sale of Series C-1 preferred stock   | 236,629                                | 4,838      | —                     | —      | —                          | —                   | —                                    | —                           |
| Accretion of Series C & Series C-1 preferred stock to redemption value                                  | —                                      | 2,069      | —                     | —      | (588)                      | (1,481)             | —                                    | (2,069)                     |
| Accretion of Series C & Series C-1 preferred stock in lieu of 8% dividend                               | —                                      | 9,992      | —                     | —      | —                          | (9,992)             | —                                    | (9,992)                     |
| Foreign currency translation adjustment   | —                                      | —          | —                     | —      | —                          | —                   | (13)                                 | (13)                        |
| Net loss  | —                                      | —          | —                     | —      | —                          | (28,314)            | —                                    | (28,314)                    |
| Balance at December 31, 2015  | 6,875,514                              | \$ 155,059 | 4,049,668             | \$ 4   | \$ —                       | \$ (161,255)        | \$ (141)                             | \$ (161,392)                |
| Stock compensation expense  | —                                      | —          | —                     | —      | 599                        | —                   | —                                    | 599                         |
| Exercise of common stock options  | —                                      | —          | 18,049                | —      | 55                         | —                   | —                                    | 55                          |
| Accretion of Series C & Series C-1 preferred stock to redemption value                                  | —                                      | 2,109      | —                     | —      | (654)                      | (1,455)             | —                                    | (2,109)                     |
| Accretion of Series C & Series C-1 preferred stock in lieu of 8% dividend                               | —                                      | 11,005     | —                     | —      | —                          | (11,005)            | —                                    | (11,005)                    |
| Foreign currency translation adjustment   | —                                      | —          | —                     | —      | —                          | —                   | 42                                   | 42                          |
| Net loss  | —                                      | —          | —                     | —      | —                          | 22,613              | —                                    | 22,613                      |
| Balance at December 31, 2016  | 6,875,514                              | \$ 168,173 | 4,067,717             | \$ 4   | \$ —                       | \$ (151,102)        | \$ (99)                              | \$ (151,197)                |
| Conversion of convertible debt to Series C-2 preferred stock  | 687,474                                | 19,527     | —                     | —      | —                          | —                   | —                                    | —                           |
| Sale of Series D preferred stock, net of issuance costs   | 1,117,578                              | 36,494     | —                     | —      | —                          | —                   | —                                    | —                           |
| Stock compensation expense  | —                                      | —          | —                     | —      | 5,096                      | —                   | —                                    | 5,096                       |
| Accretion of Series C, Series C-1 & Series D preferred stock to redemption value                        | —                                      | 1,096      | —                     | —      | (1,096)                    | —                   | —                                    | (1,096)                     |
| Accretion of Series C, Series C-1, Series C-2 & Series D preferred stock in lieu of 8% dividend         | —                                      | 11,969     | —                     | —      | (704)                      | (11,265)            | —                                    | (11,969)                    |
| Sale of common stock upon consummation of initial public offering, net of issuance costs                | —                                      | —          | 8,625,000             | 9      | 125,462                    | —                   | —                                    | 125,471                     |
| Reclassification of redeemable convertible preferred stock upon consummation of initial public offering | (8,680,566)                            | (237,259)  | 25,068,556            | 25     | 237,234                    | —                   | —                                    | 237,259                     |
| Exercise of stock options, net of shares withheld for income taxes                                      | —                                      | —          | 41,283                | —      | (154)                      | —                   | —                                    | (154)                       |
| Foreign currency translation adjustment   | —                                      | —          | —                     | —      | —                          | —                   | (12)                                 | (12)                        |
| Net loss  | —                                      | —          | —                     | —      | —                          | (48,902)            | —                                    | (48,902)                    |
| Balance at December 31, 2017  | —                                      | \$ —       | 37,802,556            | \$ 38  | \$ 365,838                 | \$ (211,269)        | \$ (111)                             | \$ 154,496                  |

See accompanying notes to consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

|  | Year Ended<br>December 31, |           |             |
|--|----------------------------|-----------|-------------|
|  | 2017                       | 2016      | 2015        |
| <b>Operating activities:</b>   |                            |           |             |
| Net (loss) income  | \$ (48,902)                | \$ 22,613 | \$ (28,314) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: |                            |           |             |
| Depreciation and amortization  | 164                        | 83        | 75          |
| Stock-based compensation   | 5,096                      | 599       | 588         |
| Amortization of debt discount and issuance costs   | 198                        | 776       | 195         |
| Loss on sale of equipment  | 2                          | —         | —           |
| Changes in operating assets and liabilities:   |                            |           |             |
| Grants and other receivables   | 337                        | 65        | 144         |
| Deposits and other assets  | 2,387                      | (3,888)   | 1,504       |
| Inventory  | (2,013)                    | —         | —           |
| Accounts payable   | 392                        | (130)     | 450         |
| Accrued expenses   | 5,834                      | (1,097)   | (3,814)     |
| Accrued interest   | 668                        | 2,740     | 669         |
| Deferred other income  | 186                        | (41)      | (211)       |
| Cash (used in) provided by operating activities  | (35,651)                   | 21,720    | (28,714)    |
| <b>Investing activities:</b>   |                            |           |             |
| Purchases of property and equipment  | (2,406)                    | (215)     | (80)        |
| Cash used in investing activities  | (2,406)                    | (215)     | (80)        |
| <b>Financing activities:</b>   |                            |           |             |
| Proceeds from the sale of Series C-1 preferred stock   | —                          | —         | 5,000       |
| Proceeds from the sale of Series D preferred stock   | 36,712                     | —         | —           |
| Proceeds from the sale of common stock units in connection with initial public offering            | 138,000                    | —         | —           |
| Proceeds from issuance of convertible notes payable, net   | —                          | —         | 14,285      |
| Proceeds from long-term debt   | 75,000                     | —         | —           |
| Proceeds from the exercise of stock options  | 134                        | 55        | —           |
| Payments of withholdings on shares withheld for income taxes                                       | (288)                      | —         | —           |
| Cash paid for financing costs  | (13,433)                   | —         | (162)       |
| Cash provided by financing activities  | 236,125                    | 55        | 19,123      |
| Effects of exchange rate changes on cash and cash equivalents                                      | (11)                       | 39        | (14)        |
| Net increase in cash and cash equivalents  | 198,057                    | 21,599    | (9,685)     |
| Cash and cash equivalents at beginning of period   | 36,797                     | 15,198    | 24,883      |
| Cash and cash equivalents at end of period   | \$ 234,854                 | \$ 36,797 | \$ 15,198   |
| <b>Supplemental disclosure of noncash financing activities:</b>                                    |                            |           |             |
| Deemed dividend  | \$ 11,969                  | \$ 11,005 | \$ 9,992    |
| Accretion to redemption value  | \$ 1,096                   | \$ 2,109  | \$ 2,069    |
| Financing costs within accounts payable and accrued expenses                                       | \$ 2,454                   | \$ —      | \$ —        |
| Conversion of convertible notes payable and accrued interest into Series C-2 preferred stock       | \$ 19,527                  | \$ —      | \$ —        |
| Conversion of redeemable convertible preferred stock into common stock                             | \$ 237,259                 | \$ —      | \$ —        |

See accompanying notes to consolidated financial statements

**OptiNose, Inc.**  
**Notes to Consolidated Financial Statements**  
**(in thousands, except share and per share data)**

## **1. Organization and Description of Business**

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and has facilities in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England. The Company's predecessor entity, OptiNose AS, was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's first two products approved by the United States Food and Drug Administration (FDA) utilize its proprietary Exhalation Delivery Systems (EDS), which are capable of deep intranasal deposition of medication. OptiNose developed its first product, Onzetra<sup>®</sup> Xsail<sup>®</sup> (sumatriptan nasal power) through the completion of Phase III clinical trials and subsequently out-licensed the product to Avanir Pharmaceuticals, Inc (Avanir). Onzetra Xsail received FDA approval and was launched in the United States (US) in 2016. The Company's second product, XHANCE<sup>™</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic that utilizes its EDS to deliver a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps. On September 18, 2017, the FDA approved the Company's New Drug Application (NDA) for XHANCE for the treatment of nasal polyps in patients 18 years of age or older, and XHANCE is in development for the treatment of chronic sinusitis.

In October 2017, the Company completed an initial public offering (IPO) of its common stock, selling 8,625,000 shares at \$16.00 per share. As a result of the IPO, the Company received \$125,471 in net proceeds, after deducting discounts and commissions of \$9,660 and offering expenses of approximately \$2,869 payable by the Company. Upon consummation of the IPO, all of the outstanding shares of the Company's redeemable convertible preferred stock were converted into an aggregate of 25,068,556 shares of common stock.

## **2. Liquidity**

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, preparing for the launch of XHANCE. The Company has not generated any revenue from product sales to date. As of December 31, 2017, the Company had cash and cash equivalents of \$234,854.

During the year ended December 31, 2017, the Company sold 1,117,578 shares of Series D preferred stock, which resulted in gross proceeds to the Company of \$36,712 (Note 12). Additionally, in October 2017, the Company completed an IPO of its common stock, selling 8,625,000 shares at \$16.00 per share. As a result of the IPO, the Company received \$125,471 in net proceeds. In December 2017, the Company entered into a note purchase agreement which provided for the issuance of up to \$100,000 of senior secured notes, of which \$75,000 (Note 9) of such notes were issued immediately.

The Company may need to secure additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources in order to service the Company's existing obligations under outstanding notes, including repayment, and to carry out all of the Company's planned development and commercial activities. If additional capital is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital, the development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products.

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
**(in thousands, except share and per share data)**

### **3. Summary of Significant Accounting Policies**

#### ***Basis of presentation***

The accompanying consolidated financial statements have been prepared in conformity with US generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

#### ***Principles of consolidation***

The consolidated financial statements include the accounts of OptiNose, Inc. and its wholly-owned subsidiaries, OptiNose US, Inc., OptiNose AS and OptiNose UK Ltd. All inter-company balances and transactions have been eliminated in consolidation.

#### ***Use of estimates***

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

#### ***Stock Split***

On October 10, 2017, the Company effected a 2.8879-for-1 reclassification, or stock split, of the Company's common stock in connection with its initial public offering, or the IPO. All common share and per share amounts in these consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the stock split.

#### ***Cash and cash equivalents***

All highly liquid investments purchased with an original maturity date of three months or less at the date of purchase are considered to be cash equivalents. The Company generally invests its cash in deposits with high credit quality financial institutions. Additionally, the Company performs periodic evaluations of the relative credit standing of these financial institutions.

The Company maintains its cash and cash equivalent balances at foreign and domestic financial institutions. Bank deposits with Norwegian banks are insured up to approximately 2,000 Norwegian krone by the Norwegian Banks' Guarantee Fund. Bank deposits with US banks are insured up to \$250 by the Federal Deposits Insurance Corporation. The Company had uninsured cash balances of \$233,772 and \$35,866 at December 31, 2017 and 2016, respectively.

#### ***Fair value of financial instruments***

The Company measures certain assets and liabilities at fair value, which is defined as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The FASB accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company uses quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of the inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.



**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
**(in thousands, except share and per share data)**

- Level 2 — Valuations based on observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At December 31, 2017 and 2016, the Company's financial instruments included cash and cash equivalents, grants receivable, accounts payable, and accrued expenses. The carrying amounts reported in the Company's financial statements for these instruments approximates their respective fair values because of the short-term nature of these instruments. In addition, at December 31, 2017, the Company believes the carrying value of debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At December 31, 2017 and 2016, there were no financial assets or liabilities measured at fair value on a recurring basis.

The Company's financial instruments also included convertible debt at December 31, 2016 (Note 8).

***Inventory***

Prior to receiving FDA approval for XHANCE in September 2017, inventory purchases were expensed as incurred and recorded as a component of research and development expense. Subsequent to receiving FDA approval, inventories are stated at the lower of cost or net realizable value, net of reserves for excess and obsolete inventory. Cost is computed using standard cost (which approximates actual cost) on a first-in, first-out basis. Inventory consisted of the following:

|                 | December 31, |      |
|-----------------|--------------|------|
|                 | 2017         | 2016 |
| Raw materials   | \$ 1,385     | \$ — |
| Work-in-process | 628          | —    |
| Finished goods  | —            | —    |
| Total           | \$ 2,013     | \$ — |

***Deposits and other assets***

Deposits and other assets consist primarily of prepaid insurance, payments made in advance to outsourced contract manufacturers and equipment suppliers, as well as a receivable due from the FDA at December 31, 2016 related to a Prescription Drug User Fee Act (PDUFA) New Drug Application fee that the FDA refunded to the Company in March 2017.

Throughout 2017 and 2016, the Company made upfront payments to outsourced plastic mold development manufacturers and equipment suppliers for molds and equipment that are expected to be used for the commercial production of XHANCE. The Company received the majority of this equipment in 2017. For equipment received prior to FDA approval, the Company recorded the cost associated with the equipment purchase as a component of research and development expense if there was no alternative future use of the equipment without FDA approval. Conversely, deposits on equipment received after the September 18, 2017 FDA approval of XHANCE were capitalized as fixed assets when the equipment was received and therefore classified as long-term deposits at December 31, 2017.

***Property and equipment***

Property and equipment is recorded at cost less accumulated depreciation. Significant additions or improvements are capitalized, and expenditures for repairs and maintenance are charged to expense as incurred. Gains and

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
**(in thousands, except share and per share data)**

losses on disposal of assets are included in the consolidated statements of operations. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets.

The estimated useful lives of equipment are as follows:

|                                  |                                      |
|----------------------------------|--------------------------------------|
| Computer equipment               | 3 years                              |
| Software                         | 3 years                              |
| Machinery & production equipment | 5-10 years                           |
| Furniture & fixtures             | 3-5 years                            |
| Leasehold improvements           | Shorter of lease term or useful life |

### **Long lived assets**

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell. The Company has not recognized any impairment or disposition of long-lived assets for the years ended December 31, 2017, 2016 or 2015.

### **Revenue recognition**

Through December 31, 2017, the Company's revenues have been generated through licensing arrangements, which generally contain multiple elements, or deliverables, including licenses and research and development activities to be performed by the Company on behalf of the licensee. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectibility is reasonably assured.

To date, the Company's revenues have been generated pursuant to the terms of a single license agreement (the AVP-825 License Agreement) with Avanir Pharmaceuticals, Inc. (Avanir) (Note 7). The AVP-825 License Agreement includes licensed rights to patented technology, non-refundable up-front license fees, research services, and regulatory and sales milestones as well as royalty payments. As of December 31, 2017, only possible sales milestones and royalty payments remain to be earned under the license AVP-825 License Agreements. Such amounts would only be earned after net sales in the US, Canada and Mexico exceed a certain threshold.

For arrangements with multiple elements, the Company recognizes revenue in accordance with the FASB ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which provides guidance for separating and allocating consideration in a multiple element arrangement. The selling prices of deliverables under an arrangement may be derived using third-party evidence (TPE), or a best estimate of selling price (BESP), if vendor-specific objective evidence of selling price (VSOE) is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the License Agreement was sold on a standalone basis. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting for the Company's collaborations, the Company evaluated whether the AVP-825 License Agreement has standalone value to the collaborator based on consideration of the relevant

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facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not (i) the collaborator could use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license was dependent on the undelivered items and (iii) the collaborator or other vendors could provide the undelivered items.

Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

Development milestones may be triggered either by the results of the Company's research efforts or by events external to it, such as regulatory approval to market a product. Consideration that is contingent upon achievement of a development milestone is recognized in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must (i) be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the AVP-825 License Agreement. As of December 31, 2017, all development milestones have been achieved.

#### ***Advertising expenses***

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$1,833, \$26 and \$44 for the years ended December 31, 2017, 2016 and 2015, respectively.

#### ***Research and development***

Research and development costs are expensed as incurred. Research and development costs consist primarily of device development, clinical trial related costs, and regulatory related costs. The Company enters into agreements with contract research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development activities for the Company's clinical trials. These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. The Company prepays certain CRO fees whereby the prepayments are recorded as a current or non-current prepaid asset and are amortized into research and development expense over the period of time the contracted research and development services were performed. The Company's CRO contracts generally also included other fees such as project management and pass through fees whereby the Company expenses these costs as incurred, using the Company's best estimate. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs. Pass through fees incurred are based on the amount of work completed for the clinical trials and are monitored through reporting provided by the Company's CROs.

#### ***Stock-based compensation***

The Company measures and recognizes compensation expense for all stock options awarded to employees and nonemployees and shares issued under the employee stock purchase plan based on the estimated fair value of the awards on the respective grant dates. The Company uses the Black-Scholes option pricing model to value its stock option awards and shares issued under the employee stock purchase plan. The Company recognizes compensation expense for time-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The Company recognizes compensation expense for performance based awards when the performance condition is probable of achievement. Stock-based awards issued to nonemployees are revalued at each reporting period until the award vests. The Company accounts for forfeitures of stock option awards as they occur.

Estimating the fair value of options and shares issued under the employee stock purchase plan requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, the expected life of the

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options, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective.

**Income taxes**

Income taxes are accounted for under the asset and liability method. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2017 and 2016, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

**Grant income**

Government grants are agreements that provide cost reimbursement for certain research and development activities over a contractually defined period. Income from government grants is recognized in the period in which related costs are incurred, provided that the conditions under which government grants were provided have been met and only perfunctory obligations are outstanding. Grant income received in excess of costs incurred is recognized as deferred other income.

**Net income (loss) per common share**

The Company used the two-class method to compute net income (loss) per common share for the year ended December 31, 2016 as the Company realized net income and had issued securities (redeemable convertible preferred stock) that entitled the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by the amount of any dividends earned and the accretion of redeemable convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of redeemable convertible preferred stock to the extent that each preferred security may share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the redeemable convertible preferred stock have no obligation to fund losses. For the year ended December 31, 2016, the Company presented diluted net income per common share using the two-class method, which was more dilutive than the "if-converted" method.

Diluted net income (loss) per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, warrants, and convertible debt. In addition, the Company analyzes the potential dilutive effect of the outstanding redeemable convertible preferred stock and convertible debt under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding redeemable convertible preferred stock or convertible debt converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (two class or "if-converted") as their diluted net income per share during the period.

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common stockholders by the weighted average common shares outstanding during the period. For the years ended December 31, 2017 and 2015, the outstanding common stock option and common stock warrants have been excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

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The following table sets forth the computation of basic and diluted net income (loss) per share for the periods indicated:

|   | Year Ended December 31, |           |             |
|---|-------------------------|-----------|-------------|
|   | 2017                    | 2016      | 2015        |
| Basic net (loss) income per common share calculation:           |                         |           |             |
| Net (loss) income attributable to common stockholders           | \$ (61,967)             | \$ 9,499  | \$ (40,375) |
| Less: undistributed earnings to participating securities        | —                       | (7,884)   | —           |
| Net (loss) income attributable to common stockholders — basic   | (61,967)                | 1,615     | (40,375)    |
| Weighted average common shares outstanding — basic              | 10,999,121              | 4,054,316 | 4,049,668   |
| Net (loss) income per share of common stock — basic             | \$ (5.63)               | \$ 0.40   | \$ (9.97)   |
| Diluted net (loss) income per common share calculation:         |                         |           |             |
| Net (loss) income attributable to common stockholders           | \$ (61,967)             | \$ 9,499  | \$ (40,375) |
| Less: undistributed earnings to participating securities        | —                       | (7,884)   | —           |
| Net (loss) income attributable to common stockholders — diluted | (61,967)                | 1,615     | (40,375)    |
| Weighted average common shares outstanding — basic              | 10,999,121              | 4,054,316 | 4,049,668   |
| Stock options   | —                       | 925,865   | —           |
| Weighted average common shares outstanding — diluted            | 10,999,121              | 4,980,181 | 4,049,668   |
| Net (loss) income per share of common stock — diluted           | \$ (5.63)               | \$ 0.32   | \$ (9.97)   |

Diluted net income (loss) per common share for the periods presented do not reflect the following potential common shares, as the effect would be antidilutive:

|                             | Year Ended December 31, |            |            |
|-----------------------------|-------------------------|------------|------------|
|                             | 2017                    | 2016       | 2015       |
| Stock options               | 2,141,367               | 2,346,073  | 3,413,178  |
| Common stock warrants       | 1,890,489               | 1,890,489  | 1,890,489  |
| Convertible debt            | —                       | 1,917,522  | 1,888,484  |
| Convertible preferred stock | —                       | 19,855,772 | 19,855,772 |
| Total                       | 4,031,856               | 26,009,856 | 27,047,923 |

### Recent accounting pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation - Scope of Modification Accounting*. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The FASB issued the update to require the recognition of lease assets and liabilities on the balance sheet of lessees. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. Early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will replace numerous requirements in US GAAP, including industry-specific requirements. This guidance provides a five-step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The new standard also defines accounting for certain costs related to origination and fulfillment of contracts with customers, including whether such costs should be capitalized.

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This statement requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance and assets recognized from costs incurred to obtain or fulfill a contract. The guidance is effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented — referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings — referred to as the modified retrospective method.

The Company has assessed the impact that ASU No. 2014-09 will have on its financial statements and related disclosures. To date, the Company has derived its revenues from a single licensing agreement with Avanir (the AVP-825 License Agreement). The consideration the Company has received to date includes an upfront payment, research and development funding and development milestone payments. Additionally, the Company is eligible to receive sales milestone payments and royalties in the future once net product sales exceed a certain threshold. The Company analyzed the performance obligations under the AVP-825 License Agreement, and the consideration received to date and that the Company may receive in the future, as part of its analysis of the impact of ASU 2014-09 on this arrangement. The Company has completed its initial assessment of the AVP-825 License Agreement, and currently does not expect the adoption of the ASU to have a material impact on its financial statements but is expected to result in expanded footnote disclosures. The Company will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusion.

The Company plans to adopt the new standard effective January 1, 2018 using the modified retrospective approach.

#### 4. Deposits and Other Assets

Deposits and other assets consisted of the following:

|  | December 31,    |                 |
|--|-----------------|-----------------|
|  | 2017            | 2016            |
| <i>Short-term</i>                          |                 |                 |
| Receivable due from the FDA                | \$ —            | \$ 2,038        |
| Deposits on equipment                      | —               | 1,201           |
| Prepaid expenses and other                 | 1,254           | 255             |
| Total short-term deposits and other assets | \$ 1,254        | \$ 3,494        |
| <i>Long-term</i>                           |                 |                 |
| Deposits on equipment                      | \$ 329          | \$ 499          |
| Other                                      | 76              | 54              |
| Total long-term deposits and other assets  | 405             | 553             |
|  | <u>\$ 1,659</u> | <u>\$ 4,047</u> |



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## 5. Property and Equipment

Property and equipment, net, consisted of:

|                                 | December 31,    |               |
|---------------------------------|-----------------|---------------|
|                                 | 2017            | 2016          |
| Computer equipment and software | \$ 307          | \$ 293        |
| Furniture and fixtures          | 89              | 121           |
| Machinery and equipment         | 2,495           | 255           |
| Leasehold improvements          | 28              | 28            |
|                                 | <u>2,919</u>    | <u>697</u>    |
| Less: accumulated depreciation  | (355)           | (374)         |
|                                 | <u>\$ 2,564</u> | <u>\$ 323</u> |

Depreciation expense was \$164, \$83 and \$75 for the years ended December 31, 2017, 2016 and 2015, respectively. During the year ended December 31, 2017, the Company disposed of \$209 of fully depreciated assets.

## 6. Accrued Expenses

Accrued expenses consisted of:

|  | December 31,    |                 |
|--|-----------------|-----------------|
|  | 2017            | 2016            |
| Research and development expenses            | \$ 80           | \$ 736          |
| Selling, general and administrative expenses | 3,463           | 290             |
| Bonus expense                                | 4,163           | 1,390           |
| Payroll and benefit expenses                 | 633             | 125             |
| Interest expense                             | 45              | —               |
| Other  | 314             | —               |
|  | <u>\$ 8,698</u> | <u>\$ 2,541</u> |

## 7. AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra® Xsail®), a product combining a low-dose powder form of sumatriptan with the Company's EDS technology platform, for the acute treatment of migraines in adults and any follow-on products under development that consist of a formulation that contains triptans as the sole active ingredient. Through December 31, 2017, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of \$70,000 in connection with the initial signing and the achievement of certain development milestones. Under the terms of the License Agreement, the Company is eligible to receive up to \$50,000 upon the achievement of sales milestones as well as tiered low double-digit royalty payments on net sales in the US, Canada and Mexico after such cumulative sales exceed a certain threshold.

The Company determined that there were two deliverables under the AVP-825 License Agreement: (i) the license which was delivered in July 2013 and (ii) its obligation to provide certain research and development services in execution of the development plan and to share equally in certain qualified third party development costs through FDA approval. The Company concluded that the license had standalone value to Avanir and was separable from the research and development services, given Avanir has significant research capabilities in the field.

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As a result, the license and research services qualify as separate units of accounting and the value of the license and the value of the research services were separately valued based upon the estimated selling price of each deliverable. The value attributable to the license was recognized up-front upon delivery of the license and the values attributable to the research services were deferred and recognized over the period in which the related services were to be delivered based upon a percentage of costs incurred in each respective reporting period. The estimated selling price of each deliverable was determined using the BESP. The BESP reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis.

In conjunction with the AVP-825 License Agreement, the Company recognized \$47,500 as licensing revenue during the year ended December 31, 2016. The revenue was related to the achievement of the FDA approval milestone in January 2016. The Company did not recognize any licensing revenue during the year ended December 31, 2017.

## 8. Convertible Notes

At December 31, 2017 and 2016, the Company's convertible notes payable, net, balance was as follows:

|                                | December 31, |                  |
|--------------------------------|--------------|------------------|
|                                | 2017         | 2016             |
| Face amount                    | \$ —         | \$ 15,000        |
| Front end fees                 | —            | (75)             |
| Debt issuance costs            | —            | (44)             |
| Back end fees                  | —            | 375              |
| Convertible notes payable, net | <u>\$ —</u>  | <u>\$ 15,256</u> |

On September 30, 2015, the Company entered into a Senior Secured Convertible Note Purchase Agreement (Notes) with various existing stockholders. The Notes provided the Company with up to \$30,000 in capital available in two separate tranches. The first tranche of \$15,000 closed on September 30, 2015. The second tranche of up to \$15,000 was available to the Company until March 30, 2017 but was never drawn. The Notes bore an annual interest rate of 17% and were scheduled to mature on September 30, 2020 if not otherwise converted to Series C-2 shares. The Notes also bore front-end fees of \$450, which were paid at issuance, and back end fees of \$450 plus interest that was to be paid at maturity. The Notes could be repaid at any time in \$100 increments, did not contain any prepayment penalties and were secured by assets of OptiNose Inc. and OptiNose US, Inc. At the option of the majority purchaser of the Notes after March 30, 2017, or prior to March 30, 2017 if an event of default occurred or was continuing under the Notes, all note principal along with any accrued interest and back end fees thereon, could be converted into Series C-2 shares of preferred stock at a conversion price based upon a Company valuation equal to the lower of fair market value or \$300,000.

As of December 31, 2016, the fair value of the Notes was \$21,814, which was estimated based on the as converted value of the Notes as of that date.

On March 24, 2017, in connection with the Series D Financing, the Notes and associated accrued interest and back end fees thereon totaling \$19,527 converted into 687,474 shares of Series C-2 preferred stock at a per share conversion price of approximately \$28.40.

The Company recorded interest expense of \$862, \$3,517 and \$819 during the years ended December 31, 2017, 2016 and 2015, respectively, in conjunction with the Notes. Total coupon interest on the Notes and back end fees was \$743 and \$2,740 during the years ended December 31, 2017 and 2016, respectively. The front-end fees of \$450 were recorded as debt discount at issuance and were amortized to interest expense over the 18 month loan conversion period. During the years ended December 31, 2017 and 2016, the Company recorded a total of \$75 and \$300 of interest expense, respectively, related to the front end fees. Additionally, back end fees of \$450 were amortized to interest expense over the 18 month loan conversion period of which \$90 and \$300 have been recorded as interest expense and as an increase in the carrying amount of the Notes during the years ended December 31, 2017 and 2016, respectively. The Company also incurred \$265 in debt issuance costs during the

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year ended December 31, 2015 which were amortized to interest expense over the 18 month loan conversion period.

As of December 31, 2017, none of the Notes were outstanding.

## **9. Long-term Debt**

On December 29, 2017, the Company entered into a Senior Secured Note Purchase Agreement (the Senior Secured Notes) with Athyrium Opportunities III Acquisition LP. The Senior Secured Notes provided the Company with up to \$100,000 in capital, of which \$75,000 was issued immediately. The remaining \$25,000 (the Delayed Draw Notes) may be issued between April 1, 2019 and August 14, 2019, subject to the Company achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Note Purchase Agreement) of \$15,000 and a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00, and certain other conditions.

The Senior Secured Notes bear interest at 9.0% plus the three-month London Inter-bank Offered Rate (LIBOR) rate, subject to a 1.0% floor and are scheduled to mature on June 29, 2023. The interest rate was 10.75% at December 31, 2017. The Senior Secured Notes bore front-end fees of 1% of the aggregate principal amount, which were paid at issuance. The Company is also required to pay an exit fee of 2% of any principal payments (whether mandatory, voluntary, or at maturity) made throughout the term of the note purchase agreement.

The Company is required to make quarterly, interest only payments until the maturity date. The Company may make voluntary prepayments of the Senior Secured Notes, in whole or in part, and subject to certain exceptions, is required to make mandatory prepayments upon the occurrence of certain events as defined in the agreement, including, the occurrence of a change of control.

All mandatory and voluntary prepayments of the Senior Secured Notes are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the second anniversary of the applicable date of issuance, an amount equal to the amount by which (a) the present value of 102% of the principal prepaid plus all interest that would have accrued on such principal through such second anniversary exceeds (b) the amount of principal prepaid, (ii) if prepayment occurs on or after the second anniversary of the applicable date of issuance but prior to the third anniversary of such issuance, an amount equal to 2% of the principal prepaid, and (iii) if prepayment occurs on or after the third anniversary of the applicable date of issuance but prior to the fourth anniversary of such issuance, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid after the fourth anniversary of the applicable date of issuance of any Senior Secured Notes.

The Senior Secured Notes are secured by a pledge of substantially all of the Company's assets and contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its subsidiaries' ability to, among other things, incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, grant certain license rights related to the Company's products, technology and other intellectual property rights, pay dividends and distributions, repay junior indebtedness and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Senior Secured Notes contains financial covenants requiring the Company to maintain (i) at least \$10,000 of cash and cash equivalents and (ii) following the issuance of the Delayed Draw Notes or upon entering into certain exclusive licenses of XHANCE, a total debt to trailing four quarter net revenue ratio of less than 6.50 to 1.00 initially, and thereafter declining quarterly by equal half-steps to a ratio of less than 3.00 to 1.00. As of December 31, 2017, the Company was in compliance with the covenants.

The Company recorded interest expense of \$48 during the year ended December 31, 2017, in conjunction with the Senior Secured Notes. Interest expense included total coupon interest, back end fees, front end fees and the amortization of debt issuance costs. The front-end fees of \$1,000 were recorded as debt discount at issuance and are being amortized to interest expense over the 5.5 year term of the loan. Additionally, back end fees of \$2,000 are being amortized to interest expense and are recorded as, an increase in the carrying amount throughout the term of the Senior Secured Notes. The Company also incurred \$2,140 in debt issuance costs during the year ended December 31, 2017 which are also being amortized to interest expense over the term of the Senior Secured Notes.

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As of December 31, 2017, the long-term debt balance is comprised of the following:

|                     | <u>December 31,</u> |
|---------------------|---------------------|
|                     | <u>2017</u>         |
| Face amount         | \$ 75,000           |
| Front end fees      | (999)               |
| Debt issuance costs | (2,139)             |
| Back end fees       | 1                   |
| Long-term debt, net | <u>\$ 71,863</u>    |

## 10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan, which covers all employees. Employees are eligible on the first of the month following their date of hire. Under the 401(k) retirement plan, participating employees may defer up to 100% of their pre-tax salary but not more than statutory limits. In October 2017, the Company adopted a 401(k) matching program for its US employees. The Company matches 100% of the first 3% of participating employee contributions and 50% of the next 2% of participating employee contributions, subject to applicable IRC limits. For 2017, the 401(k) match was applied to eligible earnings starting January 1, 2017. As of December 31, 2017, approximately \$230 related to the Company match applicable to 2017 employee contributions, which Company match will be made in the first quarter of 2018. There were no contributions to the plan by the Company in the years ended December 31, 2016 or 2015. The Company's contributions are made in cash. The Company's common stock is not currently an investment option available to participants in the 401(k) retirement plan.

For Norway and UK employees, the Company maintains defined contribution pension plans which meet statutory requirements of those jurisdictions. The Company incurred costs of \$45, \$24 and \$24 related to the pension plans for the years ended December 31, 2017, 2016 and 2015, respectively.

## 11. Commitments and Contingencies

### Leases

The Company leases office space under four operating leases. Rent expense is recognized as incurred.

The following is a schedule of future minimum annual payments as of December 31, 2017 under non-cancellable operating lease agreements:

For the years ending December 31:

|   |               |
|---|---------------|
| 2018  | 187           |
| Total future minimum lease payments as of December 31, 2017 | <u>\$ 187</u> |

Rent expense under these operating leases was \$689, \$407 and \$312 for the years ended December 31, 2017, 2016 and 2015, respectively.

In January 2018, the Company amended its existing office lease agreement for the Company's headquarters in Yardley, PA (the Lease Amendment). Under the terms of the Lease Amendment, the Company's leased office space was increased from approximately 20,050 square feet to approximately 30,000 square feet, and the term of the lease was extended from March 31, 2018 to May 31, 2021 (the Extended Term), with an option to renew the lease for an additional three-year term. The Company's rent payments during the Extended Term will be approximately

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\$2,750 in the aggregate, and the Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises.

**Purchase commitments**

In November 2017, the Company entered into agreement with a contract sales organization for the recruitment, deployment and management of a contract sales force to market XHANCE in the US. Subject to certain limited exceptions, the Company may not terminate this agreement until after the first anniversary of the deployment of the sales force (which occurred in March 2018). The Company estimates the expenses related to the non-cancellable services during this period to be approximately \$16,354. Thereafter, the Company may terminate the agreement subject to potential early termination fees ranging from \$100 to \$700.

As of December 31, 2017, the Company had no other outstanding non-cancellable purchase commitments related to inventory and other goods and services, including pre-commercial manufacturing scale-up and sales and marketing activities.

**Employment agreements**

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment by the Company without cause or by the employee for good reason. In addition, in the event of termination of employment following a change in control, the vesting of certain equity awards may be accelerated.

**Litigation**

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

**12. Stockholders' equity (deficit)****Common stock**

In October 2017, the Company increased the number of authorized common shares from 10,624,486 to 200,000,000 and completed an initial public offering (IPO) of its common stock, selling 8,625,000 shares at \$16.00 per share. As a result of the IPO, the Company received \$125,471 in net proceeds, after deducting discounts and commissions of \$9,660 and offering expenses of approximately \$2,869 payable by the Company.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through December 31, 2017.

**Common stock warrants**

As of December 31, 2017, the Company had 1,890,489 warrants outstanding to purchase shares of the Company's common stock with an exercise price of \$8.16. The warrants expire on November 1, 2020.

**Redeemable convertible preferred stock**

During the year ended December 31, 2017, the Company sold 1,117,578 shares of Series D Preferred Stock at a per share purchase price of \$32.85, resulting in gross proceeds to the Company of \$36,712 (the Series D Financing). In connection with the Series D Financing, the Company's existing convertible notes and associated accrued interest and back end fees thereon totaling \$19,527 converted into 687,474 shares of Series C-2 Preferred Stock at a per share conversion price of approximately \$28.40 (Note 8).

In conjunction with the Series D financing, the number of authorized shares of common stock was increased from 10,624,486 to 13,067,149 and the number of authorized shares of preferred stock was increased from 6,875,514 to 8,932,851, of which 1,369,863 shares were designated as Series D shares and 687,474 shares were designated as Series C-2 shares. Also, the redemption date for all classes of the Company's preferred stock was extended to March 24, 2020 and the terms upon which all classes of Preferred Stock would mandatorily convert into common stock in connection with an underwritten public offering were revised to align with the terms of the Series C-2 preferred stock.

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Upon consummation of the IPO in October 2017, all of the outstanding shares of the Company's redeemable convertible preferred stock were converted into an aggregate of 25,068,556 shares of common stock. In connection with the IPO, 5,000,000 shares of preferred stock, with a par value of \$0.001 per share, were authorized for issuance. As of December 31, 2017, no preferred stock was issued or outstanding.

### 13. Stock-based compensation

The Company issues stock-based awards pursuant to its 2010 Stock Incentive Plan. Effective as of October 12, 2017, the Company's 2010 Stock Incentive Plan was amended and restated (A&R Plan). The A&R Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, deferred stock units, performance shares, stock appreciation rights and other equity-based awards. The Company's employees, officers, directors and other persons are eligible to receive awards under the A&R Plan. As of December 31, 2017, 6,894,445 shares of the Company's common stock were authorized to be issued under the A&R Plan, and 546,131 shares were reserved for future awards under the A&R Plan. The number of shares of the Company's common stock authorized under the A&R Plan will automatically increase on January 1st of each year, commencing on January 1, 2018 and continuing until the expiration of the A&R Plan, in an amount equal to four percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the Company's board of directors or compensation committee to determine a lesser number of shares shall be added for such year.

The amount, terms of grants, and exercisability provisions are determined and set by the Company's board of directors or compensation committee. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. Stock-based awards issued to non-employees are revalued until the award vests.

#### *Service-based stock options*

Options issued under the A&R Plan generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the board of directors. Vesting generally occurs over a period of not greater than four years. The following table summarizes the activity related to service-based stock option grants to employees and nonemployees for the years ended December 31, 2017:

|  | Shares           | Weighted average exercise price per share | Weighted average remaining contractual life |
|--|------------------|---|---|
| Outstanding at December 31, 2016                 | 1,894,083        | \$ 3.09                                   | 6.67  |
| Granted  | 2,341,096        | 14.00                                     |   |
| Exercised  | (26,047)         | 2.34                                      |   |
| Expired  | (2,887)          | 5.68                                      |   |
| Forfeited  | (96,036)         | 9.29                                      |   |
| Outstanding at December 31, 2017                 | <u>4,110,209</u> | \$ 9.16                                   | 7.89  |
| Exercisable at December 31, 2017                 | <u>1,327,843</u> | \$ 2.36                                   | 4.53  |
| Vested and expected to vest at December 31, 2017 | <u>4,110,209</u> | \$ 9.16                                   | 7.89  |

During the year ended December 31, 2017, time-based options to purchase 2,341,096 shares of common stock were granted to employees that generally vest over four years. The options had an estimated weighted average grant date fair value of \$9.68. The grant date fair value of each option grant was estimated at the time of grant using the Black-Scholes option-pricing model.

The total aggregate intrinsic value of service-based options exercised during the years ended December 31, 2017 and 2016 was \$435 and \$20, respectively. There were no service-based options exercised during the year ended December 31, 2015. The aggregate intrinsic value of service-based options outstanding and service-based options exercisable as of December 31, 2017 was \$40,102 and \$21,961, respectively. At December 31, 2017, the unrecognized compensation cost related to unvested service-based stock options expected to vest was \$22,198.



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This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 3.89 years.

**Performance-based stock options**

The Company has issued performance-based stock options under the A&R Plan which generally have a ten-year life from the date of grant and may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued options in excess of the fair market value of common shares on the issuance date that are only exercisable upon a change in control or upon or after an initial public offering. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

The following table summarizes the activity related to performance-based stock option grants to employees and nonemployees for the years ended December 31, 2017:

|  | Shares           | Weighted<br>average<br>exercise price<br>per share | Weighted<br>average<br>remaining<br>contractual life |
|--|------------------|--|--|
| Outstanding at December 31, 2016                 | 2,171,760        | \$ 9.59  | 6.55   |
| Granted  | —                | —  |  |
| Exercised  | (30,393)         | 2.44   |  |
| Forfeited  | —                | —  |  |
| Outstanding at December 31, 2017                 | <u>2,141,367</u> | \$ 9.69  | 5.56   |
| Exercisable at December 31, 2017                 | <u>1,708,181</u> | \$ 8.02  | 5.04   |
| Vested and expected to vest at December 31, 2017 | <u>2,141,367</u> | \$ 9.69  | 5.56   |

The total aggregate intrinsic value of performance-based options exercised during the years ended December 31, 2017 and 2016 was \$505 and \$20 respectively. There were no performance-based options exercised during the year ended December 31, 2015. The aggregate intrinsic value of performance-based options outstanding and performance-based options exercisable as of December 31, 2017 was \$19,713 and \$18,592, respectively. As of December 31, 2017, there was \$563 of unrecognized compensation cost related to unvested performance-based stock options that will vest and be expensed over an estimated weighted average amortization period of 2.68 years.

**2017 Employee Stock Purchase Plan**

The Company's 2017 Employee Stock Purchase Plan (the 2017 Plan) became effective on October 12, 2017. The 2017 Plan authorized the issuance of up to 144,395 shares of the Company's common stock pursuant to purchase rights granted to its employees or to employees of any of its participating affiliates. The number of shares of the Company's common stock that may be issued pursuant to rights granted under the 2017 Plan shall automatically increase on January 1st of each year, commencing on January 1, 2018 and continuing until the expiration of the 2017 Plan, in an amount equal to one percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the board of directors or compensation committee to determine a lesser number of shares shall be added for such year.

Under the 2017 Plan, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the administrator. The 2017 Plan is administered by the compensation committee. Under the 2017 Plan, eligible employees may purchase the Company's common stock at discount of up to 85% of the lower of the fair market value of the Company's common stock on the first day of the offering period or on the last day of the offering period. Eligible employees may contribute up to 15% of their eligible compensation. Under the 2017 Plan, a participant may not accrue rights to purchase more than \$25,000 worth of the Company's common stock for each calendar year in which such right is outstanding.

Effective October 12, 2017, employees who elected to participate in the 2017 Plan commenced payroll withholdings that accumulate through June 30, 2018. Beginning on January 1, 2018, employees who elected to participate in the 2017 Plan will commence payroll withholdings that accumulate through June 30, 2018.

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At the end of each of the current offering periods, shares of the Company's common stock may be purchased at 85% of the lower of the fair market value of the Company's common stock on the first or last day of the respective offering period. In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company's common stock at the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the 2017 Plan is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the requisite service period of the option. The Company has recognized stock-based compensation expense of \$106 during the year ended December 31, 2017 related to the 2017 Plan.

**Stock-based compensation expense**

The Company recorded stock-based compensation expense in the following expense categories of its accompanying consolidated statements of operations for the years ended December 31, 2017 and 2016:

|   | Year ended December 31, |               |               |
|---|-------------------------|---------------|---------------|
|   | 2017                    | 2016          | 2015          |
| Research and development                      | \$ 1,288                | \$ 362        | \$ 354        |
| General and administrative                    | 3,808                   | 237           | 234           |
| <b>Total stock-based compensation expense</b> | <b>\$ 5,096</b>         | <b>\$ 599</b> | <b>\$ 588</b> |

The Company utilized the Black-Scholes valuation model for estimating the fair value of stock options granted and the option component of the 2017 Plan. The Company calculated the fair value of each option grant and the option component of the 2017 Plan on the respective dates of grant using the following weighted average assumptions:

|                          | 2010 A&R Stock<br>Incentive Plan | 2017 Employee Stock<br>Purchase Plan |
|--------------------------|----------------------------------|--------------------------------------|
|                          | December 31,<br>2017             | December 31,<br>2017                 |
| Risk free interest rate  | 2.06%                            | 1.27%                                |
| Expected term (in years) | 6.06                             | 0.72                                 |
| Expected volatility      | 78.67%                           | 91.18%                               |
| Annual dividend yield    | 0.00%                            | 0.00%                                |

Option valuation methods, including Black-Scholes, require the input of subjective assumptions, which are discussed below.

- The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.
- The expected volatility is based on historical volatilities of similar entities within the Company's industry which were commensurate with the expected term assumption as described in SAB No. 107.
- The risk-free interest rate is based on the interest rate payable on US Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

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**14. Income taxes**

The Tax Cuts and Jobs Act, or the TCJA, was enacted on December 22, 2017 and became effective January 1, 2018. Among other changes, the TCJA significantly lowers the US corporate income tax rate, implements a territorial tax system and imposes a one-time transition tax on deemed repatriated earnings of foreign subsidiaries.

The TCJA reduces the US corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the US corporate income tax rate, the Company revalued its net deferred tax assets at December 31, 2017. Due to the full valuation allowance on the Company's deferred tax assets, no tax expense or benefit associated with the re-measurement was recognized in the Company's consolidated statement of operations for the year ended December 31, 2017. The change in the US corporate tax rate is also included in the Company's deferred tax table.

The TCJA provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits, or E&P. As the Company's foreign subsidiaries did not have consolidated accumulated E&P, the Company did not record any income tax expense related to the transition tax.

Due to the timing of and the substantial changes made by the TCJA, the Staff of the Securities and Exchange Commission, or the SEC, issued Staff Accounting Bulletin No. 118, or SAB 118, which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA. Accordingly, the Company's preliminary estimate of the impact of the TCJA and the re-measurement of its deferred tax assets and liabilities is subject to finalization of its analysis of certain matters, such as developing interpretations of the TCJA provisions, changes to certain estimates and the filing of its tax returns. US Treasury regulations, administrative interpretations or court decisions interpreting the TCJA may require adjustments to the Company's initial estimates. The final determination of the TCJA provisions and re-measurement of the Company's deferred tax assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the TCJA.

Income taxes have been recorded on the following income (loss) before income tax expense:

|   | Year ended December 31, |                  |
|---|-------------------------|------------------|
|   | 2017                    | 2016             |
| Domestic operations                             | \$ (30,463)             | \$ (4,967)       |
| Foreign operations                              | (18,439)                | 27,580           |
| Income (loss) before provision for income taxes | <u>\$ (48,902)</u>      | <u>\$ 22,613</u> |

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A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

|                                      | Year ended December 31, |              |
|--------------------------------------|-------------------------|--------------|
|                                      | 2017                    | 2016         |
| Income tax expense at statutory rate | 35.0 %                  | 35.0 %       |
| Permanent items                      | 0.5                     | —            |
| Foreign rate differential            | (4.2)                   | (12.2)       |
| State taxes, net of federal benefit  | 0.8                     | (1.4)        |
| Tax rate changes                     | (15.4)                  | —            |
| Change in valuation allowance        | (16.7)                  | (21.4)       |
| <b>Effective income tax rate</b>     | <b>0.0 %</b>            | <b>0.0 %</b> |

Tax rate changes includes both the impact of the reduction in the US tax rate under the TCJA and a reduction in the Norway tax rate.

The principal components of the Company's deferred tax assets and liabilities were as follows:

|  | Year ended December 31, |               |
|--|-------------------------|---------------|
|  | 2017                    | 2016          |
| <b>Deferred tax assets:</b>                        |                         |               |
| Accrued expenses and other                         | \$ 972                  | \$ 539        |
| Fixed assets                                       | 55                      | —             |
| Interest expense                                   | 783                     | 677           |
| Stock compensation                                 | 1,701                   | 1,092         |
| Research and development                           | 2,485                   | 2,183         |
| Net operating losses                               | 29,636                  | 22,695        |
| <b>Total deferred tax assets</b>                   | <b>35,632</b>           | <b>27,186</b> |
| <b>Deferred tax liabilities:</b>                   |                         |               |
| Fixed assets                                       | —                       | (46)          |
| <b>Total deferred tax liabilities:</b>             | <b>—</b>                | <b>(46)</b>   |
| Less: Valuation allowance                          | (35,632)                | (27,140)      |
| <b>Total net deferred tax assets (liabilities)</b> | <b>\$ —</b>             | <b>\$ —</b>   |

The TCJA, in addition to the changes indicated above, contained other provisions that may have a future impact on the Company. The provisions include limitations on the deductibility of interest based on the amount of adjusted taxable income, the deferral of research and development deductions, the acceleration of deductions related to fixed asset additions, changes to the utilization of net operating loss carry forwards and changes in the carry forward period, and global intangible low-taxed income provisions that subject foreign subsidiary income that exceeds an allowable return to current US taxation.

As of December 31, 2017, the Company had foreign net operating loss, or NOL, carry forwards of \$96,616 primarily from its operations in Norway. As of December 31, 2017, the Company had federal and state NOL's of \$30,327 and \$13,702, respectively. These domestic NOL carry forwards may be subject to an annual limitation in the event of cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%. This could limit the amount of NOLs that the Company can utilize annually to offset future domestic taxable income or

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tax liabilities, if any. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The federal and state NOL's will expire beginning in 2030 and through 2037.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that all or a portion of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2017 and 2016, respectively, because the Company's management has determined that it is more likely than not that these assets will not be fully realized. The Company experienced a net change in valuation allowance of \$8,492 during the year ended December 31, 2017.

The Company files income tax returns in Norway, the UK, the US, and various states. The Company is subject to examination by federal, state and foreign jurisdictions. The Company's tax years in the US are open under statute from inception to present. All open years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

The Company's policy is to record interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2017, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations.

## 15. Related-party transactions

### *Debt and equity transactions*

All of the Company's convertible debt (see Note 8) was issued to holders of the Company's convertible preferred stock.

During the year-ended December 31, 2017, the Company reimbursed Avista Capital Holdings, LP and related parties \$157 in expenses, primarily related to legal fees incurred in conjunction with our IPO in October 2017 and the issuance of Series D redeemable convertible preferred stock March 2017.

## 16. Quarterly Financial Information (unaudited)

The following table summarizes the unaudited consolidated financial results of operations for the quarters ended (amounts in thousands except per share data):

|   | 2017 Quarters Ended |           |               |              |
|---|---------------------|-----------|---------------|--------------|
|   | March 31,           | June 30,  | September 30, | December 31, |
| Revenues  | \$ —                | \$ —      | \$ —          | \$ —         |
| Research and development                              | 3,073               | 5,906     | 6,641         | 1,212        |
| Selling, general and administrative                   | 4,230               | 2,431     | 6,553         | 18,484       |
| Total operating expenses                              | 7,303               | 8,337     | 13,194        | 19,696       |
| Income (loss) from operations                         | (7,303)             | (8,337)   | (13,194)      | (19,696)     |
| Net income (loss)                                     | (8,075)             | (8,208)   | (13,068)      | (19,551)     |
| Net income (loss) attributable to common stockholders | (11,671)            | (12,836)  | (17,192)      | (20,268)     |
| Basic net income (loss) per common share              | \$ (2.87)           | \$ (3.16) | \$ (4.23)     | \$ (0.64)    |
| Diluted net income (loss) per common share            | \$ (2.87)           | \$ (3.16) | \$ (4.23)     | \$ (0.64)    |

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|   | 2016 Quarters Ended |           |               |              |
|---|---------------------|-----------|---------------|--------------|
|   | March 31,           | June 30,  | September 30, | December 31, |
| Revenues  | \$ 47,500           | \$ —      | \$ —          | \$ —         |
| Research and development                              | 4,961               | 3,412     | 3,868         | 3,070        |
| Selling, general and administrative                   | 2,250               | 1,046     | 1,761         | 1,812        |
| Total operating expenses                              | 7,211               | 4,458     | 5,629         | 4,882        |
| Income (loss) from operations                         | 40,289              | (4,458)   | (5,629)       | (4,882)      |
| Net income (loss)                                     | 39,572              | (5,265)   | (6,106)       | (5,588)      |
| Net income (loss) attributable to common stockholders | 36,294              | (8,544)   | (9,385)       | (8,866)      |
| Basic net income (loss) per common share              | \$ 1.52             | \$ (2.10) | \$ (2.32)     | \$ (2.18)    |
| Diluted net income (loss) per common share            | \$ 1.25             | \$ (2.10) | \$ (2.32)     | \$ (2.18)    |



## INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "Agreement") is made as of \_\_\_\_\_, 201\_\_ by and between OptiNose, Inc., a Delaware corporation (the "Corporation"), in its own name and on behalf of its direct and indirect subsidiaries, and \_\_\_\_\_, an individual ("Indemnitee"). This Agreement supersedes and replaces any and all previous Agreements between the Corporation and Indemnitee covering the subject matter of this Agreement.

### RECITALS:

**WHEREAS**, directors, officers, employees, controlling persons, fiduciaries and other agents ("Representatives") in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the corporation or business enterprise itself;

**WHEREAS**, the Board of Directors of the Company (the "Board") believes that highly competent persons have become more reluctant to serve corporations as Representatives unless they are provided with adequate protection through insurance and adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation or business enterprise;

**WHEREAS**, the Board has determined that the increased difficulty in attracting and retaining highly competent persons is detrimental to the best interests of the Corporation and its stockholders and that the Corporation should act to assure such persons that there will be increased certainty of protection against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the Corporation;

**WHEREAS**, it is reasonable, prudent and necessary for the Corporation contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Corporation free from undue concern regarding such risks;

**WHEREAS**, (a) the Amended and Restated Bylaws of the Corporation (the "Bylaws") require indemnification of the officers and directors of the Corporation, (b) Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware, as it may be amended from time to time (the "DGCL") and (c) the Bylaws and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive and thereby contemplate that contracts may be entered into between the Corporation and its Representatives with respect to indemnification;

**WHEREAS**, this Agreement is a supplement to and in furtherance of the Bylaws and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefore, nor to diminish or abrogate any rights of Indemnitee thereunder; and

**WHEREAS**, (a) Indemnitee does not regard the protection available under the Bylaws and insurance as adequate in the present circumstances, (b) Indemnitee may not be willing to serve or continue to serve as a Representative without adequate protection, (c) the Corporation desires Indemnitee to serve or continue to serve in such capacity and (d) Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Corporation on the condition that he/she be so indemnified.

**AGREEMENT:**

**NOW, THEREFORE**, in consideration of the premises and the covenants contained herein, the Corporation and Indemnitee do hereby covenant and agree as follows:

Section 1. Definitions.

(a) As used in this Agreement:

“Agreement” shall have the meaning ascribed to such term in the Preamble hereto.

“Beneficial Owner” shall have the meaning given to such term in Rule 13d-3 under the Exchange Act (as defined below); provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Corporation approving a merger of the Corporation with another entity.

“Board” shall have the meaning ascribed to such term in the Recitals hereto.

“Bylaws” shall have the meaning ascribed to such term in the Recitals hereto.

“Certificate of Incorporation” shall mean the Fourth Amended and Restated Certificate of Incorporation of the Corporation.

A “Change in Control” shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below), other than the Sponsor Entities (as defined below), is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Corporation representing fifteen percent (15%) or more of the combined voting power of the Corporation’s then outstanding securities, unless the change in relative Beneficial Ownership of the Corporation’s securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Corporation to effect a transaction described herein) whose election by the Board or nomination for election by the Corporation’s stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Corporation with any other entity, other than a merger or consolidation which would result in the voting securities of the Corporation outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity in any such transaction) more than fifty percent (50%) of the combined voting power of the voting securities of such surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;

iv. Liquidation. The approval by the stockholders of the Corporation of a complete liquidation of the Corporation or an agreement for the sale or disposition by the Corporation of all or substantially all of the Corporation's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Corporation is then subject to such reporting requirement.

“Corporate Status” describes the status of an individual who is or was a Representative of an Enterprise.

“Corporation” shall have the meaning ascribed to such term in the Preamble hereto.

“DGCL” shall have the meaning ascribed to such term in the Recitals hereto.

“Enterprise” shall mean the Corporation and any other Person, employee benefit plan, joint venture or other enterprise of which Indemnitee is or was serving at the request of the Corporation as a Representative.

“Exchange Act” shall mean the Securities Exchange Act of 1934, as amended from time to time, and the rules and regulations thereunder.

“Expenses” shall include all reasonable costs, expenses, fees and charges, including, without limitation, attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include, without limitation, (i) expenses incurred in connection with any appeal resulting from any Proceeding, including, without limitation, the premium, security for, and other costs relating to any cost bond, supersedes bond, or other appeal bond or its equivalent, (ii) for purposes of Section 12(d) only, expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise, (iii) any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement (on a grossed up basis), (iv) excise taxes and penalties under the Employee Retirement Income Security Act of 1974, and (v) any interest, assessments or other charges in respect of the foregoing.

“Indemnitee” shall have the meaning ascribed to such term in the Preamble hereto.

“Indemnity Obligations” shall mean all obligations of the Corporation to Indemnitee under this Agreement, including, without limitation, the Corporation's obligations to provide indemnification to Indemnitee and advance Expenses to Indemnitee under this Agreement.

“Independent Counsel” shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five (5) years has been, retained to represent: (i) the Corporation or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements) or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder; provided, however, that the term “Independent Counsel” shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Corporation or Indemnitee in an action to determine Indemnitee's rights under this Agreement.

“Liabilities” shall mean all claims, liabilities, damages, losses, judgments, orders, fines, penalties and other amounts payable in connection with, arising out of, in respect of, relating to or occurring as a direct or indirect consequence of, any Proceeding, including, without limitation, amounts paid in whole or partial settlement of any Proceeding, all Expenses incurred in complying with any judgment, order or decree issued or entered in connection with any Proceeding or any settlement agreement, stipulation or consent decree entered into or issued in settlement of any Proceeding, and any consequential damages resulting from any Proceeding or the settlement, judgment, or result thereof.

“Person” shall mean any individual, corporation, partnership, limited partnership, limited liability company, trust, governmental agency or body or any other legal entity.

“Proceeding” shall include any threatened, pending or completed action, claim, suit, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, formal or informal hearing, inquiry or investigation, administrative hearing or any other actual, threatened or completed judicial, administrative or arbitration proceeding (including, without limitation, any such proceeding under the Securities Act of 1933, as amended, or the Exchange Act or any other federal law, state law, statute or regulation), whether brought in the right of the Corporation or otherwise, and whether of a civil, criminal, administrative legislative or investigative nature, including any appeal therefrom, in which Indemnitee was, is or will be, or is threatened to be, involved as a party, potential party, non-party witness or otherwise (i) by reason of the fact that Indemnitee is or was a Representative of the Corporation, (ii) by reason of any actual or alleged action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee’s part while acting as Representative of the Corporation or (iii) by reason of the fact that Indemnitee is or was serving at the request of the Corporation as a Representative of another Person, whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

“Representative” shall have the meaning ascribed to such term in the Recitals hereto.

“Sponsor Entities” shall mean funds affiliated with Avista Capital Partners and any of their respective Affiliates who beneficially own shares of common stock, par value \$0.001 per share, of the Corporation, and any securities into which such shares of common stock shall have been changed or any securities resulting from any reclassification or recapitalization of such shares of common stock from time to time; provided, however, that neither the Corporation nor any of its subsidiaries shall be considered Sponsor Entities hereunder.

“Submission Date” shall have the meaning ascribed to such term in Section 11(a).

(b) For the purpose hereof, references to “fines” shall include any excise tax assessed with respect to any employee benefit plan; references to “serving at the request of the Corporation” shall include any service as a Representative of the Corporation which imposes duties on, or involves services by, such Representative with respect to an employee benefit plan, its participants or beneficiaries; and a Person who acted in good faith and in a manner he/she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in manner “not opposed to the best interests of the Corporation” as referred to in this Agreement.

Section 2. Indemnity in Third-Party Proceedings. The Corporation shall indemnify and hold harmless Indemnitee, to the fullest extent permitted by applicable law, from and against all Liabilities and Expenses suffered or incurred by Indemnitee or on Indemnitee’s behalf in connection with or as a consequence of any Proceeding (other than any Proceeding brought by or in the right of the Corporation to procure a judgment in its favor which

shall be governed by the provisions set forth in Section 3 below), if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in, or not opposed to, the best interests of the Corporation and, in the case of a criminal proceeding, had no reasonable cause to believe that his conduct was unlawful. For the avoidance of doubt, a finding, admission or stipulation that an Indemnitee has not met such applicable standard of conduct or that Indemnitee acted with gross negligence or recklessness shall not, of itself, be a defense to any action pursuant to this Agreement or create a presumption that such Indemnitee has failed to meet the standard of conduct required for indemnification in this Section 2.

Section 3. Indemnity in Proceedings by or in the Right of the Corporation. The Corporation shall indemnify and hold harmless Indemnitee, to the fullest extent permitted by applicable law, from and against all Liabilities and Expenses suffered or incurred by Indemnitee or on Indemnitee's behalf in connection with or as a consequence of any Proceeding brought by or in the right of the Corporation to procure a judgment in its favor, or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in, or not opposed, to the best interests of the Corporation. No indemnification for Liabilities and Expenses shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Corporation, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability, but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such Liabilities and Expenses which the Court of Chancery or such other court shall deem proper. For the avoidance of doubt, a finding, admission or stipulation that an Indemnitee has not met such applicable standard of conduct or that Indemnitee acted with gross negligence or recklessness shall not, of itself, be a defense to any action pursuant to this Agreement or create a presumption that such Indemnitee has failed to meet the standard of conduct required for indemnification in this Section 3.

Section 4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, and without limiting the rights of Indemnitee under any other provision hereof, to the extent that Indemnitee is a party to (or a participant in) any Proceeding and is successful on the merits or otherwise (including, without limitation, settlement thereof), as to one or more but less than all claims, issues or matters in such Proceeding, in whole or in part, then the Corporation shall indemnify Indemnitee, to the fullest extent permitted by applicable law, against all Liabilities and Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf, in connection with or as a consequence of each successfully resolved claim, issue or matter. For purposes of this Section 4 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 5. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Corporation for some or a portion of Expenses, but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 6. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Liabilities and Expenses suffered or incurred by him or on his behalf in connection therewith.

Section 7. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 2, 3, 4 or 5, the Corporation shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to, or threatened to be made a party to, any Proceeding (including, without limitation, a Proceeding by or in the right of the Corporation to procure a judgment in its favor), by reason of Indemnitee's Corporate Status.

(b) For purposes of Section 7(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

(i) to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to, or replacement of, the DGCL, and

(ii) to the fullest extent authorized or permitted by any amendments to, or replacements of, the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 8. Exclusions. Notwithstanding any provision in this Agreement, the Corporation shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) subject to Section 14, for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Corporation within the meaning of Section 16(b) of the Exchange Act (as defined in Section 1(a) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Corporation by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Corporation, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Corporation of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Corporation by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section 13(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Corporation or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the Corporation under applicable law.

Section 9. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 13(d)), the Corporation shall advance, to the fullest extent permitted by law, Expenses incurred by Indemnitee in connection with any Proceeding (or part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board, and such advancement shall be made within ten (10) days after the receipt by the Corporation of a statement or statements requesting such advances from time to time, whether prior to, or after, final disposition of any Proceeding. Advances shall be unsecured and interest free. Indemnitee shall be entitled to continue to receive advancement of Expenses pursuant to this Section 9 unless and until the matter of Indemnitee's entitlement to indemnification hereunder has been finally adjudicated by court order or judgment from which no further right or appeal exists. Advances shall be made without regard to Indemnitee's ability to repay Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 13(d), advances shall include any and all Expenses incurred pursuing an action to enforce this right of advancement, including, without limitation, Expenses incurred preparing and forwarding statements to the Corporation to support the advances claimed. Indemnitee shall qualify for advances upon the execution and delivery to the Corporation of this Agreement, which shall constitute an undertaking, providing that Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Corporation. No other form of undertaking shall be required other than the execution of this Agreement. This Section 9 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 8.

Section 10. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Corporation in writing of any Proceeding with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Corporation shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Corporation a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. Any delay or failure by Indemnitee to notify the Corporation hereunder will not relieve the Corporation from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, nor shall such delay or failure constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Corporation shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) In the event Indemnitee seeks indemnification and/or advancement of Expenses with respect to any Proceeding, Indemnitee may, at Indemnitee's option, (i) retain legal counsel selected by Indemnitee and approved by the Corporation (which approval shall not be unreasonably withheld, conditioned or delayed) to defend Indemnitee in such Proceeding, at the sole expense of the Corporation or (ii) have the Corporation assume the defense of Indemnitee in the Proceeding, in which case the Corporation shall assume the defense of such Proceeding with legal counsel selected by the Corporation and approved by Indemnitee (which approval shall not be unreasonably withheld, conditioned or delayed) within ten (10) days of the Corporation's receipt of written notice of Indemnitee's election to cause the Corporation to do so. If the Corporation is required to assume the defense of any such Proceeding, it shall engage legal counsel for such defense, and shall be solely responsible for all Expenses of such legal counsel and otherwise of such defense. Such legal counsel may represent both Indemnitee and the Corporation (and/or any other party or parties entitled to be indemnified by the Corporation with respect to such matter) unless, in the reasonable opinion of legal counsel to Indemnitee, there is a conflict of interest between Indemnitee and the Corporation (or any other such party or parties) or there are legal defenses available to Indemnitee that are not available to the Corporation (or any such other party or parties). Notwithstanding either party's assumption of responsibility for defense of a Proceeding, each party shall have the right to engage separate legal counsel at its own expense. The party having responsibility for defense of a Proceeding shall provide the other party and its legal counsel with all copies of pleadings and material correspondence relating to the Proceeding. Indemnitee and the Corporation shall reasonably cooperate in the defense of any Proceeding with respect to which indemnification is sought hereunder, regardless of whether the Corporation or Indemnitee assumes the defense thereof. Indemnitee may not settle or compromise any Proceeding without the prior written consent of the Corporation (which consent shall not be unreasonably withheld, conditioned or delayed). The Corporation may not settle or compromise any Proceeding without the prior written consent of Indemnitee (which consent shall not be unreasonably withheld, conditioned or delayed).

Section 11. Procedure Upon Application for Indemnification.

(a) Upon receipt of a written request by Indemnitee for indemnification pursuant to Section 10(a) (the "Submission Date"), if any determination by the Corporation is required by applicable law with respect to Indemnitee's ultimate entitlement to indemnification, such determination shall be made (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the



Corporation. If it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the Person(s) making such determination with respect to Indemnitee's entitlement to indemnification, including, without limitation, providing to such Person(s), upon reasonable advance request, any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Expenses incurred by Indemnitee in so cooperating with the Person(s) making such determination shall be borne by the Corporation (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Corporation hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Corporation will not deny any written request for indemnification hereunder made in good faith by Indemnitee unless a determination as to Indemnitee's entitlement to such indemnification described in this Section 11(a) has been made. The Corporation agrees to pay Expenses of the Independent Counsel referred to above and to fully indemnify the Independent Counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(b) In the event that the determination of entitlement to indemnification is to be made by the Independent Counsel pursuant to Section 11(a) hereof, the Independent Counsel shall be selected as provided in this Section 11(b). If a Change in Control has not occurred, the Independent Counsel shall be selected by the Board, and the Corporation shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control has occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Corporation advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Corporation, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Corporation or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1(a) of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court of Chancery has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 10(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Corporation or Indemnitee may petition the Delaware Court of Chancery for resolution of any objection which shall have been made by the Corporation or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 11(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 13(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

#### Section 12. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the Person(s) making such determination shall, to the fullest extent permitted by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Corporation shall, to the fullest extent permitted by law, have the burden of proof to overcome that presumption with clear and convincing evidence in connection with the making by any Person(s) of any determination contrary to that presumption. Neither the failure of the Corporation (including, without limitation, by its directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met

the applicable standard of conduct, nor an actual determination by the Corporation (including, without limitation, by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 12(e), if the Person(s) empowered or selected under Section 10 hereof to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Corporation of the request therefore, the requisite determination of entitlement to indemnification shall, to the fullest extent permitted by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent a prohibition of such indemnification under applicable law; provided, however, that such sixty (60) day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if (i) the determination is to be made by the Independent Counsel and there is an objection to the selection of the Independent Counsel and (ii) the Person(s) making such determination requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 12(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 11(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Corporation of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he/she reasonably believed to be in, or not opposed to, the best interests of the Corporation or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

(d) Reliance as Safe Harbor. For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise, or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. The provisions of this Section 12(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) Actions of Others. The knowledge and/or actions, or failure to act, of any Representative (other than Indemnitee) of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

### Section 13. Remedies of Indemnitee.

(a) Subject to Section 12(d), in the event that (i) a determination is made pursuant to Section 11 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 9 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 11(a) of this Agreement within ninety (90) days after the Submission Date, (iv) payment of indemnification is not made pursuant to Section 4, 5, 6 or 11(a) of this Agreement within ten (10) days after receipt by the Corporation of a written

request therefore, (v) payment of indemnification pursuant to Section 2, 3 or 7 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or (vi) in the event that the Corporation or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, Indemnitee, the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification and/or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within one hundred and eighty (180) days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 13(a). The Corporation shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 11 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 13 shall be conducted in all respects as a *de novo* trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 13, the Corporation shall have the burden of proving by clear and convincing evidence Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 11 of this Agreement that Indemnitee is entitled to indemnification, the Corporation shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 13, absent (i) a misstatement by the Indemnitee of a material fact, or an omission by the Indemnitee of a material fact necessary to make the Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Corporation shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 13 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Corporation is bound by all the provisions of this Agreement. It is the intent of the Corporation that, to the fullest extent permitted by law, Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to Indemnitee hereunder. In addition, the Corporation shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all such Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Corporation of a written request therefore) advance, to the fullest extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Corporation under this Agreement or under any directors' and officers' liability insurance policies maintained by the Corporation if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only in connection with each successfully resolved claim, issue or matter, or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding; provided, that in absence of any such determination with respect to such Proceeding, the Corporation shall pay Liabilities and advance Expenses with respect to such Proceeding as if Indemnitee has been determined to be entitled to indemnification and advancement of Expenses with respect to such Proceeding.

Section 14. Non-Exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders, a resolution of directors or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in applicable law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation, the Bylaws and/or this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) The Corporation hereby acknowledges that Indemnitee may have certain rights to indemnification, advancement of Expenses and/or insurance provided by one or more Persons with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity). The Corporation hereby acknowledges and agrees that (i) the Corporation shall be the indemnitor of first resort with respect to any Proceeding, Expense, Liability or matter that is the subject of the Indemnity Obligations, (ii) the Corporation shall be primarily liable for all Indemnity Obligations and any indemnification afforded to Indemnitee in respect of any Proceeding, Expense, Liability or matter that is the subject of Indemnity Obligations, whether created by law, organizational or constituent documents, contract (including, without limitation, this Agreement) or otherwise, (iii) any obligation of any other Persons with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) to indemnify Indemnitee and/or advance Expenses to Indemnitee in respect of any proceeding shall be secondary to the obligations of the Corporation hereunder, (iv) the Corporation shall be required to indemnify Indemnitee and advance Expenses to Indemnitee hereunder to the fullest extent provided herein without regard to any rights Indemnitee may have against any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or insurer of any such Person and (v) the Corporation irrevocably waives, relinquishes and releases any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) from any claim of contribution, subrogation or any other recovery of any kind in respect of amounts paid by the Corporation hereunder. In the event that any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or their insurers advances or extinguishes any liability or loss which is the subject of any Indemnity Obligation owed by the Corporation or payable under any insurance policy provided under this Agreement, such payor shall have a right of subrogation against the Corporation or its insurer or insurers for all amounts so paid which would otherwise be payable by the Corporation or its insurer or insurers under this Agreement. In no event will payment of an Indemnity Obligation of the Corporation under this Agreement by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or their insurers, affect the obligations of the Corporation hereunder or shift primary liability for any Indemnity Obligation to any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity). Any indemnification and/or insurance or advancement of Expenses provided by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity), with respect to any liability arising as a result of Indemnitee's Corporate Status or capacity as an officer or director of any Person, is specifically in excess of any Indemnity Obligation of the Corporation or valid and any collectible insurance (including, without limitation, any malpractice insurance or professional errors and omissions insurance) provided by the Corporation under this Agreement, and any obligation to provide indemnification and/or insurance or advance Expenses provided by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) shall be reduced

by any amount that Indemnitee collects from the Corporation as an indemnification payment or advancement of Expenses pursuant to this Agreement.

(c) The Corporation shall use its best efforts to obtain and maintain in full force and effect an insurance policy or policies providing liability insurance for Representatives of the Corporation or of any other Enterprise, and Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such Representative under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Corporation maintains an insurance policy or policies providing liability insurance for Representatives of the Corporation or of any other Enterprise, the Corporation shall give prompt notice of the commencement of such Proceeding to the insurers in accordance with the procedures set forth in the respective policy or policies. The Corporation shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies. In the event of a Change in Control or the Corporation's becoming insolvent, the Corporation shall maintain in force any and all insurance policies then maintained by the Corporation in providing insurance (directors' and officers' liability, fiduciary, employment practices or otherwise) in respect of Indemnitee for a period of six years thereafter.

(d) In the event of any payment under this Agreement, the Corporation shall not be subrogated to, and hereby waives any rights to be subrogated to, any rights of recovery of Indemnitee, including, without limitation, rights of indemnification provided to Indemnitee from any other Person or entity with whom Indemnitee may be associated (including, without limitation, any Sponsor Entity) as well as any rights to contribution that might otherwise exist; provided, however, that the Corporation shall be subrogated to the extent of any such payment of all rights of recovery of Indemnitee under insurance policies of the Corporation or any of its subsidiaries, and the Indemnitee shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Corporation to bring suit to enforce such rights.

(e) The indemnification and contribution provided for in this Agreement will remain in full force and effect regardless of any investigation made by or on behalf of Indemnitee.

Section 15. Duration of Agreement; Not Employment Contract. This Agreement shall continue until and terminate upon the latest of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a Representative of the Corporation or any other Enterprise and (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 13 of this Agreement relating thereto. This Agreement shall be binding upon the Corporation and its successors and assigns and shall inure to the benefit of Indemnitee and Indemnitee's heirs, executors and administrators. The Corporation shall require and cause any direct or indirect successor (whether by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Corporation, by written agreement, expressly or to assume and agree to perform this agreement in the same manner and to the same extent that the Corporation would be required to perform if no such succession had taken place. This Agreement shall not be deemed an employment contract between the Corporation (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Corporation (or any of its subsidiaries or any Enterprise), if any, is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Corporation (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a Representative of the Corporation, by the Certificate of Incorporation, Bylaws and the DGCL.

Section 16. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent

permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 17. Enforcement.

(a) The Corporation expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a Representative of the Corporation, and the Corporation acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a Representative of the Corporation.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Bylaws and applicable law, and shall not be deemed a substitute therefore, nor to diminish or abrogate any rights of Indemnitee thereunder.

(c) The Corporation shall not seek from a court, or agree to, a “bar order” which would have the effect of prohibiting or limiting the Indemnitee’s right to receive advancement of expenses under this Agreement.

Section 18. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties thereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver. The failure of any party to enforce any of the provisions of this Agreement shall in no way be construed as a waiver of such provisions and shall not affect the right of such party thereafter to enforce each and every provision of this Agreement in accordance with its terms.

Section 19. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Corporation.

(b) If to the Corporation to:

OptiNose, Inc.  
1020 Stony Hill Road, Suite 300  
Yardley, Pennsylvania 19067  
Attn: Chief Legal Officer  
Facsimile: (267) 395-2119

or to any other address as may have been furnished to Indemnitee by the Corporation.

Section 20. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Corporation, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines,

penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of the Proceeding in order to reflect (a) the relative benefits received by the Corporation and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (b) the relative fault of the Corporation (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 21. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 13(a), the Corporation and Indemnitee hereby irrevocably and unconditionally (a) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court of Chancery, and not in any other state or federal court in the United States of America or any court in any other country, (b) consent to submit to the exclusive jurisdiction of the Delaware Court of Chancery for purposes of any action or proceeding arising out of or in connection with this Agreement, (c) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court of Chancery and (d) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court of Chancery has been brought in an improper or inconvenient forum.

Section 22. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Section 23. Third-Party Beneficiaries. The Sponsor Entities are intended third-party beneficiaries of this Agreement.

Section 24. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[SIGNATURE PAGE FOLLOWS]



IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

OPTINOSE, INC.

---

Name: Peter Miller

Title: Chief Executive Officer

[Signature Page to Indemnification Agreement]

INDEMNITEE:

---

[ ]

[Signature Page to Indemnification Agreement]

### Schedule to Exhibit 10.1

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.1 except as to the name of the signatory and the date of each signatory's Indemnification Agreement, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

| <b>INDEMNITEE</b>             | <b>DATE</b>        |
|-------------------------------|--------------------|
| Peter K. Miller               | October 2, 2017    |
| Ramy A. Mahmoud, M.D., M.P.H. | October 2, 2017    |
| Thomas E. Gibbs               | October 2, 2017    |
| Keith A. Goldan               | October 2, 2017    |
| Michael F. Marino             | October 2, 2017    |
| Larry G. Pickering            | October 1, 2017    |
| William F. Doyle              | October 1, 2017    |
| Sriram Venkataraman           | September 29, 2017 |
| Joshua A. Tamaroff            | September 29, 2017 |
| Joseph C. Scodari             | October 5, 2017    |
| Wilhelmus Groenhuysen         | October 5, 2017    |
| Sandra K. Helton              | February 22, 2018  |

NEITHER THIS NOTE PURCHASE AGREEMENT NOR THE NOTES ISSUED HEREUNDER HAVE BEEN REGISTERED PURSUANT TO THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR QUALIFIED PURSUANT TO ANY APPLICABLE STATE SECURITIES LAW. THE NOTES ISSUED UNDER THIS NOTE PURCHASE AGREEMENT MAY BE RESOLD ONLY IF REGISTERED PURSUANT TO THE PROVISIONS OF THE SECURITIES ACT AND QUALIFIED PURSUANT TO APPLICABLE STATE SECURITIES LAWS OR IF AN EXEMPTION FROM SUCH REGISTRATION AND QUALIFICATION IS AVAILABLE, EXCEPT UNDER CIRCUMSTANCES WHERE NEITHER SUCH REGISTRATION, QUALIFICATION NOR EXEMPTION IS REQUIRED BY LAW.

NOTE PURCHASE AGREEMENT

Dated as of December 29, 2017

among

OPTINOSE AS and OPTINOSE US, INC.,  
as the Issuers,

OPTINOSE, INC.,  
as Parent and a Guarantor

The other Guarantors from time to time party hereto

The Purchasers from time to time party hereto

and

ATHYRIUM OPPORTUNITIES III ACQUISITION LP,  
as Collateral Agent

Initial Notes:

\$75,000,000 Senior Secured Notes Due 2023

Delayed Draw Notes:

\$25,000,000 Senior Secured Notes Due 2023

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## SCHEDULES

II Notes, Purchase Prices and Delayed Draw Note Commitments  
12.02 Certain Addresses for Notices

## EXHIBITS

A-1 Form of Initial Note  
A-2 Form of Delayed Draw Note  
B Form of Joinder Agreement  
C Form of Assignment and Assumption  
D Form of Compliance Certificate

## NOTE PURCHASE AGREEMENT

This NOTE PURCHASE AGREEMENT is entered into as of December 29, 2017 among OPTINOSE AS, a Norwegian private limited liability company with Norwegian business registration number 982 483 131 (the “Norwegian Issuer”), OPTINOSE US, INC., a Delaware corporation (the “US Issuer”; together with the Norwegian Issuer, the “Issuers” and each, an “Issuer”), OPTINOSE, INC., a Delaware corporation (“Parent”), OPTINOSE UK LIMITED, a limited liability company formed under the laws of England and Wales (“OptiNose UK”), the other Guarantors (defined herein) from time to time party hereto, the Purchasers (defined herein) from time to time party hereto and ATHYRIUM OPPORTUNITIES III ACQUISITION LP, as Collateral Agent.

The Issuers have proposed to issue and sell, on the Closing Date, to the Purchasers and the Purchasers have agreed to purchase, their respective Senior Secured Notes due 2023, in an aggregate original principal amount of \$75,000,000, of which \$50,000,000 will be issued by the Norwegian Issuer and \$25,000,000 will be issued by the US Issuer, in each case in the amounts and for the consideration set forth on Schedule II and upon the terms and conditions hereinafter provided. In addition, the US Issuer has proposed to issue and sell, on the Delayed Draw Note Closing Date, to the Purchasers and the Purchasers have agreed to purchase, additional Senior Secured Notes due 2023, in the aggregate original principal amount of \$25,000,000, for the consideration and upon the terms and conditions hereinafter provided.

In consideration of the mutual covenants and agreements herein contained, the parties hereto covenant and agree as follows:

### ARTICLE I

#### DEFINITIONS AND ACCOUNTING TERMS

##### 1.01 Defined Terms.

As used in this Agreement, the following terms shall have the meanings set forth below:

“Acquisition” means, with respect to any Person, the acquisition by such Person, in a single transaction or in a series of related transactions, of (a) assets of another person which constitute all or substantially all of the assets of such Person, or of any division, line of business or other business unit of such Person, including any Acquired Product or (b) at least a majority of the Voting Stock of another Person, in each case whether or not involving a merger, amalgamation or consolidation with such other Person and whether for cash, property, services, assumption of Indebtedness, securities or otherwise.

“Acquired Product” means any Product of the type described in clause (b) of the definition thereof and/or related IP Rights acquired or licensed by a Note Party or any of its Wholly-Owned Subsidiaries from a Third Party to facilitate the advertisement, development, importing, manufacturing, marketing, offering for sale, promotion, sale, testing, use or distribution of such Product by a Note Party or a Wholly-Owned Subsidiary.

“Affiliate” means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified. No Person will be deemed to be an Affiliate of a Permitted Holder solely because such Person is a portfolio company of a Permitted Holder.

“Agreement” means this Note Purchase Agreement.

“Approved Fund” means any Fund that is administered or managed by (a) a Purchaser, (b) an Affiliate of a Purchaser or (c) an entity or an Affiliate of an entity that administers or manages a Purchaser.

“Assignment and Assumption” means an assignment and assumption agreement entered into by a Purchaser and an Eligible Assignee (with the consent of any party whose consent is required by Section 12.06) to which a Delayed Draw Note Commitment or Note is being transferred, in substantially the form of Exhibit C hereto.

“Athyrium” means Athyrium Capital Management, LP and its successors and assigns.

“Attributable Indebtedness” means, on any date, (a) in respect of any Capital Lease of any Person, the capitalized amount thereof that would appear on a balance sheet of such Person prepared as of such date in accordance with GAAP, (b) in respect of any Synthetic Lease of any Person, the capitalized amount of the remaining lease payments under the relevant lease that would appear on a balance sheet of such Person prepared as of such date in accordance with GAAP if such lease were accounted for as a Capital Lease and (c) in respect of any Securitization Transaction of any Person, the outstanding principal amount of such financing, after taking into account reserve accounts and making appropriate adjustments, determined by the Required Purchasers in their reasonable judgment.

“Audited Financial Statements” means the audited consolidated balance sheet of Parent and its Subsidiaries for the fiscal year ended December 31, 2016, and the related consolidated statements of income or operations, shareholders’ equity and cash flows for such fiscal year of Parent and its Subsidiaries, including the notes thereto, audited by independent public accountants of recognized national standing and prepared in conformity with GAAP.

“Availability Period” means that period commencing on and including April 1, 2019 and ending on the earliest of (i) the date on which no Notes remain outstanding, (ii) the Delayed Draw Note Closing Date, and (iii) August 14, 2019.

“Avanir Agreement” means that certain License Agreement between Norwegian Issuer and Avanir Pharmaceuticals, Inc., dated as of July 1, 2013, as amended by that certain First Amendment of License Agreement dated as of April 24, 2014 and that certain Amendment to License Agreement dated as of August 6, 2015.

“Bail-In Action” means the exercise of any Write-Down and Conversion Powers by the applicable EEA Resolution Authority in respect of any liability of an EEA Financial Institution.

“Bail-In Legislation” means, with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law for such EEA Member Country from time to time which is described in the EU Bail-In Legislation Schedule.

“Board of Directors” means (a) with respect to a corporation, the board of directors of the corporation or any committee thereof duly authorized to act on behalf of such board, (b) with respect to a partnership, the Board of Directors of the general partner of the partnership, (c) with respect to a limited liability company, the managing member or members or any controlling committee of managing members thereof, (d) with respect to a limited liability company registered in Norway, the board of directors of that company and (e) with respect to any other Person, the board or committee of such Person serving a similar function.

“Bringdown Date” means each of the Delayed Draw Note Closing Date, any date on which a Permitted Acquisition is consummated and any other date after the Closing Date when the representations and warranties are required to be made by the Note Parties (including, to the extent set forth therein, any amendment hereto).

“Business Day” means any day other than a Saturday, Sunday or other day on which commercial banks are authorized to close under the Laws of, or are in fact closed in, New York, New York.

“Businesses” means, at any time, a collective reference to the businesses operated by Parent and its Subsidiaries at such time.

“Capital Lease” means, subject to Section 1.03(b), as applied to any Person, any lease of any property by that Person as lessee which, in accordance with GAAP, is required to be accounted for as a capital lease on the balance sheet of that Person.

“Cash Equivalents” means, as at any date, (a) securities issued or directly and fully guaranteed or insured by the United States or any agency or instrumentality thereof (provided, that, the full faith and credit of the United States is pledged in support thereof) having maturities of not more than twelve months from the date of acquisition, (b) Dollar denominated time deposits and certificates of deposit of (i) any United States commercial bank of recognized standing having capital and surplus in excess of \$500,000,000 or (ii) any bank whose short-term commercial paper rating from S&P is at least A-1 or the equivalent thereof or from Moody’s is at least P-1 or the equivalent thereof (any such bank being an “Approved Bank”), in each case with maturities of not more than 270 days from the date of acquisition, (c) commercial paper and variable or fixed rate notes issued by any Approved Bank (or by the parent company thereof) or any commercial paper or fixed or variable rate notes issued by, or guaranteed by, any domestic corporation rated A-1 (or the equivalent thereof) or better by S&P or P-1 (or the equivalent thereof) or better by Moody’s and maturing within twelve months of the date of acquisition, (d) repurchase agreements entered into by any Person with a bank or trust company (including any of the Purchasers) or recognized securities dealer having capital and surplus in excess of \$500,000,000 for direct obligations issued by or fully guaranteed by the United States in which such Person shall have a perfected first priority security interest (subject to no other Liens) and having, on the date of purchase thereof, a fair market value of at least 100% of the amount of the repurchase obligations, (e) Investments, classified in accordance with GAAP as current assets, in money market investment programs registered under the Investment Company Act of 1940 which are administered by reputable financial institutions having capital of at least \$500,000,000 and the portfolios of which are limited to Investments of the character described in the foregoing subdivisions (a) through (d), (f) other short term liquid investments approved in writing by the Collateral Agent (such approval not to be unreasonably withheld or delayed), and (g) instruments equivalent to those referred to in clauses (a) through (f) above denominated in euro or any other foreign currency comparable in credit quality and tenor to those referred to above and customarily used by corporations for cash management purposes in any jurisdiction outside the United States to the extent reasonably required in connection with any business conducted by Parent or any of its Subsidiaries organized in such jurisdiction.

“CFC” means any Subsidiary that is a “controlled foreign corporation” within the meaning of Section 957 of the Internal Revenue Code.

“Change in Law” means the occurrence, after the date of this Agreement, of any of the following: (i) the adoption or taking effect of any law, rule, regulation or treaty, (ii) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority or (iii) the making or issuance of any request, rule, guideline or directive (whether or not having

the force of law) by any Governmental Authority; provided that, notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a “Change in Law”, regardless of the date enacted, adopted or issued.

“Change of Control” means the occurrence of any of the following events:

(a) any “person” or “group” (as such terms are used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, but excluding any employee benefit plan of such person or its subsidiaries, and any person or entity acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan), other than a Permitted Holder, becomes the “beneficial owner” (as defined in Rules 13d-3 and 13d-5 under the Securities Exchange Act of 1934, except that a person or group shall be deemed to have “beneficial ownership” of all securities that such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time (such right, an “option right”)), directly or indirectly, of Equity Interests representing 40% or more of the aggregate ordinary voting power in the election of the Board of Directors of Parent represented by the issued and outstanding Equity Interests of Parent on a fully-diluted basis (and taking into account all such securities that such person or group has the right to acquire pursuant to any option right); or

(b) during any period of twelve (12) consecutive months, a majority of the members of the Board of Directors of Parent cease to be composed of individuals (i) who were members of that Board of Directors on the first day of such period, (ii) whose election, appointment or nomination to that Board of Directors was approved by individuals referred to in clause (i) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors or (iii) whose election, appointment or nomination to that Board of Directors was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors; or

(c) any “Change of Control” (or any comparable term) shall occur under any document, instrument or other agreement evidencing any Indebtedness with an aggregate principal amount in excess of the Threshold Amount; or

(d) Parent shall cease to directly or indirectly own, beneficially and of record (other than director’s qualifying shares of investments by foreign nationals to the extent mandated by applicable Laws), 100% of the issued and outstanding Equity Interests of each Issuer.

“Closing Date” means the date hereof.

“Collateral” means a collective reference to all real and personal property with respect to which Liens in favor of the Collateral Agent, for the benefit of the Purchasers, are purported to be granted pursuant to and in accordance with the terms of the Collateral Documents.

“Collateral Access Agreement” means an agreement in form and substance reasonably satisfactory to the Collateral Agent pursuant to which a lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor or other bailee of inventory or other property owned by any Note Party, in each case in an aggregate amount in excess of \$1,000,000, acknowledges the Liens of the Collateral

Agent and waives (or, if approved by the Collateral Agent, subordinates) any Liens held by such Person on such property, and permits the Collateral Agent reasonable access to any Collateral stored or otherwise located thereon.

“Collateral Agent” means Athyrium Opportunities III Acquisition LP, in its capacity as collateral agent under any of the Note Documents, or any successor collateral agent.

“Collateral Documents” means a collective reference to the Security Agreement, the Pledge Agreement, the Deposit Account Control Agreements, the Collateral Questionnaires, the Collateral Access Agreements, the Norwegian Security Documents, the English Security Documents, the Real Estate Security Documents and other security documents as may be executed and delivered by the Note Parties pursuant to the terms of Section 7.14.

“Collateral Questionnaires” means those certain collateral questionnaires or perfection certificates, in form and substance reasonably satisfactory to Collateral Agent, executed by each Issuer and Guarantor as of the Closing Date.

“Competitor” means, at any time of determination, any Person that is an operating company directly and primarily engaged in the same or substantially the same line of business as Parent and its Subsidiaries.

“Compliance Certificate” means a certificate substantially in the form of Exhibit D.

“Confidential Information” means all non-public information, whether written, oral or in any electronic, visual or other medium, that is the subject of reasonable efforts to keep it confidential and that is owned by Parent or any Subsidiary or that Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and that is used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product.

“Consolidated Debt” means, for any date, for Parent and its Subsidiaries on a consolidated basis, the total amount of Funded Indebtedness (including the Notes) outstanding as of such date.

“Consolidated EBITDA” shall mean, for Parent and its Subsidiaries, for any period, an amount equal to the sum of (i) Consolidated Net Income for such period plus (ii) solely to the extent deducted (or included, with respect to gains) in determining Consolidated Net Income for such period, and without duplication, (A) Consolidated Interest Expense, (B) income tax expense determined on a consolidated basis in accordance with GAAP, (C) depreciation and amortization determined on a consolidated basis in accordance with GAAP, (D) non-cash charges and expenses related to stock option awards or other equity compensation, (E) adjustments relating to purchase price allocation accounting with any future acquisitions or dispositions, (F) any unrealized losses (or minus any such gains) in respect of Swap Contracts, (G) any foreign currency translation losses (or minus any such gains), (H) accruals, payments, fees and expenses (including legal, tax and structuring fees and expenses) in connection with (x) the execution, delivery and performance of this Agreement and the other Note Documents by the Note Parties, the issuance of the Notes and the granting of the Liens under the Collateral Documents and (y) any Permitted Acquisition or Investment and, to the extent permitted hereunder, issuances or incurrences of Indebtedness, issuances of Equity Interests, Dispositions, consolidations, recapitalizations or refinancing transactions and modifications of Indebtedness, whether or not consummated, and the aggregate amount under this clause (H) shall not exceed \$1,000,000 in any four fiscal quarter period, (I) any net losses (or minus any net gains) attributable to the early extinguishment or conversion of Indebtedness, and (J) all other non-cash charges approved by the Required Purchasers in their sole discretion, minus (iii) sales, development or other milestone payments and upfront payments (other than, for the avoidance of doubt, any royalty payments) made to Parent and its Subsidiaries



under any licensing or similar transactions, in each case for such period and determined on a consolidated basis in accordance with GAAP.

“Consolidated Interest Expense” shall mean, for Parent and its Subsidiaries, for any period, the consolidated total interest expense (including that portion attributable to capital leases in accordance with GAAP and capitalized interest), in each case whether or not paid in cash during such period.

“Consolidated Net Income” shall mean, for Parent and its Subsidiaries for any period, the net income (or loss) of Parent and its Subsidiaries for such period determined on a consolidated basis in accordance with GAAP, but excluding therefrom (to the extent otherwise included therein) (i) extraordinary or non-recurring gains or losses (any losses that are in excess of \$1,000,000 in the aggregate for any such period are to be mutually agreed upon by the Required Purchasers and the Parent), (ii) any non-cash gains or losses attributable to write-ups or write-downs of assets, (iii) the net income (or loss) of any other Person that is not a Subsidiary (or is accounted for by the equity method of accounting) except to the extent of actual payment of cash dividends or distributions by such Person to Parent or one of its Subsidiaries, (iv) any income (or loss) of any Person accrued prior to the date it becomes a Subsidiary or is merged into or consolidated with Parent or any Subsidiary on the date that such Person’s assets are acquired by Parent or any Subsidiary, (v) any gains or losses from discontinued operations, (vi) any gains or losses from dispositions and (vii) the income (or loss) of any Subsidiary that is not a Note Party to the extent that the declaration or payment of dividends or similar distributions by that Subsidiary of the income resulting from such revenues is not at the time permitted by operation of the terms of its Organization Documents or any agreement, instrument, judgment, decree, order, statute, rule or governmental regulation applicable to that Subsidiary.

“Consolidated Revenues (General)” means, for any period, for Parent and its Subsidiaries on a consolidated basis, the aggregate amount of revenue recognized under GAAP, consistently applied, less all rebates, discounts and other price allowances. “Consolidated Revenues (General)” shall be determined in a manner consistent with the methodologies, practices and procedures used in developing Parent’s audited financial statements.

“Consolidated Revenues (Product)” means, for any period, for Parent and its Subsidiaries on a consolidated basis, the total of (a) gross revenues solely attributable to the sale of commercial products for such period as determined in accordance with GAAP minus (b) the sum of, without duplication, (i) trade, quantity and cash discounts allowed by Parent and its Subsidiaries plus (ii) discounts, refunds, rebates, charge backs, retroactive price adjustments and any other allowances which effectively reduce net selling price plus (iii) product returns and allowances plus (iv) set-offs and counterclaims plus (v) any other similar and customary deductions used by Parent and its Subsidiaries in determining net revenues, all for such period and as determined in accordance with GAAP; provided, that, “Consolidated Revenues (Product)” shall exclude the revenues generated by any Subsidiary that is not a Note Party to the extent that the declaration or payment of dividends or similar distributions by that Subsidiary of the income resulting from such revenues is not at the time permitted by operation of the terms of its Organization Documents or any agreement, instrument, judgment, decree, order, statute, rule or governmental regulation applicable to that Subsidiary; provided further, that, “Consolidated Revenues (Product)” shall exclude revenues in the form of sales, development or other milestone payments and upfront payments made to Parent and its Subsidiaries under any licensing or similar transactions, but shall include revenues in the form of royalty payments made to Parent and its Subsidiaries under any licensing or similar transactions. For the avoidance of doubt, payments under Section 8.3 of the Avair Agreement are included in Consolidated Revenues (Product), and payments under Sections 8.1 and 8.2 of the Avair Agreement are excluded from Consolidated Revenues (Product). “Consolidated Revenues (Product)” shall be determined in a manner consistent with the methodologies, practices and procedures used in developing Parent’s audited financial statements, to the extent applicable.

“Contractual Obligation” means, as to any Person, any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Person is a party or by which it or any of its property is bound.

“Control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise. “Controlling” and “Controlled” have meanings correlative thereto. Without limiting the generality of the foregoing, solely for purposes of Section 8.08, a Person shall be deemed to be Controlled by another Person if such other Person possesses, directly or indirectly, power to vote 20% or more of the securities having ordinary voting power for the election of directors, managing general partners or the equivalent.

“Controlled Investment Affiliate” means, with respect to any Person, any fund or investment vehicle that (a) is organized for the purposes of making equity investments in one or more companies and (b) is controlled by, or under common control with, such Person. For purposes of this definition “control” means the power to direct or cause the direction of management and policies of a Person, whether by contract or otherwise.

“Copyright License” means any agreement, whether written or oral, providing for the grant of any right to use any Work under any Copyright.

“Copyrights” means (a) all proprietary rights afforded Works pursuant to Title 17 of the United States Code, including, without limitation, all rights in mask works, copyrights and original designs, and all proprietary rights afforded such Works by other countries for the full term thereof (and including all rights accruing by virtue of bilateral or international treaties and conventions thereto), whether registered or unregistered, including, but not limited to, all applications for registration, renewals, extensions, reversions or restorations thereof now or hereafter provided for by law and all rights to make applications for registrations and recordations, regardless of the medium of fixation or means of expression, which are owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and which are used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product; and (b) all copyright rights under the copyright laws of the United States and all other countries for the full term thereof (and including all rights accruing by virtue of bilateral or international copyright treaties and conventions), whether registered or unregistered, including, but not limited to, all applications for registration, renewals, extensions, reversions or restorations of copyrights now or hereafter provided for by law and all rights to make applications for copyright registrations and recordations, regardless of the medium of fixation or means of expression, which are owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and which are used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product.

“Current Market” means, as of any date of determination, the Principal Market on which the shares of common stock of the Parent are then listed, traded and quoted.

“Debt Issuance” means the issuance by any Note Party or any Subsidiary of any Indebtedness other than Indebtedness permitted under Section 8.03.

“Debt to Revenue Ratio (General)” means, for any date, the quotient of (a) Consolidated Debt as of such date, *divided by* (b) Consolidated Revenues (General) for the four most recent fiscal quarters ending prior to such date for which financial statements have been delivered pursuant to Section 7.01.

“Debt to Revenue Ratio (Product)” means, for any date, the quotient of (a) Consolidated Debt as of such date, *divided by* (b) Consolidated Revenues (Product) for the four most recent fiscal quarters ending prior to such date for which financial statements have been delivered pursuant to Section 7.01.

“Debtor Relief Laws” means the Bankruptcy Code of the United States, and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief Laws of the United States or other applicable jurisdictions from time to time in effect.

“Default” means any event or condition that constitutes an Event of Default or that, with the giving of any notice, the passage of time, or both, would be an Event of Default.

“Default Rate” means an interest rate equal to LIBOR plus twelve percent (12.00%) per annum, to the fullest extent permitted by applicable Laws.

“Defaulting Purchaser” means, subject to Section 2.15(b), any Purchaser that (a) has failed to (i) fund all or any portion of its funding obligations hereunder within five (5) Business Days of the date required to be funded by it hereunder (provided, that, such Purchaser shall cease to be a Defaulting Purchaser pursuant to this clause (a) upon such Purchaser actually funding its funding obligations), (b) has notified the Issuers or the Collateral Agent in writing that it does not intend to comply with its funding obligations hereunder, or has made a public statement to that effect (provided, that, such Purchaser shall cease to be a Defaulting Purchaser pursuant to this clause (b) upon written notice to the Issuers and the Collateral Agent that it intends to comply with its funding obligations), (c) has failed, within five (5) Business Days after written request by the Collateral Agent or the Issuers, to confirm in writing to the Collateral Agent and the Issuers that it will comply with its prospective funding obligations hereunder (provided, that, such Purchaser shall cease to be a Defaulting Purchaser pursuant to this clause (c) upon receipt of such written confirmation by the Collateral Agent and the Issuers), or (d) has, or has a direct or indirect parent company that has, (i) become the subject of a proceeding under any Debtor Relief Law, (ii) had appointed for it a receiver, custodian, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or assets, including the Federal Deposit Insurance Corporation or any other state or federal regulatory authority acting in such a capacity, or (iii) become the subject of a Bail-In Action; provided, that, a Purchaser shall not be a Defaulting Purchaser solely by virtue of the ownership or acquisition of any Equity Interest in that Purchaser or any direct or indirect parent company thereof by a Governmental Authority so long as such ownership interest does not result in or provide such Purchaser with immunity from the jurisdiction of courts within the United States or from the enforcement of judgments or writs of attachment on its assets or permit such Purchaser (or such Governmental Authority) to reject, repudiate, disavow or disaffirm any contracts or agreements made with such Purchaser. Any determination by the Collateral Agent that a Purchaser is a Defaulting Purchaser under any one or more of clauses (a) through (d) above, and the effective date of such status, shall be conclusive and binding absent manifest error, and such Purchaser shall be deemed to be a Defaulting Purchaser (subject to Section 2.15(b)) as of the date established therefor by the Collateral Agent in a written notice of such determination, which shall be delivered by the Collateral Agent to the Issuers and each other Purchaser promptly following such determination. Notwithstanding anything to the contrary in the foregoing or herein, if all Purchasers consist of Athrium and its Controlled Investment Affiliates, and each of such Purchasers would be a Defaulting Purchaser, then no such Purchaser shall be a Defaulting Purchaser hereunder and the provisions relating to “Defaulting Purchasers” shall have no force or effect.

“Delayed Draw Note” and “Delayed Draw Notes” have the meanings specified in Section 2.01(b).

“Delayed Draw Note Closing Date” means (a) before the issuance, sale and purchase of the Delayed Draw Notes, the date proposed by the US Issuer as the Delayed Draw Note Closing Date in the Notice of Issuance in accordance with the terms hereof; and (b) after the issuance, sale and purchase of the Delayed Draw Notes, the date when such issuance, sale and purchase occurred; provided, that, in no event shall the Delayed Draw Note Closing Date be earlier than the beginning of the Availability Period or later than the expiration of the Availability Period.

“Delayed Draw Note Commitment” means for each Purchaser, the amount set forth opposite such Purchaser’s name on Schedule II, as the same may be terminated pursuant to the terms of this Agreement or adjusted from time to time as a result of assignments to or from such Purchaser.

“Deposit Account” means a “deposit account” (as defined in Article 9 of the Uniform Commercial Code), investment account (including securities accounts) or other account in which funds are held or invested to or for the credit or account of any Note Party.

“Deposit Account Control Agreement” means (a) in respect of any United States Deposit Account, any account control agreement by and among a Note Party, the applicable depository bank (or securities intermediary, as the case may be) and the Collateral Agent, (b) in respect of any Norwegian Deposit Account, a pledge agreement in respect of such Deposit Account, perfected by notification to the relevant Deposit Account manager, and (c) in respect of any Deposit Account outside the United States or Norway, any similar agreement, instrument or document required or customarily delivered under the laws of such jurisdiction to perfect a security interest in Deposit Accounts in such jurisdiction, in each case in form and substance reasonably satisfactory to the Required Purchasers.

“Designated Jurisdiction” means any country or territory to the extent that such country or territory is the subject of any comprehensive Sanction that is territorial in nature (for avoidance of doubt, as of the Closing Date, Cuba, Iran, North Korea, Syria and the Crimea region).

“Disclosure Letter” means that certain disclosure letter dated as of the Closing Date containing certain schedules delivered by the Note Parties to the Collateral Agent and the Purchasers.

“Disposition” or “Dispose” means the sale, transfer, license, lease or other disposition (including any Sale and Leaseback Transaction or any issuance by any Subsidiary of its Equity Interests) of any property by any Note Party or any Subsidiary of the Parent, including any sale, assignment, transfer or other disposal, with or without recourse, of any notes or accounts receivable or any rights and claims associated therewith, but excluding the following (collectively, the “Permitted Transfers”): (a) the sale, lease, license, transfer or other disposition of inventory in the ordinary course of business, (b) the sale, lease, license, transfer or other disposition in the ordinary course of business of surplus, obsolete or worn out property no longer used or useful in the conduct of business of any Note Party and its Subsidiaries, (c) any sale, lease, license, transfer or other disposition of property to any Note Party or any Subsidiary; provided, that, if the transferor of such property is a Note Party, (i) the transferee thereof must be a Note Party or (ii) to the extent such transaction constitutes an Investment, such transaction is permitted under Section 8.02, (d) the abandonment or other disposition of IP Rights that are not material and are no longer used or useful in any material respect in the business of Parent and its Subsidiaries, (e) licenses, sublicenses, leases or subleases (other than relating to intellectual property) granted to third parties in the ordinary course of business and not interfering with the Businesses, (f) any Involuntary Disposition, (g) dispositions of cash and Cash Equivalents in the ordinary course of business or otherwise in transactions permitted hereunder, (h) dispositions consisting of the sale, transfer, assignment or other disposition of unpaid and overdue accounts receivable in connection with the collection, compromise or settlement thereof in the ordinary course of business and not as part of a financing transaction, (i) Permitted Licenses, (j) the sale, transfer, issuance or other disposition of a *de minimis* number

of shares of the Equity Interests of a Foreign Subsidiary of a Note Party in order to qualify members of the governing body of such Foreign Subsidiary if required by applicable Law, (k) the sale of any Product by a Note Party or any of its Subsidiaries to any Subsidiary or a Note Party, as applicable, or to end users (through wholesalers or other typical sales channels) or to distributors in the ordinary course of business, (l) any disposition or other transfer of any Product, without the payment or provision of consideration to any Note Party or any of its Subsidiaries for such Product (other than expense reimbursement), reasonably necessary for the conduct of any then on-going clinical trial or other development or regulatory activities associated with such Product, (m) any disposition or other transfer of any Product as promotional support in the ordinary course of business or in consideration of services in the ordinary course of business, (n) to the extent constituting a sale, assignment, conveyance, transfer or other disposition hereunder, any transaction permitted by Section 8.04, Liens permitted by Section 8.01, Investments permitted by Section 8.02 (c), (d), (g), (l) or (p), and Restricted Payments permitted by Section 8.06(a), (b) or (g), (o) the termination of Swap Contracts permitted hereunder, and (p) a disposition of property to the extent that (A) such property is exchanged for credit against the purchase price of similar replacement property or (B) the proceeds (determined on an after-tax basis) of such disposition are applied to the purchase price of such replacement.

“Disqualified Capital Stock” means any Equity Interest which, by its terms (or by the terms of any security into which it is convertible or for which it is exchangeable), or upon the happening of any event, (a) matures (excluding any maturity as the result of an optional redemption by the issuer thereof) or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, or is redeemable at the option of the holder thereof, in whole or in part, prior to the ninety-first (91<sup>st</sup>) day after the Maturity Date (other than (x) settlements, conversions, redemptions and payments made solely in the form of Qualified Capital Stock and (y) cash in lieu of fractional shares), (b) requires the payment of any cash dividends at any time prior to the ninety-first (91<sup>st</sup>) day after the Maturity Date (other than the payment of cash in lieu of fractional shares), (c) contains any repurchase obligation at the option of the holder thereof, in whole or in part, which may come into effect prior to payment in full of all Obligations (other than (x) any obligation for repurchases solely made with Qualified Capital Stock and (y) cash in lieu of fractional shares), or (d) is convertible into or exchangeable (unless at the sole option of the issuer thereof) for (i) debt securities or (ii) any Equity Interests referred to in clause (a), (b) or (c) above, in each case at any time prior to the ninety-first (91<sup>st</sup>) day after the Maturity Date ; provided, that, any Equity Interests that would not constitute Disqualified Capital Stock but for provisions thereof giving holders thereof (or the holders of any security into or for which such Equity Interests are convertible, exchangeable or exercisable) the right to require the issuer thereof to redeem or repurchase such Equity Interests upon the occurrence of a change in control occurring prior to the ninety-first (91<sup>st</sup>) day after the Maturity Date shall not constitute Disqualified Capital Stock if such Equity Interests provide that the issuer thereof will not redeem or repurchase any such Equity Interests pursuant to such provisions prior to the payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Note Documents; provided, further, that, if such Equity Interests are issued pursuant to a plan for the benefit of employees of the Parent or any Subsidiary or by any such plan to such employees, such Equity Interests shall not constitute Disqualified Capital Stock solely because such employee may deliver such Equity Interests to Parent and its Subsidiaries (or the Parent or such Subsidiary withholds such Equity Interests) in satisfaction of any exercise price or tax withholding obligations with respect to such Equity Interests.

“Dollar” and “\$” mean lawful money of the United States.

“Domestic Subsidiary” means any Subsidiary that is organized under the laws of any state of the United States or the District of Columbia.

“Domain Names” means all domain names and URLs that are registered and/or owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to.

“Drug Application” means (a) New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) as those terms are defined in section 505 of the FDCA, or (b) a Biologics License Application (BLA) (including a biosimilar application), as that term is defined in section 351 of the PHSA, for any Product, as appropriate, in each case of Parent or any Subsidiary.

“Earn Out Obligations” means, with respect to an Acquisition, all obligations of Parent or any Subsidiary to make earn out or other contingency payments (including purchase price adjustments, non-competition and consulting agreements, or other indemnity obligations) pursuant to the documentation relating to such Acquisition. For purposes of determining the aggregate consideration paid for an Acquisition at the time of such Acquisition, the amount of any Earn Out Obligations shall be deemed to be the maximum amount of the earn-out payments in respect thereof as specified in the documents relating to such Acquisition, excluding any such payments, the amount of which is not upon achieving a contingency upon which payment is conditioned, a fixed amount or a range of fixed amounts, but is determined based on a percentage of revenue or sales or similar metric (e.g. a royalty). For purposes of determining the amount of any Earn Out Obligations to be included in the definition of Funded Indebtedness, the amount of Earn Out Obligations shall be deemed to be the aggregate liability in respect thereof, as determined in accordance with GAAP.

“EEA Financial Institution” means (a) any credit institution or investment firm established in any EEA Member Country which is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country which is a parent of an institution described in clause (a) of this definition, or (c) any financial institution established in an EEA Member Country which is a subsidiary of an institution described in clauses (a) or (b) of this definition and is subject to consolidated supervision with its parent.

“EEA Member Country” means any of the member states of the European Union, Iceland, Liechtenstein, Norway, and the United Kingdom (if and to the extent it remains a member of the European Economic Area after it has ceased to be a member state of the European Union).

“EEA Resolution Authority” means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegatee) having responsibility for the resolution of any EEA Financial Institution.

“Eligible Assets” means assets (other than current assets) that are used or useful in any line of business of Parent and its Subsidiaries not prohibited by Section 8.07.

“Eligible Assignee” means any Person that meets the requirements to be an assignee under Section 12.06 (subject to such consents, if any, as may be required under Section 12.06).

“English Debenture” means the English law governed debenture dated on or about the date hereof between the Norwegian Issuer and OptiNose UK, as chargors, and the Collateral Agent creating: (i) a fixed and floating charge over all the present and future assets of OptiNose UK; and (ii) security over the shares held by the Norwegian Issuer in OptiNose UK.

“English Security Documents” means (a) the English Debenture; and (b) any other security documents governed by English law as may be executed and delivered by any Note Parties pursuant to the terms of Section 7.14 or otherwise designated as Collateral Documents.

“ENT Field” means the diagnosis, prevention, mitigation and treatment of any disease or condition primarily affecting the ear, nose and/or throat, as promoted to ear, nose and throat specialists (for the avoidance of doubt, including allergy specialists) other than primary care physicians.

“Environmental Laws” means any and all federal, state, local, foreign and other applicable statutes, laws, regulations, ordinances, rules, judgments, orders, decrees, permits, concessions, grants, franchises, licenses, agreements or governmental restrictions relating to pollution and the protection of the environment or the release of any materials into the environment, including those related to hazardous substances or wastes, air emissions and discharges to waste or public systems.

“Environmental Liability” means any liability, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of Parent, any other Note Party or any of their respective Subsidiaries directly or indirectly resulting from or based upon (a) violation of any Environmental Law, (b) the generation, use, handling, transportation, storage, treatment or disposal of any Hazardous Materials, (c) exposure to any Hazardous Materials, (d) the release or threatened release of any Hazardous Materials into the environment or (e) any contract, agreement or other consensual arrangement pursuant to which liability is assumed or imposed with respect to any of the foregoing.

“Equity Interests” means, with respect to any Person, all of the shares of capital stock of (or other ownership or profit interests in) such Person, all of the warrants, options or other rights for the purchase or acquisition from such Person of shares of capital stock of (or other ownership or profit interests in) such Person, all of the securities convertible into or exchangeable for shares of capital stock of (or other ownership or profit interests in) such Person or warrants, rights or options for the purchase or acquisition from such Person of such shares (or such other interests), and all of the other ownership or profit interests in such Person (including partnership, member, membership or trust interests therein), whether voting or nonvoting, and whether or not such shares, warrants, options, rights or other interests are outstanding on any date of determination; provided that Equity Interests shall not include any Permitted Convertible Bond Indebtedness.

“ERISA” means the Employee Retirement Income Security Act of 1974.

“ERISA Affiliate” means any trade or business (whether or not incorporated) under common control with Parent within the meaning of Section 414(b) or (c) of the Internal Revenue Code (and Sections 414(m) and (o) of the Internal Revenue Code for purposes of provisions relating to Section 412 of the Internal Revenue Code).

“ERISA Event” means (a) a Reportable Event with respect to a Pension Plan, (b) the withdrawal of Parent or any ERISA Affiliate from a Pension Plan subject to Section 4063 of ERISA during a plan year in which such entity was a “substantial employer” as defined in Section 4001(a)(2) of ERISA or a cessation of operations that is treated as such a withdrawal under Section 4062(e) of ERISA, (c) a complete or partial withdrawal by Parent or any ERISA Affiliate from a Multiemployer Plan, (d) the filing of a notice of intent to terminate, the treatment of a Pension Plan amendment as a termination under Sections 4041 or 4041A of ERISA, (e) the institution by the PBGC of proceedings to terminate a Pension Plan, (f) any event or condition which constitutes grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Pension Plan, (g) the determination that any Pension Plan is considered an at-risk plan or a plan in endangered or critical status within the meaning of Sections 430, 431 and 432 of the Internal Revenue Code or Sections 303, 304 and 305 of ERISA, or (h) the imposition of any liability under Title IV of ERISA, other than for PBGC premiums due but not delinquent under Section 4007 of ERISA, upon Parent or any ERISA Affiliate.



“EU Bail-In Legislation Schedule” means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor person), as in effect from time to time.

“Event of Default” has the meaning set forth in Section 9.01.

“Excluded Accounts” means Deposit Accounts (i) used exclusively for trust, payroll, payroll taxes and other employee wage or employee benefit payments to or for the benefit of any Note Party’s employees, (ii) that are zero balance accounts (including any such accounts where payments pursuant to Medicaid, Medicare, TRICARE or other state or federal healthcare payor programs are deposited), (iii) which constitute cash collateral in respect of a Permitted Lien of the type described in any of Sections 8.01 (e), (f), (p), (r), (u), (v) or (w) and (iv) in which the amount on deposit that constitute “Excluded Accounts” in reliance on this clause (iv) does not exceed \$100,000 in the aggregate for all such accounts at any time.

“Excluded Property” means, with respect to any Note Party, including any Person that becomes a Note Party after the Closing Date as contemplated by Section 7.12, (a) any owned or leased real or personal property which is located outside of the United States and the jurisdiction where such Note Party is organized unless reasonably requested by the Collateral Agent or Required Purchasers (other than, for the avoidance of doubt, any Equity Interests of a Foreign Subsidiary required to be pledged pursuant to Section 7.14), (b) any personal property located in the United States (including, without limitation, motor vehicles) in respect of which perfection of a Lien is not either (x) governed by the Uniform Commercial Code or (y) effected by appropriate evidence of the Lien being filed in either the United States Copyright Office or the United States Patent and Trademark Office, unless requested by the Collateral Agent or the Required Purchasers, (c) the Equity Interests of any Foreign Subsidiary or Foreign Subsidiary Holding Company, in each case, to the extent not required to be pledged to secure the Obligations pursuant to Section 7.14(a), (d) any property which, subject to the terms of Section 8.09, is subject to a Lien of the type described in Section 8.01(i) pursuant to documents which prohibit such Note Party from granting any other Liens in such property, (e)(i) any leasehold interest of any Note Party in real property and (ii) any fee owned real property of any Note Party with a fair market value of less than \$1,000,000, (f) any United States intent-to-use trademark applications to the extent that, and solely during the period in which, the grant of a security interest therein would impair the validity or enforceability of such intent-to-use trademark applications under applicable federal law; provided, that, upon submission and acceptance by the United States Patent and Trademark Office of an amendment to allege use pursuant to 15 U.S.C. Section 1060(a) (or any successor provision), such intent-to-use trademark application shall no longer constitute “Excluded Property” and shall be considered Collateral, (g) any general intangible, permit, lease, license, contract or other instrument of a Note Party if the grant of a security interest in such general intangible, permit, lease, license, contract or other instrument in the manner contemplated by the Collateral Documents, under the terms thereof or under applicable Law, is prohibited and would result in the termination thereof or give the other parties thereto the right to terminate, accelerate or otherwise alter such Note Party’s rights, titles and interests thereunder (including upon the giving of notice or lapse of time or both); provided, that, (x) any such limitation described in this clause (g) on the security interests granted under the Collateral Documents shall only apply to the extent that any such prohibition would not be rendered ineffective pursuant to the Uniform Commercial Code or any other applicable Law or principles of equity and (y) in the event of the termination or elimination of any such prohibition or the requirement for any consent contained in any applicable Law, general intangible, permit, lease, license, contract or other instrument, to the extent sufficient to permit any such item to become Collateral, a security interest in such general intangible, permit, lease, license, contract or other instrument shall be automatically and simultaneously granted under the applicable Collateral Document and such general intangible, permit, lease, license, contract or other instrument shall no longer constitute “Excluded Property” and shall be considered Collateral, (h) those assets with respect to which the granting of security interests in such assets would be prohibited by applicable Law or regulation (other than to the extent that any such

Law, regulation or prohibition would be rendered ineffective pursuant to the Uniform Commercial Code or any other applicable Law or principles of equity), or would require governmental consent (after giving effect to the applicable anti-assignment provisions of the Uniform Commercial Code or other applicable Law or principles of equity); provided, that, immediately upon the ineffectiveness, lapse or termination of any such Law, regulation, prohibition or requirement for consent or the obtaining of any such consent, a security interest in such assets shall be automatically and simultaneously granted under the applicable Collateral Document and such assets shall no longer constitute “Excluded Property” and shall be considered Collateral, (i) any real or personal property reasonably identified by the Parent to the Collateral Agent as to which, after reasonable and good faith discussion between the Collateral Agent and the Parent, the Collateral Agent and Parent reasonably agree in writing that the costs or other consequences (including adverse tax consequences) of obtaining a security interest or perfection thereof are excessive in view of the benefits to be obtained by the Purchasers therefrom, (j) Equity Interests in any Person that is not a Subsidiary to the extent the pledge thereof is not permitted by the terms of such Person’s Organization Documents or any agreement governing Indebtedness of such Person, solely if such Person’s business and operations do not relate to XHANCE or the ENT Field, (k) any Excluded Accounts described in clauses (i), (ii) (solely to the extent payments pursuant to Medicaid, Medicare, TRICARE, CHAMPUS, CHAMPVA or other state or federal healthcare payor programs are deposited therein) or (iii) thereof and (l) any treasury stock of Parent that constitutes margin stock (within the meaning of Regulation U issued the FRB).

“Excluded Subsidiary” means any Subsidiary that is not a Wholly-Owned Subsidiary of Parent; provided that, in the case of any Subsidiary that is not a Wholly-Owned Subsidiary for which Parent directly or indirectly owns 70% or more of such Subsidiary’s Equity Interests, the Note Parties shall have used commercially reasonable efforts, promptly following the acquisition or formation of such Subsidiary, to cause such Subsidiary to become a Norwegian Notes Guarantor and/or US Notes Guarantor, as applicable, by obtaining any necessary consents, approvals or waivers from Third Parties for such Subsidiary to become a Norwegian Notes Guarantor and/or US Notes Guarantor, as applicable, and to the extent any such approvals or waivers could not be obtained, the Note Parties shall have delivered evidence reasonably satisfactory to the Purchasers of the foregoing (it being understood that (x) the failure of the Note Parties to obtain such consents, approvals or waivers after exercising commercially reasonable efforts shall not constitute a Default or Event of Default hereunder and (y) no Note Party shall be required to offer any financial incentive or other material concession in order to obtain such consents, approvals or waivers).

“Extraordinary Receipts” means any cash received by or paid to or for the account of any Person not in the ordinary course of business, including pension plan reversions, indemnity payments and any purchase price adjustments in connection with Acquisitions, but excluding: (i) tax refunds, (ii) proceeds of insurance, (iii) condemnation awards (and payments in lieu thereof), (iv) working capital adjustments in connection with any Acquisition, (v) indemnification payments to the extent constituting reimbursement for cash expenses incurred by any Note Party or Subsidiary with respect to the event giving rise to the related indemnity claims and (vi) any milestone, upfront, royalty and other similar payments from licensing or other similar transactions.

“Facilities” means, at any time, a collective reference to the facilities and real properties owned, leased or operated by any Note Party or any Subsidiary.

“FATCA” means Sections 1471 through 1474 of the Internal Revenue Code as of the Closing Date (or any amended or successor version that is substantively comparable and not materially more onerous to comply with) and any current or future regulations thereunder, official interpretations thereof, any agreement entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code and any intergovernmental agreements entered into thereunder.

“FDA” means the Food and Drug Administration of the United States of America or any successor entity thereto.

“FDCA” means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. Section 301 et seq. and all regulations promulgated thereunder.

“Foreign Purchaser” has the meaning set forth in Section 3.01.

“Foreign Subsidiary” means any Subsidiary that is not a Domestic Subsidiary.

“Foreign Subsidiary Holding Company” means any Domestic Subsidiary all or substantially all of the assets of which consist of, directly or indirectly, the Equity Interests in one or more CFCs and/or Indebtedness of one or more CFCs and any other assets incidental thereto.

“FRB” means the Board of Governors of the Federal Reserve System of the United States.

“Fund” means any Person (other than a natural Person) that is (or will be) engaged in making, purchasing, holding or otherwise investing in notes, loans and/or similar extensions of credit in the ordinary course of its activities.

“Funded Indebtedness” means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with GAAP:

(a) all obligations, whether current or long-term, for borrowed money (including the Obligations) and all obligations of such Person evidenced by bonds, debentures, notes, loan agreements or other similar instruments;

(b) all purchase money Indebtedness;

(c) the principal portion of all obligations under conditional sale or other title retention agreements relating to property purchased by such Person or any Subsidiary thereof (other than customary reservations or retentions of title under agreements with suppliers entered into in the ordinary course of business);

(d) all reimbursement or payment obligations due and payable and arising under letters of credit (including standby and commercial), bankers’ acceptances, bank guaranties, surety bonds and similar instruments;

(e) all obligations in respect of the deferred purchase price of property or services (other than (i) trade accounts payable or other accounts payable in the ordinary course of business and not past due more than 90 days after the date on which such account payable was created or otherwise being contested in good faith, and (ii) any Earn Out Obligations unless such Earn Out Obligations have not been paid after becoming due and payable);

(f) the Attributable Indebtedness of Capital Leases, Securitization Transactions and Synthetic Leases;

(g) all obligations of such Person to purchase, redeem, retire, defease or otherwise make any payment in respect of any Disqualified Capital Stock in such Person or any other Person, valued,

in the case of a redeemable preferred interest, at the greater of its voluntary or involuntary liquidation preference plus accrued and unpaid dividends;

(h) all Funded Indebtedness of others secured by (or for which the holder of such Funded Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on, or payable out of the proceeds of production from, property owned or acquired by such Person, whether or not the obligations secured thereby have been assumed;

(i) all Guarantees with respect to Funded Indebtedness of the types specified in clauses (a) through (h) above of another Person; and

(j) all Funded Indebtedness of the types referred to in clauses (a) through (i) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person is a general partner or joint venturer, except to the extent that Funded Indebtedness is expressly made non-recourse to such Person.

“GAAP” means generally accepted accounting principles in the United States set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board, consistently applied and as in effect from time to time.

“Governmental Authority” means the government of the United States or any other nation, or of any political subdivision thereof, including state or local, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including any supra-national bodies such as the European Union or the European Central Bank).

“Governmental Licenses” means all applications to and requests for approval from a Governmental Authority to manufacture, test, develop, import, store, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product, including, without limitation, all Drug Applications, and all authorizations issuing from a Governmental Authority based upon or as a result of such applications and requests, of which in each case are owned by Parent or any Subsidiary, acquired by Parent or any Subsidiary via assignment, purchase or otherwise or that Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to.

“Guarantee” means, as to any Person, (a) any obligation, contingent or otherwise, of such Person guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation payable or performable by another Person (the “primary obligor”) in any manner, whether directly or indirectly, and including any obligation of such Person, direct or indirect, (i) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation, (ii) to purchase or lease property, securities or services for the purpose of assuring the obligee in respect of such Indebtedness or other obligation of the payment or performance of such Indebtedness or other obligation, (iii) to maintain working capital, equity capital or any other financial statement condition or liquidity or level of income or cash flow of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation, or (iv) entered into for the purpose of assuring in any other manner the obligee in respect of such Indebtedness or other obligation of the payment or performance thereof or to protect such obligee against loss in respect thereof (in whole or in part), or (b) any Lien on any assets of such Person securing any Indebtedness or other obligation of any other Person, whether or not such Indebtedness or other obligation is assumed by such Person (or any right, contingent or otherwise, of any holder of such Indebtedness to obtain any such Lien). The amount of any Guarantee shall be deemed to be an amount equal to the stated or determinable amount

of the related primary obligation, or portion thereof, in respect of which such Guarantee is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by the guaranteeing Person in good faith. The term "Guarantee" as a verb has a corresponding meaning.

"Guarantors" means, collectively, the Norwegian Notes Guarantors and the US Notes Guarantors (and "Guarantor" shall mean, as the context may require, each of them individually), together with their successors and permitted assigns.

"Guaranty" means the Guaranty made by the Guarantors in favor of the Collateral Agent and the Purchasers pursuant to Article IV.

"Hazardous Materials" means all explosive or radioactive substances or wastes and all hazardous or toxic substances, wastes or other pollutants, including petroleum or petroleum distillates, asbestos or asbestos-containing materials, polychlorinated biphenyls, radon gas, infectious or medical wastes and all other substances or wastes of any nature regulated pursuant to any Environmental Law.

"HHS" means the United States Department of Health and Human Services and any successor agency thereof.

"Immaterial Subsidiary" means each Subsidiary of the Parent that has assets with a value of less than \$100,000.

"Indebtedness" means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with GAAP:

(a) all Funded Indebtedness;

(b) all obligations arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments;

(c) the Swap Termination Value of any Swap Contract;

(d) all obligations in respect of the deferred purchase price of property or services (other than trade accounts payable or other accounts payable in the ordinary course of business and not past due more than 90 days after the date on which such account payable was created or otherwise being contested in good faith,), including Earn Out Obligations;

(e) all Guarantees with respect to outstanding Indebtedness of the types specified in clauses (a) through (d) above of any other Person; and

(f) all Indebtedness of the types referred to in clauses (a) through (d) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person or a Subsidiary thereof is a general partner or joint venturer, unless such Indebtedness is expressly made non-recourse to such Person or such Subsidiary.

For purposes hereof, the amount of any direct obligation arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments shall be the maximum amount available to be drawn thereunder.

For the avoidance of doubt, “Indebtedness” shall not include Permitted Bond Hedge Transactions or Permitted Warrant Transactions.

“Indemnified Taxes” has the meaning set forth in Section 3.01(b).

“Indemnitee” has the meaning set forth in Section 11.04(b).

“Indirect Purchaser” means any Person that is not a U.S. Person and either (1) directly holds equity interests in a Purchaser that is treated as a partnership or disregarded entity for United States federal income tax purposes or (2) directly holds equity interests in a U.S. Person that is treated as a partnership or disregarded entity for U.S. federal income tax purposes that, directly, or indirectly through entities each of which is treated a partnership or a disregarded entity for U.S. federal income tax purposes, holds equity interests in a Purchaser.

“Information” has the meaning set forth in Section 11.07.

“Infringement” and “Infringe” mean the infringement, misappropriation or other violation of know-how, trade secrets, confidential information and/or other IP Rights.

“Initial Note” has the meaning specified in Section 2.01(a).

“Interest Payment Date” means (a) the 15<sup>th</sup> day of each March, June, September and December; provided, that, if any such 15<sup>th</sup> day is not a Business Day, the applicable “Interest Payment Date” shall be the first Business Day following such 15<sup>th</sup> day, and (b) the Maturity Date.

“Interest Period” means, (a) initially, the period beginning on (and including) the date on which the Initial Notes or Delayed Draw Notes, as applicable, are issued and purchased hereunder and ending on (and including) the next following Interest Payment Date, and (b) thereafter, the period beginning on (and including) the first day immediately following such Interest Payment Date and ending on the earlier of (and including) (i) the next following Interest Payment Date and (ii) the Maturity Date.

“Interim Financial Statements” means the unaudited consolidated financial statements of Parent and its Subsidiaries for the fiscal quarter ended September 30, 2017, including balance sheets and statements of income or operations, shareholders’ equity and cash flows.

“Internal Revenue Code” means the United States Internal Revenue Code of 1986.

“Internal Revenue Service” means the United States Internal Revenue Service.

“Investment” means, as to any Person, any direct or indirect acquisition or investment by such Person, whether by means of (a) the purchase or other acquisition of Equity Interests of another Person, (b) a loan, advance or capital contribution to, Guarantee or assumption of debt of, or purchase or other acquisition of any other debt or equity participation or interest in, another Person, including any partnership or joint venture interest in such other Person and any arrangement pursuant to which the investor Guarantees Indebtedness of such other Person, or (c) an Acquisition. For purposes of covenant compliance, the amount of any Investment shall be the amount actually invested (which, in the case of any Investment constituting the contribution of an asset or property, shall be based on such Person’s good faith estimate of the fair market value of such asset or property at the time such Investment is made), less the amount of cash and Cash Equivalents or the fair market value (as determined by such Person in good faith) of any other property received, returned or repaid as a result of dispositions, distributions or liquidations of all or a portion of such

Investment, without adjustment for subsequent increases or decreases in the value of such Investment or write-ups, write-downs or write-offs with respect thereto.

“Involuntary Disposition” means any loss of, damage to or destruction of, or any condemnation or other taking for public use of, any property of any Note Party or any of their Subsidiaries.

“IP Rights” means, collectively, all Confidential Information, all Copyrights, all Copyright Licenses, all Domain Names, all Drug Applications, all Governmental Licenses, all Other Intellectual Property, all Other IP Agreements, all Patents, all Patent Licenses, all Proprietary Databases, all Proprietary Software, all Trademarks, all Trademark Licenses, all Trade Secrets, all Websites and all Website Agreements.

“Joinder Agreement” means a joinder agreement substantially in the form of Exhibit B executed and delivered by a Domestic Subsidiary in accordance with the provisions of Section 7.12.

“Joint Venture” means a joint venture, partnership or other similar arrangement, in corporate, partnership or similar legal form with a Person other than Parent or its Subsidiaries.

“Junior Debt” means (a) any Indebtedness that is contractually subordinated in right of payment to the Obligations, (b) any Indebtedness secured by Liens on any Collateral contractually junior to those created under the Collateral Documents and (c) any unsecured Indebtedness for borrowed money.

“Laws” means, collectively, all international, foreign, federal, state and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case whether or not having the force of law.

“LIBOR” means, for any Interest Period, the three-month London Interbank Offered Rate (or a comparable or successor rate which rate is approved by the Collateral Agent in its sole discretion) for deposits in Dollars at approximately 11:00 a.m. (London, England time), quoted by the Collateral Agent from the appropriate Bloomberg page selected by the Collateral Agent (or any successor thereto or similar source determined by the Collateral Agent from time to time), in effect two Business Days prior to the first day of such Interest Period, adjusted for any reserve requirement and any subsequent costs arising from a change in governmental regulation, if applicable, such rate to be rounded up to the nearest 1/16 of 1%. The Collateral Agent’s determination of LIBOR and internal records of applicable interest rates shall be determinative in the absence of manifest error. For all purposes hereunder, in no event shall LIBOR be less than 1.00%.

“Lien” means any mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or other), charge, or preference, priority or other security interest or preferential arrangement in the nature of a security interest of any kind or nature whatsoever (including any conditional sale or other title retention agreement, any easement, right of way or other encumbrance on title to real property, and any financing lease having substantially the same economic effect as any of the foregoing).

“Make-Whole Amount” means, on any date of determination, with respect to any amount of the Notes that is prepaid or required to be prepaid, an amount equal to the amount, if any, by which (a) the present value as of such date of determination (as determined by the Required Purchasers in accordance with customary practice (it being understood that for purposes of this definition “present value” shall be calculated using the X-NPV function of Microsoft Excel at the time of such calculation)) of (i) one hundred and two percent (102%) of the principal amount of the Notes prepaid or required to be prepaid plus (ii) all interest

that would have accrued on the principal amount of the Notes prepaid or required to be prepaid through and including the second anniversary of the Closing Date (with respect to any Initial Notes) or the second anniversary of the Delayed Draw Closing Date (with respect to any Delayed Draw Notes) computed using a discount rate equal to the Three Month Treasury Rate plus one percent (1.00%), but for such prepayment or requirement to prepay, exceeds (b) the principal amount of the Notes prepaid or required to be prepaid.

“Market Capitalization” means, as of any date of determination, the product of (a) the number of issued and outstanding shares of common stock of Parent as of such date (exclusive of any shares of common stock issuable upon the exercise of options or warrants or conversion of any convertible securities), multiplied by (b) the volume weighted average price per share for the Parent’s shares of common stock for the ten immediately preceding Trading Days on the Current Market.

“Market Withdrawal” means the removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, such as normal stock rotation practices and routine equipment adjustments and repairs, as this term is defined in FDA’s regulations at 21 CFR 7.3(j).

“Material Adverse Effect” means (a) a material adverse change in, or a material adverse effect upon, the business, assets, properties, liabilities (actual or contingent) or financial condition of Parent and its Subsidiaries taken as a whole, (b) a material impairment of the rights and remedies of the Collateral Agent or any Purchaser under any Note Document to which it is a party or a material impairment in the perfection or priority of the Collateral Agent’s security interests in the Collateral, (c) a material impairment of the ability of the Note Parties, taken as a whole, to perform their material obligations under any Note Document, or (d) a material adverse effect upon the legality, validity, binding effect or enforceability against any Note Party of any material provision of any Note Document to which it is a party.

“Material Contracts” has the meaning set forth in Section 6.24.

“Material IP Rights” means IP Rights that (a) are material to the operations, assets, business, property or financial condition of Parent and its Subsidiaries taken as a whole or (b) the loss of which could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

“Material Product” means (a) XHANCE, and (b) any other Product, which, in the case of this clause (b), is material to the operations, business, property or financial condition of the Parent and its Subsidiaries, taken as a whole.

“Maturity Date” means June 29, 2023.

“Maximum Rate” has the meaning set forth in Section 11.09.

“Moody’s” means Moody’s Investors Service, Inc. and any successor thereto.

“Mortgages” means the mortgages, deeds of trust or deeds to secure debt that purport to grant to the Collateral Agent, for the benefit of the Purchasers, a security interest in the freehold interest or fee interest of any Note Party in real property (other than Excluded Property).

“Multiemployer Plan” means any employee benefit plan of the type described in Section 4001(a)(3) of ERISA, to which Parent or any ERISA Affiliate makes or is obligated to make contributions, or during the preceding five plan years, has made or been obligated to make contributions.



“Multiple Employer Plan” means a Plan which has two or more contributing sponsors (including Parent or any ERISA Affiliate) at least two of whom are not under common control, as such a plan is described in Section 4064 of ERISA.

“Net Cash Proceeds” means the aggregate cash or Cash Equivalents proceeds received by any Note Party or any Subsidiary in respect of any Disposition, Debt Issuance, Involuntary Disposition or Extraordinary Receipts, net of (a) direct costs incurred in connection therewith (including, without limitation, legal, accounting and investment banking fees, and sales commissions), (b) taxes paid or payable as a result thereof, (c) in the case of any Disposition or Involuntary Disposition, the amount necessary to retire any Indebtedness secured by a Permitted Lien on the related property and (d) in the case of any Extraordinary Receipt, direct costs incurred in connection with the collection of such proceeds, awards or other payments; it being understood that “Net Cash Proceeds” shall include, without limitation, any cash or Cash Equivalents received upon the sale or other disposition of any non-cash consideration received by any Note Party or any Subsidiary in any Disposition, Debt Issuance, Involuntary Disposition or Extraordinary Receipt.

“Non-Consenting Purchaser” means any Purchaser that does not approve any consent, waiver or amendment that (a) requires the approval of all Purchasers or all affected Purchasers in accordance with the terms of Section 12.01 and (b) has been approved by the Required Purchasers.

“Norwegian Notes Guarantor” means, Parent and each Subsidiary of Parent (other than the Norwegian Issuer, any Excluded Subsidiary and any Immaterial Subsidiary), together with each other Person that joins as a Norwegian Notes Guarantor pursuant to Section 7.12.

“Norwegian Security Documents” means (a) a share pledge agreement over the shares in the Norwegian Issuer granted by the Parent and (b) a security agreement granted by the Norwegian Issuer, pledging certain monetary claims, inventory, operating assets, patents and trade receivables.

“Note” or “Notes” means the Initial Notes and the Delayed Draw Notes, individually or collectively, as appropriate.

“Note Documents” means this Agreement, each Note, the Disclosure Letter, each Joinder Agreement and the Collateral Documents.

“Note Parties” means, collectively, each Issuer and each Guarantor.

“Notice of Issuance” means a notice of the US Issuer, executed by a Responsible Officer thereof, with respect to the proposed issuance of Delayed Draw Notes setting forth (i) the proposed Delayed Draw Note Closing Date with respect to such issuance of Delayed Draw Notes (which date may be no earlier than 10 Business Days from the date on which such notice is delivered to the Purchasers), (ii) the aggregate principal amount of the Delayed Draw Notes proposed to be issued to each Purchaser with a Delayed Draw Note Commitment, and (iii) the aggregate purchase price payable by each Purchaser with a Delayed Draw Note Commitment in respect of the Delayed Draw Notes to be acquired by each such Purchaser.

“OFAC” means the Office of Foreign Assets Control of the United States Department of the Treasury.

“Obligations” means all advances to, and debts, liabilities, obligations, covenants and duties of, any Note Party arising under any Note Document or otherwise with respect to any Note, whether direct or indirect (including those acquired by assumption), absolute or contingent, due or to become due, now existing or hereafter arising and including interest and fees that accrue after the commencement by or against any Note

Party or any Subsidiary thereof of any proceeding under any Debtor Relief Laws naming such Person as the debtor in such proceeding, regardless of whether such interest and fees are allowed claims in such proceeding.

“Organization Documents” means, (a) with respect to any corporation or Norwegian private limited liability company, the certificate or articles of incorporation and the bylaws, (b) with respect to any limited liability company, the certificate or articles of formation or organization and operating agreement, and (c) with respect to any partnership, joint venture, trust or other form of business entity, the partnership, joint venture or other applicable agreement of formation or organization, including in each case equivalent or comparable constitutive documents with respect to any non-U.S. jurisdiction, and any agreement, instrument, filing or notice with respect thereto filed in connection with its formation or organization with the applicable Governmental Authority in the jurisdiction of its formation or organization and, if applicable, any certificate or articles of formation or organization of such entity.

“Other Intellectual Property” means all worldwide intellectual property rights, industrial property rights, proprietary rights and common-law rights, whether registered or unregistered, which are not otherwise included in Confidential Information, Copyrights, Copyright Licenses, Domain Names, Governmental Licenses, Other IP Agreements, Patents, Patent Licenses, Trademarks and Trademark Licenses, Proprietary Databases, Proprietary Software, Websites, Website Agreements and Trade Secrets, including, without limitation, all rights to and under all new and useful algorithms, concepts, data (including all clinical data relating to a Product), databases, designs, discoveries, inventions, know-how, methods, processes, protocols, show-how, software (other than commercially available, off-the-shelf software), specifications for Products, techniques, technology, trade dress and all improvements thereof and thereto, which is owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and which is used by Parent or any other Person to advertise, develop, manufacture, import, market, promote, offer for sale, sell, use and/or otherwise distribute a Product.

“Other IP Agreements” means any agreement, whether written or oral, providing for the grant of any right under any Confidential Information, Governmental Licenses, Proprietary Database, Proprietary Software, Trade Secret and/or any other IP Rights, to the extent that the grant of any such right is not otherwise the subject of a Copyright License, Trademark License, Patent License or Website Agreement.

“Patent License” means any agreement, whether written or oral, providing for the grant of any right under any Patent.

“Patents” means all letters patent and patent applications in the United States and all other countries (and all letters patent that issue therefrom) and all reissues, extensions, supplementary protection certificates renewals, divisions, separations and continuations (including continuations-in-part and continuing prosecution applications) thereof, for the full term thereof, together with the right to claim the priority thereto, which are owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and which is used by Parent or any other Person to advertise, develop, manufacture, import, market, promote, offer for sale, sell, use and/or otherwise distribute a Product.

“PBGC” means the Pension Benefit Guaranty Corporation or any successor thereto.

“Pension Act” means the Pension Protection Act of 2006.

“Pension Funding Rules” means the rules of the Internal Revenue Code and ERISA regarding minimum required contributions (including any installment payment thereof) to Pension Plans and set forth in Section 412, 430, 431, 432 and 436 of the Internal Revenue Code and Sections 302, 303, 304 and 305 of ERISA.

“Pension Plan” means any employee pension benefit plan (including a Multiple Employer Plan or a Multiemployer Plan) that is maintained or is contributed to by Parent or any ERISA Affiliate and that is either covered by Title IV of ERISA or is subject to minimum funding standards under Section 412 of the Internal Revenue Code.

“Permits” means licenses (including Governmental Licenses), certificates, accreditations, provider numbers or provider authorizations, other authorizations, registrations, permits or consents required in connection with the conduct of Parent’s or any Subsidiary’s Business or to comply with any applicable Laws, including drug listings and drug establishment registrations under 21 U.S.C. Section 360, registrations issued by DEA under 21 U.S.C. Section 823 (if applicable to any Product), and those issued by state governments for the conduct of Parent’s or any Subsidiary’s Business.

“Permitted Acquisitions” means an Investment consisting of an Acquisition by any Note Party or Wholly-Owned Subsidiary of a Note Party; provided, that: (a) no Default or Event of Default shall have occurred and be continuing or would result from such Acquisition, (b) the property acquired (or the property of the Person acquired) in such Acquisition is used or useful in the same or a related line of business as Parent and its Subsidiaries were engaged in on the Closing Date (or any reasonable extensions or expansions thereof), (c) the Collateral Agent shall have received all items in respect of the Equity Interests or property acquired in such Acquisition as and when required to be delivered by the terms of Section 7.12 and/or Section 7.14, (d) in the case of an Acquisition of the Equity Interests of another Person, the Board of Directors of such other Person shall have duly approved such Acquisition, (e) Parent shall have delivered to the Purchasers pro forma financial statements for Parent and its Subsidiaries after giving effect to such Acquisition for the twelve month period ending as of the most recent fiscal quarter end in a form reasonably satisfactory to the Required Purchasers, (f) the representations and warranties made by the Note Parties in each Note Document shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) at and as if made as of the date of such Acquisition (after giving effect thereto) except to the extent any such representation and warranty expressly relates to an earlier date, in which case it shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date and (g) the aggregate consideration (including cash and non-cash consideration, deferred purchase price and any Earn Out Obligations but excluding consideration paid in the form of Qualified Capital Stock of Parent or from the proceeds of any substantially contemporaneous issuance of Qualified Capital Stock of Parent (to the extent not constituting a Change of Control)) paid by the Note Parties for (x) any individual Acquisition does not exceed an amount equal to, 2.50% (or up to 10% if either (1) the Consolidated EBITDA for the four-fiscal quarter period most recently ended prior to the Permitted Acquisition Disclosure Date was at least \$20,000,000, for which Parent shall deliver to the Purchasers on the Permitted Acquisition Disclosure Date a certificate signed by a Responsible Officer of Parent certifying to such fact together with a reasonably detailed calculation of Consolidated EBITDA for such period (the “EBITDA Test Condition”) or (2)(A) the Debt to Revenue Ratio (Product) for the last day of the fiscal quarter most recently ended prior to Permitted Acquisition Disclosure Date is not greater than the lesser of (x) 6.50:1.00 or (y) if the Delayed Draw Notes have been issued and purchased or if the Permitted Acquisition Disclosure Date occurs during a Springing Covenant Compliance Period, the lowest applicable ratio then in effect as set forth in Section 8.16(b)(i) under the column “Maximum Debt to Revenue Ratio (General)” or Section 8.16(b)(ii) under the column “Maximum Debt to Revenue Ratio (Product)” for such date, for which Parent shall deliver to the Purchasers on the Permitted Acquisition Disclosure Date a certificate signed by a Responsible Officer of Parent certifying to such fact together with a reasonably detailed calculation of Debt to Revenue Ratio (Product) for such date (the “Debt to Revenue Test Condition”) and (B) with respect to that portion of the aggregate consideration for such Acquisition in excess of 2.50% of Parent’s Market Capitalization (as reasonably determined by the Parent in good faith) at the Permitted Acquisition Disclosure

Date, the cash used for such Acquisition is from the proceeds of one or more issuances of Qualified Capital Stock of Parent (to the extent not constituting a Change of Control) received within the 18-month period prior to the closing of such Acquisition in an amount not to exceed (x) the aggregate amount of such proceeds minus (y) \$35,000,000 (the “Equity Issuance Condition”) in each case, of Parent’s Market Capitalization (as reasonably determined by the Parent in good faith) at the Permitted Acquisition Disclosure Date and (y) all such Acquisitions do not exceed an aggregate amount equal to 7.50% (and if either (1) the EBITDA Test Condition, or (2) both (A) the Debt to Revenue Test Condition and (B) with respect to that portion of the aggregate consideration for all such Acquisitions in excess of 7.50% of Parent’s Market Capitalization (as reasonably determined by the Parent in good faith) at the Permitted Acquisition Disclosure Date, the Equity Issuance Condition, are met at the time of the relevant Acquisition, 25.00%), in each case, of Parent’s Market Capitalization (as reasonably determined by the Parent in good faith) at the Permitted Acquisition Disclosure Date).

“Permitted Acquisition Disclosure Date” means the date that such Acquisition is first disclosed to the Purchasers (which shall be no earlier than thirty (30) Business Days and no later than five (5) Business Days prior to entering into any definitive acquisition agreement in respect thereof).

“Permitted Bond Hedge Transaction” means any call, call spread or capped call option (or substantively equivalent derivative transaction) relating to the Parent’s common stock (or other securities or property following a fundamental change of the Parent or other change of, or adjustment with respect to, the common stock of the Parent, in each case to the extent not constituting a Change of Control) purchased or otherwise entered into by the Parent in connection with the issuance of any Permitted Convertible Bond Indebtedness; provided, that, the purchase price for such Permitted Bond Hedge Transaction, less the proceeds received by the Parent from the sale of any related Permitted Warrant Transaction (or in the case of capped calls, where such proceeds are not received but are reflected in a reduction of the premium), does not result in the incurrence of additional Indebtedness by the Parent (other than Indebtedness from the issuance of Permitted Convertible Bond Indebtedness in connection with such Permitted Bond Hedge Transaction).

“Permitted Convertible Bond Indebtedness” means Indebtedness having a feature which entitles the holder thereof to convert or exchange all or a portion of such Indebtedness into Equity Interests of Parent; provided, that (i) such Permitted Convertible Bond Indebtedness shall be unsecured, (ii) no Subsidiary of Parent shall guarantee Permitted Convertible Bond Indebtedness, (iii) Permitted Convertible Bond Indebtedness shall not include any financial maintenance covenants and shall only include covenants and defaults that are customary for public market convertible indebtedness (pursuant to a public offering or an offering under Rule 144A or Regulation S of the Securities Act), as determined by Parent in its good faith judgment, (iv) no Default or Event of Default shall have occurred and be continuing at the time of incurrence of such Permitted Convertible Bond Indebtedness or would result therefrom, (v) such Permitted Convertible Bond Indebtedness does not have a scheduled maturity date earlier than 180 calendar days after the Maturity Date, and (vi) Parent shall have delivered to the Purchasers a certificate of a Responsible Officer of Parent certifying as to the foregoing.

“Permitted Holders” means, collectively, Avista Capital Partners II, LP and its Controlled Investment Affiliates; “Permitted Holder” means any one of them.

“Permitted Licenses” means, collectively, (a) licenses of over-the-counter software that is commercially available to the public, (b) intercompany licenses or grants of rights for development, manufacture, production, commercialization (including commercial sales to end users), marketing, co-promotion, or distribution among the Note Parties, (c) any non-exclusive or exclusive license of (or covenant not to sue with respect to) IP Rights or technology or a grant of rights for development, manufacture,

production, commercialization (including commercial sales to end users), marketing, co-promotion, or distribution, in each case existing as of the date hereof, and (d) any non-exclusive and exclusive licenses for the use of (or covenant not to sue with respect to) the IP Rights of Parent or any of its Subsidiaries or a grant of rights for development, manufacture, production, commercialization (including commercial sales to end users), marketing, co-promotion or distribution; provided, that, with respect to each such license described in clause (d), (i) no Event of Default has occurred or is continuing at the time of such license, (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any intellectual property and the Note Parties shall comply, if applicable, with Section 7.18 with respect to such license, (iii) in the case of any exclusive license, (A) Parent delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to the Purchasers and delivers to the Purchasers copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, all of which shall constitute "Information" as described in Section 12.07 regardless of whether marked confidential, (B) any such license could not result in a legal transfer of title of the licensed property and (C) in the case of any such license relating to the commercialization (including commercial sales to end users), development, manufacture, production, marketing, co-promotion or distribution of XHANCE, such license may be exclusive as to the United States (or any territory therein) but only with respect to a particular market segment or indication which is outside the ENT Field (each such license described in this clause (C), a "Permitted XHANCE Exclusive US License") (for the avoidance of doubt, licenses of XHANCE may be exclusive, including as to territory outside of the United States, pursuant to clause (d) to the extent such licenses otherwise meet the requirements of such clause (d) and the other clauses of this proviso), and (iv) all upfront payments, royalties, milestone payments, sublicense revenues or other proceeds arising from the licensing agreement that are payable to Parent or any of its Subsidiaries are paid to a Deposit Account that is governed by a Deposit Account Control Agreement.

"Permitted XHANCE Exclusive US License" has the meaning set forth in the definition of "Permitted License".

"Permitted Liens" means, at any time, Liens in respect of property of any Note Party or any of its Subsidiaries permitted to exist at such time pursuant to the terms of Section 8.01.

"Permitted Transfers" has the meaning set forth in the definition of "Disposition".

"Permitted Warrant Transaction" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to the Parent's common stock (or other securities or property following a merger event or other change of the common stock of the Parent to the extent not constituting a Change of Control) sold by the Parent substantially contemporaneously with any purchase by the Parent of a related Permitted Bond Hedge Transaction, with a strike price higher than the strike price of the Permitted Bond Hedge Transaction.

"Person" means any natural person, corporation, limited liability company, trust, joint venture, association, company, partnership, Governmental Authority or other entity.

"PHSA" means the United States Public Health Service Act, 42 U.S.C. Section 201 et seq., and all regulations promulgated thereunder.

"Plan" means any employee benefit plan within the meaning of Section 3(3) of ERISA (including a Pension Plan), maintained for employees of Parent or any ERISA Affiliate or any such Plan to which Parent or any ERISA Affiliate is required to contribute on behalf of any of its employees or otherwise has any liability.

“Pledge Agreement” means the New York law governed pledge agreement dated as of the Closing Date executed in favor of the Collateral Agent, for the benefit of the Purchasers, by each of the Note Parties, as amended or modified from time to time in accordance with the terms hereof.

“Principal Market” means any of the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the NASDAQ Global Market or the NASDAQ Capital Market.

“Pro Forma Basis” means, in respect of a Specified Transaction, that such Specified Transaction and the following transactions in connection therewith (to the extent applicable) shall be deemed to have occurred as of the first day of the applicable period of measurement for the applicable covenant or requirement: (i) with respect to any Disposition, Involuntary Disposition or sale, transfer or other disposition that results in a Person ceasing to be a Subsidiary, income statement and cash flow statement items (whether positive or negative) attributable to the Person or property disposed of shall be excluded and (ii) with respect to any Acquisition or Investment, income statement and cash flow statement items (whether positive or negative) attributable to the Person or property acquired shall be included to the extent relating to any period applicable in such calculations to the extent (A) such items are not otherwise included in such income statement items for Parent and its Subsidiaries in accordance with GAAP or in accordance with any defined terms set forth in Section 1.01 and (B) such items are supported by financial statements or other information reasonably satisfactory to the Required Purchasers; provided, that, Pro Forma Basis in respect of any Specified Transaction shall be calculated in a reasonable and factually supportable manner and certified by a Responsible Officer of Parent.

“Product” means (a) XHANCE, and (b) any other prescription drug, medical device or combination product advertised, developed, imported, manufactured, marketed, offered for sale, promoted, sold, tested, used or otherwise distributed by Parent or any Subsidiary in connection with or that embody, in whole or in part, the IP Rights, including those products set forth on Schedule 1.01(b) to the Disclosure Letter (as updated from time to time in accordance with the terms of this Agreement).

“Proprietary Databases” means any material non-public proprietary database that is owned by Parent or any Subsidiary or that Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and that is used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product.

“Proprietary Software” means any proprietary software owned, licensed or otherwise used, other than any software that is generally commercially available, off-the-shelf and/or open source including, without limitation, the object code and source code forms of such software and all associated documentation, which is owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and that is used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product.

“Qualified Capital Stock” of any Person means any Equity Interests of such Person that are not Disqualified Capital Stock.

“Real Property Security Documents” means with respect to the freehold interest or fee interest of any Note Party in any real property (other than Excluded Property) located in the United States (or in the case of any such real property located in Norway or England, as otherwise required pursuant to the terms of the English Security Documents or Norwegian Security Documents, and in the case of any such real property located outside the United States, Norway or England, similar documents as customary or required under the laws of such jurisdiction):

(a) a fully executed and notarized Mortgage encumbering the freehold interest or fee interest and/or leasehold interest of such Note Party in such real property (provided, however, that the Collateral Agent's right to recover under such Mortgage shall be limited to not more than 110% of the fair market value of such real property in order to limit any documentary stamp taxes and intangible taxes due on the recording of the applicable Mortgage);

(b) if requested by the Collateral Agent in its reasonable discretion, maps or plats of an as-built survey of the sites of such real property certified to the Collateral Agent and the title insurance company issuing the policies referred to in clause (c) of this definition in a manner reasonably satisfactory to each of the Collateral Agent and such title insurance company, dated a date satisfactory to each of the Collateral Agent and such title insurance company by an independent professional licensed land surveyor, which maps or plats and the surveys on which they are based shall be sufficient to delete any standard printed survey exception contained in the applicable title policy and be made in accordance with the Minimum Standard Detail Requirements for Land Title Surveys jointly established and adopted by the American Land Title Association and the National Society of Professional Surveyors, Inc. in 2016;

(c) ALTA mortgagee title insurance policies issued by a title insurance company acceptable to the Collateral Agent with respect to such real property (to the extent available for a commercially reasonable cost in an amount not to exceed 110% of the fair market value of such real property, assuring the Collateral Agent that the Mortgage covering such real property creates a valid and enforceable first priority mortgage lien on such real property, free and clear of all defects and encumbrances except Permitted Liens, which title insurance policies shall otherwise be in form and substance reasonably satisfactory to the Collateral Agent and shall include such endorsements as are reasonably requested by the Collateral Agent (but not including zoning endorsements; provided, that, in lieu thereof, the Collateral Agent may require either a zoning compliance letter from the applicable municipality in a form reasonably acceptable to the Collateral Agent or a report issued by Planning and Zoning Resources Corp. or another professional firm reasonably acceptable to the Collateral Agent);

(d) evidence as to (i) whether such real property is in an area designated by the Federal Emergency Management Agency as having special flood or mud slide hazards (a "Flood Hazard Property") and (ii) if such real property is a Flood Hazard Property, (A) whether the community in which such real property is located is participating in the National Flood Insurance Program, (B) the applicable Note Party's written acknowledgment of receipt of written notification from the Collateral Agent (1) as to the fact that such real property is a Flood Hazard Property and (2) as to whether the community in which each such Flood Hazard Property is located is participating in the National Flood Insurance Program and (C) copies of insurance policies or certificates of insurance of Parent and its Subsidiaries evidencing flood insurance reasonably satisfactory to the Collateral Agent and naming the Collateral Agent and its successors and/or assigns as sole loss payee on behalf of the Purchasers;

(e) if requested by the Collateral Agent in its reasonable discretion, a Phase I environmental assessment report, as to such real property, in form and substance and from professional firms reasonably acceptable to the Collateral Agent;

(f) if requested by the Collateral Agent in its sole discretion, evidence reasonably satisfactory to the Collateral Agent that such real property, and the uses of such real property, are in compliance in all material respects with all applicable zoning laws; and

(g) if requested by the Collateral Agent in its sole discretion, an opinion of legal counsel to the Note Party granting the Mortgage on such real property, addressed to the Collateral Agent and each Purchaser, in form and substance reasonably acceptable to the Collateral Agent.

“Recall” means, as this term is defined in FDA’s regulations at 21 CFR 7.3(g), the removal or correction of a marketed product that the FDA considers to be in violation of the Laws it administers and against which the agency would initiate legal action, e.g., seizure. For the avoidance of doubt, Recall does not include a Market Withdrawal.

“Recipient” means any Purchaser and any other recipient of any payment by or on account of any obligation of any Note Party under any Note Document.

“Related Parties” means, with respect to any Person, such Person’s Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors, sub-advisors and representatives of such Person and of such Person’s Affiliates.

“Reportable Event” means any of the events set forth in Section 4043(c) of ERISA, other than events for which the thirty-day notice period has been waived.

“Reporting Date” means the date on which the financial statements required by Section 7.01(a) or (b) are delivered or required to be delivered to Collateral Agent and the Purchasers.

“Required Permit” means a Permit material to the operations, business, property or financial condition of the Parent and its Subsidiaries, taken as a whole, that is (a) issued or required under Laws applicable to the business of Parent or any Subsidiary and necessary in the manufacturing, testing, developing, importing, exporting, possession, ownership, warehousing, marketing, promoting, sale, labeling, furnishing, distribution or delivery of any Product under Laws applicable to the business of Parent or any Subsidiary or any Drug Application (including without limitation, at any point in time, all licenses, approvals and permits issued by the FDA or any other applicable Governmental Authority necessary for the testing, development, manufacture, marketing or sale of any Product by Parent or any Subsidiary as such activities are being conducted by Parent or such Subsidiary with respect to such Product at such time), and (b) issued by any Person from which Parent or any Subsidiary has, as of the Closing Date, received a required accreditation.

“Required Purchasers” means, as of any date, the Purchasers holding at least 51% of the aggregate principal amount of (i) the Notes outstanding on such date, and (ii) all undrawn Delayed Draw Note Commitments outstanding on such date, voting as a single class; provided, that any Notes held by Parent or any of its Subsidiaries shall be excluded; provided, further, that to the Notes and Delayed Draw Note Commitments of any Defaulting Purchaser shall be disregarded in determining Required Purchasers at any time.

“Responsible Officer” means the chief executive officer, president, chief financial officer, chief legal officer or chief operating officer, or vice president of finance of a Note Party and, solely for purposes of the delivery of certificates pursuant to Sections 5.01 or 7.12(b), the secretary or any assistant secretary of a Note Party. Any document delivered hereunder that is signed by a Responsible Officer of a Note Party shall be conclusively presumed to have been authorized by all necessary corporate, partnership and/or other action on the part of such Note Party and such Responsible Officer shall be conclusively presumed to have acted on behalf of such Note Party.



“Restricted Payment” means (a) any dividend or other distribution, direct or indirect, on account of any shares (or equivalent) of any class of Equity Interests of any Note Party or any of its Subsidiaries, now or hereafter outstanding, (b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of any shares (or equivalent) of any class of Equity Interests of any Note Party or any of its Subsidiaries, now or hereafter outstanding, and (c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Equity Interests of any Note Party or any of its Subsidiaries, now or hereafter outstanding.

“S&P” means Standard & Poor’s Financial Services LLC, a subsidiary of McGraw-Hill Financial, Inc., and any successor thereto.

“Safety Notices” has the meaning set forth in Section 6.25.

“Sale and Leaseback Transaction” means, with respect to any Note Party or any Subsidiary, any arrangement, directly or indirectly, with any Person whereby the Note Party or such Subsidiary shall sell or transfer any property used or useful in its business, whether now owned or hereafter acquired, and thereafter rent or lease such property or other property that it intends to use for substantially the same purpose or purposes as the property being sold or transferred.

“Sanction(s)” means any sanction administered or enforced by the United States government (including, without limitation, OFAC), the United Nations Security Council, the European Union, the Kingdom of Norway, Her Majesty’s Treasury (“HMT”) or other relevant sanctions authority.

“SEC” means the Securities and Exchange Commission, or any Governmental Authority succeeding to any of its principal functions.

“Securities Act” means the Securities Act of 1933.

“Securitization Transaction” means, with respect to any Person, any financing transaction or series of financing transactions (including factoring arrangements) pursuant to which such Person or any Subsidiary of such Person may sell, convey or otherwise transfer, or grant a security interest in, accounts, payments, receivables, rights to future lease payments or residuals or similar rights to payment to a special purpose subsidiary or affiliate of such Person.

“Security Agreement” means the New York law governed security agreement dated as of the Closing Date executed in favor of the Collateral Agent, for the benefit of the Purchasers, by each of the Note Parties, as amended or modified from time to time in accordance with the terms hereof.

“Solvent” or “Solvency” means, with respect to any Person as of a particular date, that on such date (a) such Person is able to pay its debts and other liabilities as they become absolute and matured in the ordinary course of business, (b) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person’s ability to pay as such debts and liabilities become absolute and matured in their ordinary course, (c) such Person is not engaged in a business or a transaction, and is not about to engage in a business or a transaction, for which such Person’s property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which such Person is engaged or is to engage, (d) the fair value of the property of such Person on a going concern basis is greater than the total amount of liabilities of such Person and (e) the present fair salable value of the assets of such Person on a going concern basis is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured in the ordinary course of business.

“Specified Transaction” means any Acquisition, any Disposition, any sale, transfer or other disposition that results in a Person ceasing to be a Subsidiary, any Involuntary Disposition or any Investment that results in a Person becoming a Subsidiary, in each case, whether by merger, consolidation or otherwise.

“Springing Covenant Trigger Date” means any date on which Parent or any Subsidiary enters into a Permitted XHANCE Exclusive US License.

“Springing Covenant Compliance Period” means that period commencing on and including a Springing Covenant Trigger Date and ending on the date all Permitted XHANCE Exclusive US Licenses have been terminated.

“Subsidiary” of a Person means a corporation, partnership, joint venture, limited liability company or other business entity of which a majority of the shares of Voting Stock is at the time beneficially owned, or the management of which is otherwise controlled, directly, or indirectly through one or more intermediaries, or both, by such Person. Unless otherwise specified, all references herein to a “Subsidiary” or to “Subsidiaries” shall refer to a Subsidiary or Subsidiaries of Parent.

“Swap Contract” means (a) any and all rate swap transactions, basis swaps, credit derivative transactions, forward rate transactions, commodity swaps, commodity options, forward commodity contracts, equity or equity index swaps or options, bond or bond price or bond index swaps or options or forward bond or forward bond price or forward bond index transactions, interest rate options, forward foreign exchange transactions, cap transactions, floor transactions, collar transactions, currency swap transactions, cross-currency rate swap transactions, currency options, spot contracts, or any other similar transactions or any combination of any of the foregoing (including any options to enter into any of the foregoing), whether or not any such transaction is governed by or subject to any master agreement, and (b) any and all transactions of any kind, and the related confirmations, which are subject to the terms and conditions of, or governed by, any form of master agreement published by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement (any such master agreement, together with any related schedules, a “Master Agreement”), including any such obligations or liabilities under any Master Agreement.

“Swap Termination Value” means, in respect of any one or more Swap Contracts, after taking into account the effect of any legally enforceable netting agreement relating to such Swap Contracts, (a) for any date on or after the date such Swap Contracts have been closed out and termination value(s) determined in accordance therewith, such termination value(s) and (b) for any date prior to the date referenced in clause (a), the amount(s) determined as the mark-to-market value(s) for such Swap Contracts, as determined based upon one or more mid-market or other readily available quotations provided by any recognized dealer in such Swap Contracts (which may include a Purchaser or any Affiliate of a Purchaser).

“Synthetic Lease” means any synthetic lease, tax retention operating lease, off-balance sheet loan or similar off-balance sheet financing arrangement whereby the arrangement is considered borrowed money indebtedness for tax purposes but is classified as an operating lease or does not otherwise appear on a balance sheet under GAAP.

“Taxes” has the meaning set forth in Section 3.01(a).

“Test Date” means, with respect to the Delayed Draw Note Closing Date, the last day of the most recent fiscal quarter ending prior to such Delayed Draw Note Closing Date. It is understood and agreed the Test Date shall be either March 31, 2019 or June 30, 2019.

“Third Party” means any entity other than Parent, any Subsidiary thereof or any Affiliate thereof.

“Three Month Treasury Rate” means, as of any date of determination, the weekly average yield as of such date of determination of actually traded United States Treasury securities adjusted to a constant maturity of three (3) months (as compiled and published in the most recent Federal Reserve Statistical Release H.15(519) that has become publically available at least two (2) Business Days prior to such date of determination (or, if such Federal Reserve Statistical Release H.15(519) is no longer published, any publically available source of similar market data)).

“Threshold Amount” means \$2,000,000.

“Trademark License” means any agreement, written or oral, providing for the grant of any right to use any Trademark.

“Trademarks” means all statutory and common-law trademarks, trade names, corporate names, company names, business names, fictitious business names, trade styles, service marks, logos and other source or business identifiers, and the goodwill associated therewith, now existing or hereafter adopted or acquired, all registrations and recordings thereof, and all applications to register in connection therewith, under the laws of the United States, any state thereof or any other country or any political subdivision thereof, or otherwise, for the full term and all renewals thereof, which are owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to, and which are used by Parent or any other Person to manufacture, develop, import, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Product.

“Trade Secrets” means any data or information that is not commonly known by or available to the public, and which (a) derives economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other Persons who can obtain economic value from its disclosure or use, (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy, and (c) which are owned by Parent or any Subsidiary or which Parent or any Subsidiary is licensed, authorized or otherwise granted rights under or to.

“Trading Day” means any day on which the shares of common stock of the Parent are traded for at least six hours on the Current Market.

“Treasury Regulations” means the regulations, including temporary regulations, promulgated by the United States Treasury Department under the Internal Revenue Code, as such regulations may be amended from time to time (including the corresponding provisions of any future regulations).

“Uniform Commercial Code” or “UCC” means the Uniform Commercial Code as in effect in the State of New York; provided that, if perfection or the effect of perfection or non-perfection or the priority of any security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of New York, “Uniform Commercial Code” or “UCC” means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions hereof or of the other Note Documents relating to such perfection, effect of perfection or non-perfection or priority.

“United States” and “U.S.” mean the United States of America.

“Upfront Fee” has the meaning set forth in Section 2.10(a).

“US Notes Guarantor” means Parent and each Domestic Subsidiary of Parent (other than the US Issuer, any Excluded Subsidiary, any Immaterial Subsidiary and any Foreign Subsidiary Holding Company), together with each other Person that joins as a US Notes Guarantor pursuant to Section 7.12.

“U.S. Person” means a “United States Person” within the meaning of Section 7701(a)(30) of the Internal Revenue Code.

“Voting Stock” means, with respect to any Person, Equity Interests issued by such Person the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of directors (or persons performing similar functions) of such Person, even though the right so to vote has been suspended by the happening of such a contingency.

“Websites” means all websites that Parent or any Subsidiary shall operate, manage or control through a Domain Name, whether on an exclusive basis or a nonexclusive basis, including, without limitations, all content, elements, data, information, materials, hypertext markup language (HTML), software and code, works of authorship, textual works, visual works, aural works, audiovisual works and functionality embodied in, published or available through each such website and all IP Rights in each of the foregoing.

“Website Agreements” means all agreements between Parent and/or any Subsidiary and any other Person pursuant to which such Person provides any services relating to the hosting, design, operation, management or maintenance of any Website, including without limitation, all agreements with any Person providing website hosting, database management or maintenance or disaster recovery services to Parent and/or any Subsidiary and all agreements with any domain name registrar, as all such agreements may be amended, supplemented or otherwise modified from time to time.

“Wholly-Owned Subsidiary” means any Person 100% of whose Equity Interests are at the time owned by Parent directly or indirectly through other Persons 100% of whose Equity Interests are at the time owned, directly or indirectly, by Parent.

“Withholding Agent” means any Note Party, and any other Person required by applicable Law to withhold or deduct amounts from a payment made by or on account of any obligation of any Note Party under any Note Document.

“Work” means any work or subject matter that is subject to protection pursuant to Title 17 of the United States Code.

“Write-Down and Conversion Powers” means, with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule.

“XHANCE” means XHANCE (fluticasone propionate) nasal spray 93, mcg.

#### 1.02 Other Interpretive Provisions.

With reference to this Agreement and each other Note Document, unless otherwise specified herein or in such other Note Document:

(a) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding

masculine, feminine and neuter forms. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” The word “will” shall be construed to have the same meaning and effect as the word “shall.” Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document (including the Note Documents and any Organization Document) shall be construed as referring to such agreement, instrument or other document as from time to time amended, modified, extended, restated, replaced or supplemented from time to time (subject to any restrictions set forth herein or in any other Note Document), (ii) any reference herein to any Person shall be construed to include such Person’s successors and assigns, (iii) the words “hereto,” “herein,” “hereof” and “hereunder,” and words of similar import when used in any Note Document, shall be construed to refer to such Note Document in its entirety and not to any particular provision thereof, (iv) all references in an Note Document to Articles, Sections, Preliminary Statements, Exhibits and Schedules shall be construed to refer to Articles and Sections of, and Preliminary Statements, Exhibits and Schedules to, the Note Document in which such references appear, (v) any reference to any law shall include all statutory and regulatory provisions consolidating, amending, replacing or interpreting such law and any reference to any law or regulation shall, unless otherwise specified, refer to such law or regulation as amended, modified, extended, restated, replaced or supplemented from time to time, and (vi) the words “asset” and “property” shall be construed to have the same meaning and effect and to refer to any and all real and personal property and tangible and intangible assets and properties, including cash, securities, accounts, contract rights and IP Rights.

(b) In the computation of periods of time from a specified date to a later specified date, the word “from” means “from and including;” the words “to” and “until” each mean “to but excluding;” and the word “through” means “to and including.”

(c) Section headings herein and in the other Note Documents are included for convenience of reference only and shall not affect the interpretation of this Agreement or any other Note Document.

### 1.03 Accounting Terms.

(a) Generally. Except as otherwise specifically prescribed herein, all accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data (including financial ratios and other financial calculations) required to be submitted pursuant to this Agreement shall be prepared in conformity with, GAAP applied on a consistent basis, as in effect from time to time, applied in a manner consistent with that used in preparing the Audited Financial Statements, except as otherwise specifically prescribed herein; provided, however, that, calculations of Attributable Indebtedness under any Synthetic Lease or the implied interest component of any Synthetic Lease shall be made by Parent in accordance with accepted financial practice and consistent with the terms of such Synthetic Lease. Notwithstanding the foregoing, for purposes of determining compliance with any covenant contained herein, Indebtedness of Parent and its Subsidiaries shall be deemed to be carried at 100% of the outstanding principal amount thereof, and the effects of FASB ASC 825 and FASB ASC 470-20 on financial liabilities shall be disregarded.

(b) Changes in GAAP. If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Note Document, and either Parent or the Required Purchasers shall so request, the Collateral Agent, the Purchasers and Issuers shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in

GAAP (subject to the approval of the Required Purchasers); provided, that, until so amended, (i) such requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) Parent shall provide to the Purchasers financial statements and other documents required under this Agreement or as requested hereunder setting forth a reconciliation between calculations of such requirement made before and after giving effect to such change in GAAP. Without limiting the foregoing, leases shall continue to be classified and accounted for on a basis consistent with that reflected in the Audited Financial Statements for all purposes of this Agreement, notwithstanding any change in GAAP relating thereto or the application thereof, unless the parties hereto shall enter into a mutually acceptable amendment addressing such changes, as provided for above.

(c) Pro Forma Calculations. Notwithstanding anything to the contrary contained herein, all calculations of Consolidated Revenues (General) and Consolidated Revenues (Product) for purposes of Sections 7.02(a) and 8.16(b) shall be made on a Pro Forma Basis with respect to all Specified Transactions occurring during the applicable four quarter period to which such calculation relates.

#### 1.04 Times of Day.

Unless otherwise specified, all references herein to times of day shall be references to Eastern time (daylight or standard, as applicable).

#### 1.05 Currency Generally.

For purposes of determining compliance with Article VIII with respect to the amount of any Indebtedness or Investment in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred solely as a result of changes in rates of currency exchange occurring after the time such Indebtedness or Investment is incurred, made or acquired (so long as such Indebtedness or Investment, at the time incurred, made or acquired, was permitted hereunder).

## ARTICLE II

### THE NOTES

#### 2.01 Authorization and Issuance of Notes.

(a) Initial Notes. The Norwegian Issuer has duly authorized the issuance, sale and delivery of its Senior Secured Notes due 2023 in the aggregate principal amount of \$50,000,000, to be dated the Closing Date, to mature on the Maturity Date, and to be substantially in the form of Exhibit A-1 hereto. The US Issuer has duly authorized the issuance, sale and delivery of its Senior Secured Notes due 2023 in the aggregate principal amount of \$25,000,000, to be dated the Closing Date, to mature on the Maturity Date, and to be substantially in the form of Exhibit A-1 hereto. All such notes originally issued pursuant to this paragraph (a), or delivered in substitution or exchange for any thereof, being collectively called the "Initial Notes" and individually an "Initial Note". Notwithstanding anything to the contrary set forth herein, the Initial Notes will, upon the occurrence of the Closing Date, be immediately separable and transferable in accordance with the terms hereof.

(b) Delayed Draw Notes. The US Issuer has duly authorized the issuance, sale and delivery, on a one-time basis, of additional Senior Secured Notes due 2023 in the aggregate principal amount of \$25,000,000, to be dated the Delayed Draw Note Closing Date, to mature on the Maturity Date, and to be substantially in the form of Exhibit A-2 hereto (all such notes originally issued pursuant to this paragraph (b), or delivered in substitution or exchange for any thereof, being collectively called the “Delayed Draw Notes” and individually an “Delayed Draw Note”). Notwithstanding anything to the contrary set forth herein, the Delayed Draw Notes, upon their issuance, will be immediately separable and transferable in accordance with the terms hereof.

## 2.02 Commitments to Purchase Delayed Draw Notes.

(a) Subject to and upon the terms and conditions set forth herein, each Purchaser severally (and not jointly) agrees on the Delayed Draw Note Closing Date to purchase Delayed Draw Notes (such Delayed Draw Notes to have a purchase price in the aggregate not greater than such Purchaser’s undrawn Delayed Draw Note Commitment at such time) from the US Issuer at a purchase price equal to 100% of the aggregate principal amount of the Delayed Draw Notes so purchased, *provided* that under no circumstances shall the aggregate purchase price of the Delayed Draw Notes required to be purchased by any Purchaser, together with the aggregate purchase price of any Delayed Draw Notes previously purchased by such Purchaser, exceed the amount of such Purchaser’s Delayed Draw Note Commitment at such time. Once drawn, no Delayed Draw Note Commitment may be redrawn, whether or not the Delayed Draw Notes related thereto have been repaid or prepaid. Upon the expiration of the Availability Period, the Delayed Draw Note Commitments shall automatically, without action by any Issuer or any Purchaser, be reduced to zero.

(b) The aggregate principal amount of Delayed Draw Notes, if any, purchased by the Purchasers hereunder shall be equal to \$25,000,000.

(c) All issuances of Delayed Draw Notes under this Agreement shall be made to the Purchasers *pro rata* on the basis of their Delayed Draw Note Commitments. It is understood that no Purchaser shall be responsible for any default by any other Purchaser of its obligation to purchase Delayed Draw Notes hereunder and that each Purchaser shall be obligated to purchase the Delayed Draw Notes required to be purchased by it hereunder regardless of the failure of any other Purchaser to fulfill its obligations under this Agreement.

## 2.03 Issuance and Sale of Securities.

(a) On the Closing Date. Subject to the terms and conditions set forth in this Agreement, on the Closing Date each of the Norwegian Issuer and the US Issuer will issue and sell the Initial Notes to be issued and sold by each of them hereunder to each of the Purchasers, severally and not jointly, and each of the Purchasers, severally and not jointly, shall purchase from the Norwegian Issuer and the US Issuer the Initial Notes to be purchased by each of them, in each case in amounts equal, with respect to each Issuer and each Purchaser, to the respective amounts set forth on Schedule II hereto opposite such Issuer’s and such Purchaser’s name, and in each case at the purchase prices set forth on Schedule II hereto.

(b) On the Delayed Draw Note Closing Date. Subject to the terms and conditions set forth in this Agreement, on a single Delayed Draw Note Closing Date, the US Issuer shall issue and sell Delayed Draw Notes in the aggregate amount specified in the Notice of Issuance (in compliance with Section 2.06) to each of the Purchasers, severally and not jointly, allocated on a pro rata basis in accordance with their respective Delayed Draw Note Commitments, and each of the Purchasers,

severally and not jointly, shall on such date purchase (for an aggregate purchase not greater than such Purchaser's undrawn Delayed Draw Note Commitment) such Delayed Draw Notes from the US Issuer on the Delayed Draw Note Closing Date specified in the Notice of Issuance, in each case at an aggregate purchase price equal to 100% of the aggregate principal amount of such Delayed Draw Notes, *provided* that under no circumstances shall the aggregate principal amount of Delayed Draw Notes so purchased by any Purchaser exceed the amount of such Purchaser's Delayed Draw Note Commitment at such time.

(c) The Issuers and Purchasers hereby acknowledge and agree that (i) the issue price (within the meaning of Section 1273(b) of the Internal Revenue Code) of each Note is determined pursuant to Section 1272-1275 of the Code and the Treasury Regulations thereunder and (ii) for United States federal income tax purposes, the issue price of each Initial Note issued by the Norwegian Issuer within the meaning of Section 1273(b) of the Internal Revenue Code, which issue price was determined pursuant to Section 1.1273-2(h)(1) of the Treasury Regulations, is equal to \$49,333,333.33 and the issue price of each Initial Note issued by the US Issuer within the meaning of Section 1273(b) of the Internal Revenue Code, which issue price was determined pursuant to Section 1.1273-2(h)(1) of the Treasury Regulations, is equal to \$24,666,666.67. The parties hereto agree to report all income tax matters with respect to the issuance of the Notes consistent with the provisions of this Section 2.03(c) unless otherwise required due to a change in applicable Law.

2.04 Notes. The Notes issued pursuant hereto shall evidence the principal amounts of all Notes sold hereunder, and the date and principal amount of each purchase and the sale of the Notes to the Purchasers by each of the Issuers, as well as each payment or prepayment made on account of the principal thereof, and, in each case, the resulting aggregate unpaid principal balance thereof, shall be recorded by each Purchaser on its books; *provided*, that failure by any Purchaser to make any such recordation shall not affect the obligations of the Issuers hereunder or under any Note. Each such recordation by a Purchaser shall be conclusive and binding for all purposes in the absence of manifest error.

2.05 The Closing Date; Delayed Draw Note Closing Date.

(a) Closing Date. The sale and delivery of the Initial Notes to be issued pursuant to Section 2.01(a) shall take place at the offices of Covington & Burling LLP, 620 Eighth Avenue, New York, NY 10018, at 10:00 A.M. New York City time, on the Closing Date (or such other time and place as the parties shall agree). On the Closing Date, subject to satisfaction of the conditions set forth herein, each Issuer will deliver to each Purchaser an Initial Note or Initial Notes registered in such Purchaser's name or in the name of its nominee, such Initial Notes to be duly executed and dated the Closing Date, in the aggregate principal amount of the Initial Notes allocated to such Issuer and such Purchaser as shown on Schedule II hereto, such Initial Notes to be in such denominations as such Purchaser may specify by two Business Days' prior written notice to the relevant Issuer (or, in the absence of such notice, one Initial Note registered in such Purchaser's name in such aggregate principal amount), against such Purchaser's delivery to the relevant Issuer of immediately available funds in the amount of such Purchaser's portion of the aggregate purchase price of the Initial Notes so purchased; and

(b) Delayed Draw Note Closing Date. The sale and delivery of any Delayed Draw Notes to be issued pursuant to Section 2.01(b) shall take place at the offices of Covington & Burling LLP, 620 Eighth Avenue, New York, NY 10018, at 10:00 A.M., New York City time on the Delayed Draw Note Closing Date specified for such issuance in the Notice of Issuance (or such other time and place as the parties shall agree). On the Delayed Draw Note Closing Date, subject to satisfaction



of the conditions set forth herein, the US Issuer will deliver to each Purchaser holding an undrawn Delayed Draw Note Commitment an Delayed Draw Note or Delayed Draw Notes registered in such Purchaser's name or in the name of its nominee, such Delayed Draw Notes to be duly executed and dated the Delayed Draw Note Closing Date, in an aggregate principal amount equal to the amount of Delayed Draw Notes allocated to such Purchaser on a pro rata basis in accordance with its respective Delayed Draw Note Commitment (which in no event shall exceed the amount of such Purchaser's Delayed Draw Note Commitment at such time), such Delayed Draw Notes to be in such denominations as such Purchaser may specify by two Business Days' prior written notice to the US Issuer (or, in the absence of such notice, one Delayed Draw Note registered in such Purchaser's name in such aggregate principal amount), against such Purchaser's delivery to the US Issuer of immediately available funds in an amount equal to the aggregate principal amount of Delayed Draw Notes so purchased by such Purchaser.

2.06 Notice of Issuance. If the US Issuer determines, in its sole discretion, to request the issuance of Delayed Draw Notes, the US Issuer shall deliver to the Purchasers an irrevocable Notice of Issuance with respect to such proposed issuance, which shall be for the entire amount of the Delayed Draw Notes and must be given (a) not earlier than the beginning of the Availability Period and (b) not later than 11:00 a.m. at least 10 Business Days in advance of the requested Delayed Draw Note Closing Date and in any event not later than July 31, 2019.

#### 2.07 Prepayments.

(a) Voluntary Prepayments. Subject to the payment of any prepayment premium as required under Section 2.07(d), the exit fee required under Section 2.10(b) and any other fees or amounts payable hereunder at such time, the US Issuer may, upon notice to the Purchasers, voluntarily prepay the Initial Notes issued by it and/or the Delayed Draw Notes, in each case, in whole or in part, and the Norwegian Issuer may, upon notice to the Purchasers, voluntarily prepay the Initial Notes issued by it, in whole or in part; provided, that, (i) such notice must be received not later than 11:00 a.m. (Eastern time) three (3) Business Days prior to the date of prepayment and (ii) any such prepayment shall be in a principal amount of \$5,000,000 or a whole multiple of \$1,000,000 in excess thereof (or, if less, the entire principal amount thereof then outstanding). Each such notice shall specify the date and amount of such prepayment. The relevant Issuer shall make such prepayment and the payment amount specified in such notice shall be due and payable on the date specified therein; provided that if such a notice expressly states that it is conditioned upon the effectiveness of other credit facilities or the closing of a specified transaction, such notice may be revoked by the relevant Issuer (by written notice to the Purchasers on or prior to the specified effective date) if such condition is not satisfied. Any prepayment pursuant to this Section 2.07(a) shall be accompanied by (x) all accrued interest on the principal amount of the Notes prepaid, (y) the prepayment premium required under Section 2.07(d) and the exit fee required under Section 2.10(b) in respect of the Notes so prepaid and (z) all fees, costs, expenses, indemnities and other amounts due and payable hereunder at the time of prepayment. Each such prepayment shall be applied first to all costs, expenses, indemnities and other amounts due and payable hereunder, then to payment of default interest, if any, then to payment of prepayment premium required by Section 2.07(d) and the exit fee as required under Section 2.10(b), then to payment of accrued interest and thereafter to the payment of principal.

#### (b) Mandatory Prepayments of Notes.

(i) Dispositions and Involuntary Dispositions. The Issuers shall promptly (and, in any event, within three (3) Business Days) upon the receipt by any Note Party or any

Subsidiary of the Net Cash Proceeds of any Dispositions or Involuntary Dispositions (other than proceeds of business interruption insurance), prepay the Notes in an aggregate amount equal to 100% of such Net Cash Proceeds, in each case, other than (A) so long as no Default or Event of Default exists at the time prepayment would otherwise be required pursuant to this Section 2.07(b)(i), such Net Cash Proceeds of Dispositions and Involuntary Dispositions not exceeding \$1,000,000 in the aggregate during any fiscal year, and (B) such Net Cash Proceeds are reinvested in Eligible Assets within 180 days of the date of the receipt of such Net Cash Proceeds (or committed to be reinvested pursuant to a legally binding commitment within such 180-day period and are so reinvested within 90 days thereafter). Any prepayment pursuant to this clause (i) shall be applied as set forth in clause (iv) below.

(ii) Extraordinary Receipts. The Issuers shall promptly (and, in any event, within three (3) Business Days) upon the receipt by any Note Party or any Subsidiary of the Net Cash Proceeds of any Extraordinary Receipt, prepay the Notes in an aggregate amount equal to 100% of such Net Cash Proceeds, in each case other than (A) so long as no Default or Event of Default exists at the time prepayment would otherwise be required pursuant to this Section 2.07(b)(ii), such Net Cash Proceeds of Extraordinary Receipts not exceeding \$1,000,000 in the aggregate during any fiscal year, and (B) such Net Cash Proceeds of any Extraordinary Receipt that are reinvested in Eligible Assets or in the case of any indemnification payment, used to pay any expense or liability incurred in connection therewith, in each case, within 180 days of the date of the receipt of such Net Cash Proceeds (or committed to be reinvested pursuant to a legally binding commitment within such 180-day period and are so reinvested within 90 days thereafter). Any prepayment pursuant to this clause (ii) shall be applied as set forth in clause (iv) below.

(iii) Debt Issuance. The Issuers shall promptly (and, in any event, within three (3) Business Days) upon the receipt by any Note Party or any Subsidiary of the Net Cash Proceeds of any Debt Issuance, prepay the Notes in an aggregate amount equal to 100% of such Net Cash Proceeds. Any prepayment pursuant to this clause (iii) shall be applied as set forth in clause (iv) below.

(iv) Application of Mandatory Prepayments. All payments under this Section 2.07(b) shall be applied first to all fees (other than, for the avoidance of doubt, prepayment premium required by Section 2.07(d) and the exit fees required by Section 2.10(b)), costs, expenses, indemnities and other amounts due and payable hereunder, then proportionately (based on the relation of such amounts to the total amount of the relevant payment under this Section 2.07(b)) to the payment or prepayment (as applicable) of the following amounts: default interest, if any, prepayment premium required by Section 2.07(d) and the exit fee required by Section 2.10(b), accrued and unpaid interest and principal; provided, however, in connection with any mandatory repayment from Net Cash Proceeds of any property or Extraordinary Receipts of a Foreign Subsidiary that is not a US Notes Guarantor, the Norwegian Issuer may, notwithstanding Section 2.12(a), first apply such proceeds to repay the Initial Notes issued by it if an adverse tax consequence would otherwise result.

(c) Change of Control. Upon the occurrence of a Change of Control, the Issuers shall, unless otherwise directed by the Required Purchasers, prepay all of the Notes together with all accrued and unpaid interest thereon plus the prepayment premium required by Section 2.07(d) and the exit fee required by Section 2.10(b) plus all other Obligations then due and owing. In connection with any prepayment pursuant to this Section 2.07(c), the Issuers shall comply with the requirements

of Rule 14e-1 under the Exchange Act and any other securities laws and regulations to the extent such laws and regulations are applicable in connection with such prepayment.

(d) Prepayment Premiums. If all or any portion of the Notes is prepaid, or required to be prepaid, pursuant to this Section 2.07, Article IX or otherwise, then, in all cases, the Issuers shall pay to the Purchasers, on the date on which such prepayment is prepaid or required to be prepaid, in addition to the other Obligations so prepaid or required to be prepaid, a prepayment premium equal to: (i) with respect to any prepayment paid or required to be paid before the second anniversary of the Closing Date (with respect to any Initial Notes prepaid or required to be prepaid) or the second anniversary of the Delayed Draw Note Closing Date (with respect to any Delayed Draw Notes prepaid or required to be prepaid), the Make-Whole Amount with respect to such prepayment, (ii) with respect to any prepayment paid or required to be paid on or after the second anniversary, but before the third anniversary, in each case of the Closing Date (with respect to any Initial Notes prepaid or required to be prepaid) or the Delayed Draw Note Closing Date (with respect to any Delayed Draw Notes prepaid or required to be prepaid), 2.00% of the principal amount of the Notes prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid on or after the third anniversary, but before the fourth anniversary, in each case of the Closing Date (with respect to any Initial Notes prepaid or required to be prepaid) or the Delayed Draw Note Closing Date (with respect to any Delayed Draw Notes prepaid or required to be prepaid), 1.00% of the principal amount of the Notes prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, as applicable, 0.00% of the principal amount of the Notes prepaid or required to be prepaid.

## 2.08 Repayment of Notes; Voluntary Termination of Delayed Draw Note Commitments.

The Issuers shall repay the outstanding principal amount of the Notes, together with all accrued and unpaid interest thereon and all other outstanding Obligations, on the Maturity Date. The Issuers may, upon written notice to the Purchasers, at any time prior to the end of the Availability Period, terminate in full the Delayed Draw Commitments; provided, that: any such notice shall be received by the Purchasers not later than 11:00 a.m. one (1) Business Day prior to the date of termination; provided, further, that the effectiveness of such notice may be expressly conditioned upon the effectiveness of other credit facilities or the closing of a specified transaction, and such notice may be revoked by the Issuers (by written notice to the Purchasers on or prior to the specified effective date) if such condition is not satisfied.

## 2.09 Interest.

(a) Pre-Default Rate. Subject to the provisions of subsection (b) below, during any Interest Period the Notes shall bear interest during such Interest Period on the outstanding principal amount thereof at a rate per annum equal to LIBOR plus nine percent (9.00%) per annum. The interest rate shall be recalculated and, if necessary, adjusted for each Interest Period, in each case pursuant to the terms hereof.

### (b) Default Rate.

(i) Upon the occurrence of and during the continuance of any Event of Default under Section 9.01(a) (without regard to any applicable grace periods) or Section 9.01(f), during any Interest Period all outstanding Obligations shall thereafter bear interest during such Interest Period at an interest rate per annum at all times equal to the Default Rate to the fullest extent permitted by applicable Laws,

(ii) upon the request of the Required Purchasers, while any Event of Default exists, the Issuers shall following such request pay interest on all outstanding Notes at an interest rate per annum equal to the Default Rate to the fullest extent permitted by applicable Laws, and

(iii) accrued and unpaid interest on past due amounts (including interest on past due interest) shall be due and payable in cash on demand. The interest rate shall be recalculated and, if necessary, adjusted for each Interest Period, in each case pursuant to the terms hereof.

(c) Interest Generally. Interest on the Notes shall be due and payable in cash in arrears on each Interest Payment Date and at such other times as may be specified herein. Interest hereunder shall be due and payable in accordance with the terms hereof before and after judgment, and before and after the commencement of any proceeding under any Debtor Relief Law.

#### 2.10 Upfront Fee and Exit Fee.

(a) Upfront Fee. Each Issuer and each Purchaser agrees that on the Closing Date, the Issuers shall pay an upfront fee in an aggregate amount equal to \$1,000,000 (the “Upfront Fee”) to Athyrium Capital Management LP, for its own account. Each Issuer agrees that the Upfront Fee shall be (i) paid in Dollars, (ii) fully earned upon the Closing Date, (iii) nonrefundable and (iv) in addition to, and not creditable against, any other fee, cost or expense payable under the Note Documents. For the avoidance of doubt, the Upfront Fee shall be paid on a *pro rata* basis by the US Issuer and the Norwegian Issuer in accordance with the aggregate principal amount of the Notes issued by each Issuer on the Closing Date.

(b) Exit Fee. Upon the prepayment or repayment of all or any portion of the Notes (or upon the date any such prepayment or repayment is required to be paid), whether pursuant to Section 2.07, Section 2.08 or Section 9.02, or otherwise, the Issuers shall pay to the Purchasers on the date on which such prepayment or repayment is paid or required to be paid, as the case may be, in addition to the other Obligations so prepaid, repaid or required to be prepaid or repaid, an exit fee in an amount equal to two percent (2%) of the principal amount of the Notes prepaid, repaid or required to be prepaid or repaid, as the case may be, on such date.

#### 2.11 Computation of Interest.

All computations of interest shall be made on the basis of a 360-day year and actual days elapsed. Interest shall accrue on the Notes for the day on which the Notes are issued, and shall not accrue on the Notes, or any portion thereof, for the day on which the Notes or such portion is paid.

#### 2.12 Payments Generally.

(a) General. All payments to be made by the Issuers shall be made free and clear of and without condition or deduction for any counterclaim, defense, recoupment or setoff. Subject to Section 9.03, all payments of principal, interest, prepayment premiums and fees on the Notes and all other Obligations payable by any Note Party under the Note Documents shall be due, without any presentment thereof, directly to the Purchasers, at such office or bank account as may be specified by each Purchaser from time to time by written notice to the Issuers, with the Norwegian Notes Obligations and the US Notes Obligations paid on a *pro rata* basis (subject to the proviso at the end of Section 2.07(b)(iv)); provided, that, if at the time of any such payment a Purchaser is a Defaulting Purchaser, such Defaulting Purchaser’s *pro rata* share of such payment shall be made directly to the

Collateral Agent. The Note Parties will make such payments in Dollars, in immediately available funds not later than 2:00 p.m. on the date due, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Purchasers may from time to time direct in writing. All payments received by the Purchasers after 2:00 p.m. shall be deemed received on the next succeeding Business Day and any applicable interest or fee shall continue to accrue. If any payment to be made by an Issuer shall come due on a day other than a Business Day, payment shall be made on the next following Business Day, and such extension of time shall be reflected in computing interest.

(b) Obligations of Purchasers are Several. The obligations of the Purchasers hereunder to purchase the Notes are several and not joint. The failure of any Purchaser to purchase the aggregate principal amount of the Initial Notes or Delayed Draw Notes to be purchased by it on any date required hereunder shall not relieve any other Purchaser of its corresponding obligation to do so on such date, and no Purchaser shall be responsible for the failure of any other Purchaser to purchase the aggregate principal amount of the Initial Notes or Delayed Draw Notes to be purchased by it.

(c) Funding Source. Nothing herein shall be deemed to obligate any Purchaser to obtain the funds to purchase any Note in any particular place or manner or to constitute a representation by any Purchaser that it has obtained or will obtain the funds to purchase any Note in any particular place or manner.

2.13 No Purchase of Notes. No Note Party or any of their respective Affiliates may acquire directly or indirectly any of the outstanding Notes, without the prior written consent of the Required Purchasers.

2.14 Sharing of Payments by Purchasers.

If any Purchaser shall, by exercising any right of setoff or otherwise, obtain payment in respect of any principal of or interest on its portion of any Note or prepayment premium or exit fee in connection therewith resulting in such Purchaser's receiving payment of a proportion of the aggregate amount of the Note and accrued interest thereon and prepayment premium or exit fees in connection therewith greater than its *pro rata share* thereof as provided herein, then such Purchaser shall (a) notify the other Purchasers of such fact and (b) purchase for cash at face value, but without recourse, ratably from each of the other Purchasers such amount of the Notes held by each such other Purchaser (or interest therein), so that the benefit of all such payments shall be shared by the Purchasers ratably in accordance with the aggregate amount of principal of, accrued interest on and prepayment premium or exit fees in connection with their respective portions of the Notes and other amounts owing them; provided, that:

(i) if any such purchase is made by any Purchaser, and if such excess payment or part thereof is thereafter recovered from such purchasing Purchaser, the related purchases from the other Purchasers shall be rescinded ratably and the purchase price restored as to the portion of such excess payment so recovered, but without interest; and

(ii) the provisions of this Section 2.14 shall not be construed to apply to (x) any payment made by or on behalf of the Issuers pursuant to and in accordance with the express terms of this Agreement (including the application of funds arising from the existence of a Defaulting Purchaser) or (y) any payment obtained by a Purchaser as consideration for the assignment of any of its portion of the Notes to any assignee, other than an assignment to Parent or any Subsidiary (as to which the provisions of this Section shall apply).

## 2.15 Defaulting Purchasers.

(a) Adjustments. Notwithstanding anything to the contrary contained in this Agreement, if any Purchaser becomes a Defaulting Purchaser, then, until such time as that Purchaser is no longer a Defaulting Purchaser, to the extent permitted by applicable Law:

(i) Waivers and Amendment. The Defaulting Purchaser's right to approve or disapprove any amendment, waiver or consent with respect to this Agreement shall be restricted as set forth in Section 12.01.

(ii) Reallocation of Payments. Any payment of principal, interest, fees or other amount received for the account of that Defaulting Purchaser (whether voluntary or mandatory, at maturity, pursuant to Article IX or otherwise, and including any amounts made available to the Collateral Agent by that Defaulting Purchaser pursuant to Section 12.08), shall be applied at such time or times as may be determined by the Collateral Agent as follows: first, to the payment of any amounts owing by that Defaulting Purchaser to the Collateral Agent hereunder; second, as the Issuers may request (so long as no Default or Event of Default exists), to the purchase of any Notes in respect of which that Defaulting Purchaser has failed to fund its portion thereof as required by this Agreement, as determined by the Collateral Agent; third, if so determined by the Collateral Agent, to be held in a non-interest bearing deposit account and released in order to satisfy obligations of that Defaulting Purchaser to purchase the Notes under this Agreement; fourth, to the payment of any amounts owing to the Purchasers as a result of any judgment of a court of competent jurisdiction obtained by any Purchaser against that Defaulting Purchaser as a result of that Defaulting Purchaser's breach of its obligations under this Agreement; fifth, so long as no Default or Event of Default exists, to the payment of any amounts owing to any Issuer as a result of any judgment of a court of competent jurisdiction obtained by such Issuer against that Defaulting Purchaser as a result of that Defaulting Purchaser's breach of its obligations under this Agreement; and sixth, to that Defaulting Purchaser or as otherwise directed by a court of competent jurisdiction; provided, that, if (x) such payment is a payment of the principal amount of any Notes in respect of which that Defaulting Purchaser has not fully funded its appropriate share and (y) such Notes were purchased at a time when the conditions set forth in Section 5.02 were satisfied or waived, such payment shall be applied solely to pay the Notes of all non-Defaulting Purchasers on a *pro rata* basis prior to being applied to the payment of any Notes of that Defaulting Purchaser. Any payments, prepayments or other amounts paid or payable to a Defaulting Purchaser that are applied (or held) to pay amounts owed by a Defaulting Purchaser pursuant to this Section 2.15(a)(ii) shall be deemed paid to and redirected by that Defaulting Purchaser, and each Purchaser irrevocably consents hereto.

(b) Defaulting Purchaser Cure. If a Defaulting Purchaser is no longer a Defaulting Purchaser pursuant to the definition thereof, or the Issuers and the Collateral Agent agree in writing in their sole discretion that a Defaulting Purchaser should no longer be deemed to be a Defaulting Purchaser, the Collateral Agent will so notify the parties hereto, whereupon as of the effective date specified in such notice and subject to any conditions set forth therein, that Purchaser will cease to be a Defaulting Purchaser; provided, that, no adjustments will be made retroactively with respect to fees accrued or payments made by or on behalf of the Issuers while that Purchaser was a Defaulting Purchaser; provided, further, that, except to the extent otherwise expressly agreed by the affected parties, no change hereunder from Defaulting Purchaser to Purchaser will constitute a waiver or

release of any claim of any party hereunder arising from that Purchaser having been a Defaulting Purchaser.

## ARTICLE III

### TAXES

#### 3.01 Taxes.

(a) All payments of principal and interest on the Notes and all other amounts payable hereunder shall be made free and clear of and without deduction for any present or future income, excise, stamp, documentary, property or franchise taxes and other taxes, fees, duties, levies, assessments, withholdings or other charges of any nature whatsoever (including interest and penalties thereon) imposed by any taxing authority, excluding (x) taxes imposed on or measured by net income imposed by the jurisdiction under which a Recipient is organized or in which its principal office or applicable lending office is located, (y) U.S. federal withholding taxes imposed on amounts payable to or for the account of a Recipient with respect to an applicable interest in any Note or Delayed Draw Note Commitment pursuant to a Law in effect on the date on which such Recipient acquires such interest in the Note or Delayed Draw Note Commitment, except in each case to the extent that, pursuant to this Section 3.01, amounts with respect to such taxes were payable by such Recipient's assignor immediately before such Recipient became a party hereto and (z) U.S. federal withholding tax imposed under FATCA (all non-excluded items being called "Taxes"). If any withholding or deduction of any Taxes from any payment by or on account of any obligation of any Note Party hereunder is required in respect of any Taxes pursuant to any applicable Law, then (i) the applicable Withholding Agent shall be entitled to make such withholding or deduction and shall pay directly to the relevant Governmental Authority the full amount required to be so withheld or deducted, (ii) the applicable Withholding Agent shall promptly forward to the Purchasers an official receipt or other documentation satisfactory to the Required Purchasers evidencing such payment to such Governmental Authority and (iii) the sum payable by the applicable Note Party shall be increased by such additional amount or amounts as is necessary to ensure that the net amount actually received by the applicable Recipient will equal the full amount such Recipient would have received had no such withholding or deduction been required.

(b) The Issuers shall indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Taxes with respect to any Note Document or any payment thereunder, ("Indemnified Taxes") (including Indemnified Taxes imposed on or attributable to amounts payable under this Section) payable or paid by such Recipient or required to be withheld or deducted from a payment by such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority.

(c) Each Purchaser that is not a U.S. Person that purports to become an assignee of an interest pursuant to Section 12.06 after the Closing Date (each such Purchaser a "Foreign Purchaser") shall execute and deliver to each Issuer on or prior to the date that such Purchaser becomes a party hereto (and from time to time thereafter upon the reasonable request of the Issuers), one or more (as the Issuers may reasonably request) duly completed and executed copies of Internal Revenue Service Forms W-8ECI, W-8BEN, W-8BEN-E, W-8IMY (as applicable) and other applicable forms, certificates or documents prescribed by the United States Internal Revenue Service or reasonably requested by the Issuers certifying as to such Purchaser's entitlement to any available exemption

from or reduction of withholding or deduction of taxes. Each Purchaser that is a U.S. Person shall execute and deliver to the Issuers on or prior to the date such Purchaser becomes a party hereto (and from time to time thereafter upon the reasonable request of the Issuers), one or more (as the Issuers may reasonably request) duly completed and executed copies of Internal Revenue Service Form W-9 certifying that such Purchaser is not subject to United States backup withholding. The Issuers shall not be required to pay additional amounts to any Purchaser pursuant to this Section 3.01 with respect to taxes attributable to the failure of such Purchaser to comply with this paragraph.

(d) Each Purchaser agrees that if any form or certification it previously delivered pursuant to this Section 3.01 expires or becomes obsolete or inaccurate in any respect, it shall promptly update such form or certification or promptly notify the Issuers of its inability to do so.

(e) If, due to a change in Sections 871(h) or 881(c) of the Internal Revenue Code (or any successor provisions) after the date a Person becomes an Indirect Purchaser under this Agreement, any withholding is required to be made by a Purchaser or any Affiliate thereof to such Indirect Purchaser attributable to payments made by any Note Party hereunder, such Note Party shall pay to such Purchaser such additional amount or amounts as is necessary to ensure that the net amount actually received by any Indirect Purchaser will equal the full amount such Indirect Purchaser would have received had no such withholding or deduction been required; *provided* that in the event additional amounts are due in respect of an Indirect Purchaser, immediately before such Indirect Purchaser transfers a direct or indirect interest in a Purchaser to a transferee and withholding is required to be made by a Purchaser or any Affiliate to such transferee Indirect Purchaser attributable to payments made by any Note Party hereunder, a Note Party shall be required to pay additional amounts pursuant to this Section in an amount not exceeding the additional amounts payable prior to the transfer by the transferor Indirect Purchaser; *provided, further* that no such additional amounts shall be payable by a Note Party to the extent such withholding could have been avoided by any Indirect Purchaser and each entity in the chain of ownership between such Indirect Purchaser and the Purchaser providing Internal Revenue Service Forms W-9, W-8ECI, W-8BEN, W-8BEN-E or W-8IMY (as applicable) or any successor forms thereto, to the Purchaser or other entity in the chain of ownership between such Indirect Purchaser and the Purchaser, as applicable.

### 3.02 Survival.

All of the Note Parties' obligations under this Article III shall survive any transfer of the Notes, the termination of the Delayed Draw Note Commitments, the repayment, satisfaction or discharge of the Obligations hereunder and the resignation or replacement of the Collateral Agent.

## ARTICLE IV

### GUARANTY

#### 4.01 The Guaranty.

Each of the Norwegian Notes Guarantors hereby jointly and severally guarantees to each Purchaser and the Collateral Agent as hereinafter provided, as primary obligor and not as surety, the prompt payment of the Obligations of the Norwegian Issuer and any other Norwegian Notes Guarantor in respect of the Notes issued by the Norwegian Issuer (collectively, the "Norwegian Notes Obligations") in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise) strictly in accordance with the terms thereof. The Norwegian Notes Guarantors hereby further agree that if any of the Norwegian Notes Obligations are not paid in full when due (whether at stated maturity, as a mandatory prepayment, by



acceleration or otherwise), the Norwegian Notes Guarantors will, jointly and severally, promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Norwegian Notes Obligations, the same will be promptly paid in full when due (whether at extended maturity, as a mandatory prepayment, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

Each of the US Notes Guarantors hereby jointly and severally guarantees to each Purchaser and the Collateral Agent as hereinafter provided, as primary obligor and not as surety, the prompt payment of the Obligations of the US Issuer and any other US Notes Guarantors in respect of the Notes issued by the US Issuer (collectively, the “US Notes Obligations”) in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise) strictly in accordance with the terms thereof. The US Notes Guarantors hereby further agree that if any of the US Notes Obligations are not paid in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise), the US Notes Guarantors will, jointly and severally, promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the US Notes Obligations, the same will be promptly paid in full when due (whether at extended maturity, as a mandatory prepayment, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

Notwithstanding any provision to the contrary contained herein or in any other of the Note Documents, the obligations of each Guarantor under this Agreement and the other Note Documents shall be limited to an aggregate amount equal to the largest amount that would not render such obligations subject to avoidance under the Debtor Relief Laws or any comparable provisions of any applicable state or federal law.

#### 4.02 Obligations Unconditional.

The obligations of the Guarantors under Section 4.01 are joint and several, absolute and unconditional, irrespective of the value, genuineness, validity, regularity or enforceability of any of the Note Documents, or any other agreement or instrument referred to therein, or any substitution, release, impairment or exchange of any other guarantee of or security for any of the Obligations, and, to the fullest extent permitted by applicable law, irrespective of any law or regulation or other circumstance whatsoever which might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, it being the intent of this Section 4.02 that the obligations of the Guarantors hereunder shall be absolute and unconditional under any and all circumstances. Each Norwegian Notes Guarantor agrees that such Guarantor shall have no right of subrogation, indemnity, reimbursement or contribution against the Norwegian Issuer or any other Norwegian Notes Guarantor for amounts paid under this Article IV until such time as the Norwegian Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full. Each US Notes Guarantor agrees that such Guarantor shall have no right of subrogation, indemnity, reimbursement or contribution against the US Issuer or any other US Notes Guarantor for amounts paid under this Article IV until such time as the US Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Delayed Draw Note Commitments have expired or terminated. Without limiting the generality of the foregoing, it is agreed that, to the fullest extent permitted by law, the occurrence of any one or more of the following shall not alter or impair the liability of any Guarantor hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to any Guarantor, the time for any performance of or compliance with any of the Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of any of the Note Documents, or any other agreement or instrument referred to in the Note Documents shall be done or omitted;

(c) the maturity of any of the Obligations shall be accelerated, or any of the Obligations shall be modified, supplemented or amended in any respect, or any right under any of the Note Documents, or any other agreement or instrument referred to in the Note Documents shall be waived or any other guarantee of any of the Obligations or any security therefor shall be released, impaired or exchanged in whole or in part or otherwise dealt with;

(d) any Lien granted to, or in favor of, the Collateral Agent or any Purchaser as security for any of the Obligations shall fail to attach or be perfected; or

(e) any of the Obligations shall be determined to be void or voidable (including, without limitation, for the benefit of any creditor of any Guarantor) or shall be subordinated to the claims of any Person (including, without limitation, any creditor of any Guarantor).

With respect to its obligations hereunder, each Guarantor hereby expressly waives diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that the Collateral Agent or any Purchaser exhaust any right, power or remedy or proceed against any Person under any of the Note Documents, or any other agreement or instrument referred to in the Note Documents, or against any other Person under any other guarantee of, or security for, any of the Obligations.

#### 4.03 Reinstatement.

The obligations of the Norwegian Notes Guarantors under this Article IV shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of any Person in respect of the Norwegian Notes Obligations is rescinded or must be otherwise restored by any holder of any of the Norwegian Notes Obligations, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and each Norwegian Notes Guarantor agrees that it will, without duplication of the indemnification obligations of the US Notes Guarantors, indemnify the Collateral Agent and each Purchaser on demand for all reasonable and documented out-of-pocket costs and expenses (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Collateral Agent and the Purchasers (taken as a whole), and, of a single local counsel to the Collateral Agent and the Purchasers (taken as a whole) in each relevant jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs the Issuers of such conflict and thereafter retains its own counsel, of one additional firm of counsel for all such affected parties (taken as a whole))) incurred by the Collateral Agent or such Purchaser in connection with such rescission or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

The obligations of the US Notes Guarantors under this Article IV shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of any Person in respect of the US Notes Obligations is rescinded or must be otherwise restored by any holder of any of the US Notes Obligations, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and each US Notes Guarantor agrees that it will, without duplication of the indemnification obligations of the Norwegian Notes Guarantors, indemnify the Collateral Agent and each Purchaser on demand for all reasonable and documented out-of-pocket costs and expenses (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Collateral Agent and the Purchasers (taken as a whole), and, of a single local counsel to the Collateral Agent and the Purchasers (taken

as a whole) in each relevant jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs the Issuers of such conflict and thereafter retains its own counsel, of one additional firm of counsel for all such affected parties (taken as a whole))) incurred by the Collateral Agent or such Purchaser in connection with such rescission or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

#### 4.04 Certain Additional Waivers.

Each Guarantor agrees that such Guarantor shall have no right of recourse to security for the Obligations, except through the exercise of rights of subrogation pursuant to Section 4.02 and through the exercise of rights of contribution pursuant to Section 4.06.

#### 4.05 Remedies.

The Norwegian Notes Guarantors agree that, to the fullest extent permitted by law, as between the Norwegian Notes Guarantors, on the one hand, and the Collateral Agent and the Purchasers, on the other hand, the Norwegian Notes Obligations may be declared to be forthwith due and payable as provided in Section 9.02 (and shall be deemed to have become automatically due and payable in the circumstances provided in said Section 9.02) for purposes of Section 4.01 notwithstanding any stay, injunction or other prohibition preventing such declaration (or preventing the Norwegian Notes Obligations from becoming automatically due and payable) as against any other Person and that, in the event of such declaration (or the Norwegian Notes Obligations being deemed to have become automatically due and payable), the Norwegian Notes Obligations (whether or not due and payable by any other Person) shall forthwith become due and payable by the Norwegian Notes Guarantors for purposes of Section 4.01. The US Notes Guarantors agree that, to the fullest extent permitted by law, as between the US Notes Guarantors, on the one hand, and the Collateral Agent and the Purchasers, on the other hand, the US Notes Obligations may be declared to be forthwith due and payable as provided in Section 9.02 (and shall be deemed to have become automatically due and payable in the circumstances provided in said Section 9.02) for purposes of Section 4.01 notwithstanding any stay, injunction or other prohibition preventing such declaration (or preventing the US Notes Obligations from becoming automatically due and payable) as against any other Person and that, in the event of such declaration (or the US Notes Obligations being deemed to have become automatically due and payable), the US Notes Obligations (whether or not due and payable by any other Person) shall forthwith become due and payable by the US Notes Guarantors for purposes of Section 4.01. The Guarantors acknowledge and agree that their obligations hereunder are secured in accordance with the terms of the Collateral Documents and that the Purchasers may exercise their remedies thereunder in accordance with the terms thereof.

#### 4.06 Rights of Contribution.

The Guarantors agree among themselves that, in connection with payments made hereunder, each Guarantor shall have contribution rights against the other Guarantors as permitted under applicable law. Such contribution rights shall be subordinate and subject in right of payment to the obligations of such Guarantors under the Note Documents and (a) no Norwegian Notes Guarantor shall exercise such rights of contribution until all Norwegian Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and (b) no US Notes Guarantor shall exercise such rights of contribution until all US Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Delayed Draw Note Commitments have been terminated.

#### 4.07 Guarantee of Payment; Continuing Guarantee.

The guarantee in this Article IV is a guaranty of payment and not of collection, is a continuing guarantee, and shall apply to all Obligations whenever arising.

### ARTICLE V

#### CONDITIONS PRECEDENT

##### 5.01 Conditions to Effectiveness of Agreement and Purchase of Initial Notes.

This Agreement shall become effective upon, and the obligation of each Purchaser to purchase the Initial Notes to be purchased by it on the Closing Date is subject to, satisfaction of the following conditions precedent:

(a) Note Documents. Receipt by the Purchasers of executed counterparts of this Agreement and the other Note Documents, each properly executed by a Responsible Officer of the signing Note Party, in each case in form and substance satisfactory to the Purchasers.

(b) Opinions of Counsel. Receipt by the Purchasers of favorable opinions of legal counsel to the US Issuer and Parent and favorable legal opinions with respect to Norwegian law and English law, in each case addressed to the Purchasers, dated as of the Closing Date, and in form and substance reasonably satisfactory to the Purchasers and their counsel.

(c) Financial Statements. The Purchasers shall have received the Audited Financial Statements, the Interim Financial Statements and such other reports, statements and due diligence items as any Purchaser shall request.

(d) No Material Adverse Change. There shall not have occurred since December 31, 2016 any event or condition that has had or could reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

(e) Litigation. There shall not exist any action, suit, investigation or proceeding pending or to the knowledge of any Responsible Officer of any Note Party, threatened in any court or before an arbitrator or Governmental Authority that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

(f) Organization Documents, Resolutions, Etc. Receipt by the Purchasers of the following, each of which shall be originals or facsimiles, in form and substance satisfactory to the Purchasers and their legal counsel:

(i) copies of the Organization Documents of each Note Party certified to be true and complete as of a recent date by the appropriate Governmental Authority of the state or other jurisdiction of its incorporation or organization, where applicable, and certified by the chief executive officer or a secretary or assistant secretary of such Note Party to be true and correct as of the Closing Date;

(ii) such certificates of resolutions or other action, incumbency certificates and/or other certificates of Responsible Officers of each Note Party as the Purchasers may reasonably require evidencing the identity, authority and capacity of each Responsible

Officer thereof authorized to act as a Responsible Officer in connection with this Agreement and the other Note Documents to which such Note Party is a party; and

(iii) such documents and certifications as the Purchasers may reasonably require to evidence that each Note Party is duly organized or formed, and is validly existing, in good standing and qualified to engage in business in its state of organization or formation, including certificates of good standing or status to the extent available in such jurisdictions.

(g) Perfection and Priority of Liens. Receipt by the Purchasers of the following:

(i) searches of Uniform Commercial Code filings in the jurisdiction of formation of each Note Party or where a filing would need to be made in order to perfect the Collateral Agent's security interest in the Collateral, copies of the financing statements on file in such jurisdictions and evidence that no Liens exist other than Permitted Liens;

(ii) UCC financing statements for each appropriate jurisdiction as is necessary, in the Collateral Agent's sole discretion, to perfect the Collateral Agent's security interest in the Collateral;

(iii) all certificates evidencing any certificated Equity Interests pledged to the Collateral Agent pursuant to the Pledge Agreement, together with duly executed in blank and undated stock powers attached thereto;

(iv) searches of ownership of, and Liens on, the IP Rights of each Note Party in the appropriate United States governmental offices;

(v) duly executed notices of grant of security interest in the form required by the Security Agreement as are necessary, in the Collateral Agent's sole discretion, to perfect the Collateral Agent's security interest in the IP Rights of the Note Parties.

(vi) [Reserved];

(vii) [Reserved]

(viii) The Norwegian Security Documents shall have been duly executed, and all notices, acknowledgements and registration forms required for the perfection of the security interest thereunder shall have been duly executed and delivered to the Collateral Agent for filing on or immediately following the Closing Date; and

(ix) Such documents or evidence as are required to be delivered on the execution of the English Debenture pursuant to the English Debenture, including all documents required to be delivered pursuant to clause 8.1 (*Deposit of title documents*).

(h) [Reserved].

(i) Evidence of Insurance. Receipt by the Collateral Agent of copies of certificates of insurance of the Note Parties, evidencing liability and casualty insurance meeting the requirements set forth in the Note Documents, including, but not limited to, naming the Collateral Agent as additional insured (in the case of general liability insurance) or lender loss payee (in the case of property insurance) on behalf of the Purchasers.

(j) Closing Certificate. Receipt by the Purchasers of a certificate signed by a Responsible Officer of Parent certifying, as of the Closing Date, (i) that the conditions specified in Sections 5.01(d), (e), and (l) and Sections 5.02(a) and (b) have been satisfied, (ii) that Parent and its Subsidiaries (after giving effect to the transactions contemplated hereby and the incurrence of Indebtedness related thereto) are Solvent on a consolidated basis, (iii) that Parent and its Subsidiaries have no Indebtedness for borrowed money, other than Indebtedness permitted by Section 8.03, (iv) that neither Parent nor any Subsidiary has outstanding any Disqualified Capital Stock and (v) as true and complete an attached description of all intercompany Indebtedness of Parent and its Subsidiaries (both before and after giving effect to the application of the proceeds of the Initial Notes).

(k) Existing Indebtedness. All of the existing Indebtedness for the borrowed money of the Note Parties and their respective Subsidiaries (other than Indebtedness permitted to exist under Section 8.03) shall be repaid in full and all security interests related thereto shall be terminated on or prior to the Closing Date.

(l) Governmental and Third Party Approvals. Parent and its Subsidiaries shall have received all material governmental, shareholder and third party consents and approvals necessary in connection with the transactions contemplated by this Agreement and the other Note Documents and all applicable waiting periods shall have expired without any action being taken by any Person that could reasonably be expected to restrain, prevent or impose any material adverse conditions on Parent or any of its Subsidiaries or such other transactions or that could seek to threaten any of the foregoing, and no law or regulation shall be applicable which could reasonably be expected to have such effect.

(m) Corporate Structure and Capitalization. The capital and ownership structure and the equity holder arrangements of Parent on the Closing Date, on a pro forma basis after giving effect to the transactions contemplated by the Note Documents, shall be reasonably satisfactory to the Purchasers.

(n) Letter of Direction. Receipt by the Purchasers of a satisfactory letter of direction containing funds flow information, with respect to the proceeds of the Initial Notes on the Closing Date.

(o) Fees. Receipt by Athyrium, the Collateral Agent and the Purchasers of any fees required to be paid on or before the Closing Date.

(p) Attorney Costs; Due Diligence Expenses. The Issuers shall have paid all reasonable and documented out-of-pocket fees, charges and disbursements of counsel to the Purchasers and Collateral Agent and all reasonable and documented out-of-pocket due diligence expenses of Athyrium and the Purchasers, in each case, incurred to the Closing Date, plus such additional amounts of such reasonable and documented out-of-pocket fees, charges and disbursements as shall constitute their reasonable estimate of such fees, charges and disbursements incurred or to be incurred by it through the closing proceedings (provided, that, such estimate shall not thereafter preclude a final settling of accounts between the Issuers and the Purchasers), it being understood and agreed that the Issuers' obligations under this Section 5.01(p) shall not exceed \$250,000.

(q) Completion of Due Diligence. The Purchasers shall have (i) completed their due diligence, in form and scope satisfactory to the Purchasers, on Parent and its Subsidiaries and (ii) received investment committee approval for the transactions contemplated by this Agreement.

(r) Other. Receipt by the Collateral Agent and the Purchasers of such other documents, instruments, agreements and information as reasonably requested by the Collateral Agent or any Purchaser, including, but not limited to, information regarding litigation, tax, accounting, labor, insurance, pension liabilities (actual or contingent), real estate leases, material contracts, debt agreements, property ownership, environmental matters, contingent liabilities and management of Parent and its Subsidiaries; such information may include, if requested by the Collateral Agent, asset appraisal reports and written audits of accounts receivable, inventory, payables, controls and systems.

Without limiting the generality of the provisions of the last paragraph of Section 10.03, for purposes of determining compliance with the conditions specified in this Section 5.01, each Purchaser that has signed this Agreement shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Purchaser unless the other Purchasers shall have received notice from such Purchaser prior to the proposed Closing Date specifying its objection thereto.

#### 5.02 Conditions to all Purchases of Notes.

The obligation of each Purchaser to purchase the Notes to be purchased by it is subject to the following conditions precedent:

(a) The representations and warranties of the Issuers and each other Note Party contained in Article VI or any other Note Document, or which are contained in any document furnished at any time under or in connection herewith or therewith, shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the Closing Date or Delayed Draw Note Closing Date, as applicable, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct as of such earlier date, and except that for purposes of this Section 5.02, the representations and warranties contained in subsections (a) and (b) of Section 6.05 shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b), respectively, of Section 7.01.

(b) No Default shall exist, or would result from such proposed issuance of the Initial Notes or Delayed Draw Notes, as applicable, or from the application of the proceeds thereof.

By issuing and delivering the Notes, each Issuer or the US Issuer, as applicable, shall be deemed to represent and warrant that the conditions specified in Sections 5.02(a) and (b) have been satisfied on and as of the Closing Date or Delayed Draw Note Closing Date, as applicable.

#### 5.03 Conditions to Purchase of Delayed Draw Notes.

The obligation of each Purchaser to purchase the Delayed Draw Notes to be purchased by it hereunder is subject to the following conditions precedent (in addition to those in Section 5.02):

(a) Consolidated Revenues (Product). Consolidated Revenues (Product) for the four-quarter period ending on the Test Date shall have been at least \$15,000,000, and the Purchasers shall have received on or before the date of delivery of a valid Notice of Issuance pursuant to Section 5.03(c), (i) a certificate signed by a Responsible Officer of Parent certifying as to such Consolidated Revenues (Product) and (ii) evidence of such Consolidated Revenues (Product) in form and substance reasonably satisfactory to the Required Purchasers.

(b) Debt to Revenue Ratio (Product). The Debt to Revenue Ratio (Product) as of the Test Date, after giving pro forma effect to the issuance and purchase of the Delayed Draw Notes, shall be no greater than 6.50:1.00, and the Purchasers shall have received on or before the date of delivery of a valid Notice of Issuance pursuant to Section 5.03(c) a certificate signed by a Responsible Officer of Parent certifying as to such Debt to Revenue Ratio (Product).

(c) Notice of Issuance; Related Notices. The Purchasers shall have received a valid Notice of Issuance meeting the requirements of Section 2.06 with respect to the issuance to be effected on the Delayed Draw Note Closing Date.

(d) Delayed Draw Note Closing Date. The Delayed Draw Note Closing Date shall not occur after August 14, 2019.

## ARTICLE VI

### REPRESENTATIONS AND WARRANTIES

The Note Parties represent and warrant to the Collateral Agent and the Purchasers that:

#### 6.01 Existence, Qualification and Power.

Each Note Party and each of its Subsidiaries (a) is duly organized or formed, validly existing and (to the extent applicable under any such laws) in good standing under the Laws of the jurisdiction of its incorporation or organization, (b) has all requisite power and authority and all requisite governmental licenses, authorizations, consents and approvals to (i) own or lease its assets and carry on its business as currently conducted and (ii) execute, deliver and perform its obligations under the Note Documents to which it is a party, and (c) is duly qualified and is licensed and in good standing under the Laws of each jurisdiction where its ownership, lease or operation of properties or the conduct of its business requires such qualification or license; except in each case referred to in clause (b)(i) or (c), to the extent that failure to do so could not reasonably be expected to have a Material Adverse Effect.

#### 6.02 Authorization; No Contravention.

The execution, delivery and performance by each Note Party of each Note Document to which such Person is party have been duly authorized by all necessary corporate or other organizational action, and do not (a) contravene the terms of any of such Person's Organization Documents, (b) conflict with in any material respect or result in any material breach or contravention of, or the creation of any Lien under, or require any payment to be made under (i) any material Contractual Obligation to which such Person is a party or affecting such Person or the properties of such Person or any of its Subsidiaries or (ii) any material order, judgment, injunction, writ or decree of any Governmental Authority or any arbitral award to which such Person or its property is subject, or (c) violate in any material respect any Law (including, without limitation, Regulation U or Regulation X issued by the FRB).

#### 6.03 Governmental Authorization; Other Consents.

No approval, consent, exemption, authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person is necessary or required in connection with the execution, delivery or performance by any Note Party of this Agreement or any other Note Document other than (a) those that have already been obtained and are in full force and effect, (b) filings to perfect the Liens created by the Collateral Documents and (c) the filing of any applicable notices under securities laws.



#### 6.04 Binding Effect.

Each Note Document has been duly executed and delivered by each Note Party that is party thereto. Each Note Document constitutes a legal, valid and binding obligation of each Note Party that is party thereto, enforceable against each such Note Party in accordance with its terms, subject to applicable Debtor Relief Laws or other Laws affecting creditors' rights generally and subject to general principles of equity.

#### 6.05 Financial Statements; No Material Adverse Effect.

(a) The Audited Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of Parent and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, and (iii) show all material indebtedness and other liabilities, direct or contingent (to the extent required by GAAP), of Parent and its Subsidiaries as of the date thereof, including material liabilities for taxes, material commitments and Indebtedness.

(b) The Interim Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of Parent and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby, subject, in the case of clauses (i) and (ii), to the absence of footnotes and to normal year-end audit adjustments, and (iii) show all material indebtedness and other liabilities, direct or contingent (to the extent required by GAAP), of Parent and its Subsidiaries as of the date thereof, including material liabilities for taxes, material commitments and Indebtedness.

(c) From the date of the Audited Financial Statements to and including the Closing Date, there has been no Disposition by any Note Party or any Subsidiary, or any Involuntary Disposition, of any material part of the business or property of the Note Parties and their respective Subsidiaries, taken as a whole, and no purchase or other acquisition by any of them of any business or property (including any Equity Interests of any other Person) material to the Note Parties and their respective Subsidiaries taken as a whole, in each case, which is not reflected in the foregoing financial statements or in the notes thereto and has not otherwise been disclosed in writing to the Purchasers on or prior to the Closing Date or publicly filed under applicable securities laws.

(d) The financial statements delivered pursuant to Section 7.01(a) and (b) have been prepared in accordance with GAAP (except as may otherwise be permitted under Section 7.01(a) or (b), as applicable) and present fairly in all material respects (on the basis disclosed in the footnotes to such financial statements) the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the dates thereof and for the periods covered thereby.

(e) Since the date of the Audited Financial Statements, there has been no event or circumstance, either individually or in the aggregate, that has had or could reasonably be expected to have a Material Adverse Effect.

#### 6.06 Litigation.

There are no actions, suits, proceedings, claims or disputes pending or, to the knowledge of any Responsible Officer of any Note Party, threatened or contemplated, at law, in equity, in arbitration or before

any Governmental Authority, by or against any Note Party or any of its Subsidiaries or against any of their properties or revenues that (a) challenge the legality, validity or enforceability of this Agreement or any other Note Document, or the consummation of any of the transactions contemplated hereby or (b) either individually or in the aggregate, could reasonably be expected to have a Material Adverse Effect.

#### 6.07 No Default.

(a) Neither any Note Party nor any Subsidiary is in default under or with respect to any Contractual Obligation that could reasonably be expected to have a Material Adverse Effect.

(b) No Default has occurred and is continuing.

#### 6.08 Ownership of Property; Liens.

Each Note Party and its Subsidiaries has good record and marketable title in fee simple to, or valid leasehold interests in, all real property necessary or used in the ordinary conduct of its business, except for such defects in title as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The property of each Note Party and its Subsidiaries is subject to no Liens, other than Permitted Liens.

#### 6.09 Environmental Compliance.

Except as could not reasonably be expected to have a Material Adverse Effect:

(a) Each of the Facilities and all operations at the Facilities are in compliance with all applicable Environmental Laws, and there is no violation of any Environmental Law with respect to the Facilities or the Businesses, and, to the knowledge of any Responsible Officer of any Note Party, there are no conditions relating to the Facilities or the Businesses that could reasonably be expected to give rise to liability under any applicable Environmental Laws.

(b) None of the Facilities contains, or, to the knowledge of any Responsible Officer of any Note Party, has previously contained, any Hazardous Materials at, on or under the Facilities in amounts or concentrations that constitute or constituted a violation of, or could reasonably be expected to give rise to liability under, Environmental Laws.

(c) Neither any Note Party nor any Subsidiary has received any written or verbal notice of, or inquiry from any Governmental Authority regarding, any violation, alleged violation, non-compliance, liability or potential liability regarding environmental matters or compliance with Environmental Laws with regard to any of the Facilities or the Businesses, nor does any Responsible Officer of any Note Party have knowledge that any such notice is being threatened.

(d) Hazardous Materials have not been transported or disposed of from the Facilities, or generated, treated, stored or disposed of at, on or under any of the Facilities or any other location, in each case by or at the direction of any Note Party or any Subsidiary in violation of, or in a manner that would be reasonably likely to give rise to liability under, any applicable Environmental Law.

(e) No judicial proceeding or governmental or administrative action is pending or, to the knowledge of any Responsible Officer of any Note Party, threatened, under any Environmental Law to which any Note Party or any Subsidiary is or will be named as a party, nor are there any consent decrees or other decrees, consent orders, administrative orders or other orders, or other

administrative or judicial requirements outstanding under any Environmental Law with respect to any Note Party, any Subsidiary, the Facilities or the Businesses.

(f) There has been no release or, to the knowledge of any Responsible Officer of any Note Party, threat of release of Hazardous Materials at or from the Facilities, or arising from or related to the operations (including, without limitation, disposal) of any Note Party or any Subsidiary in connection with the Facilities or otherwise in connection with the Businesses, in violation of or in amounts or in a manner that could give rise to liability under Environmental Laws.

#### 6.10 Insurance.

(a) The properties of the Note Parties and their Subsidiaries are insured with property and general liability insurance from financially sound and reputable insurance companies that are not Affiliates of such Persons, in such amounts, with such deductibles and covering such risks as are customarily carried by companies engaged in similar businesses and owning similar properties in localities where the applicable Note Party or the applicable Subsidiary operates. Such insurance coverage of the Note Parties and their Subsidiaries as in effect on the Closing Date is outlined as to carrier, policy number, expiration date, type, coverage amounts and deductibles on Schedule 6.10 to the Disclosure Letter.

(b) Parent and its Subsidiaries maintain, if available, fully paid flood hazard insurance on all real property that is located in a special flood hazard area and that constitutes Collateral on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise required by the Collateral Agent or the Required Purchasers.

#### 6.11 Taxes.

The Note Parties and their Subsidiaries have filed all federal, state and other material tax returns and reports required to be filed, and have paid all federal, state and other material taxes, assessments, fees and other governmental charges levied or imposed upon them or their properties, income or assets otherwise due and payable, except those which are being contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves have been provided in accordance with GAAP. There is no proposed tax assessment against any Note Party or any Subsidiary that would, if made, have a Material Adverse Effect. Neither any Note Party nor any Subsidiary thereof is party to any tax sharing agreement with any Person that is not a Note Party.

#### 6.12 ERISA Compliance.

(a) Except as could not reasonably be expected to have a Material Adverse Effect, each Plan is in compliance with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state laws. As of the Closing Date, each Plan that is intended to be qualified under Section 401(a) of the Internal Revenue Code has a favorable opinion letter on which it is entitled to rely. To the knowledge of any Responsible Officer of any of the Note Parties, nothing has occurred that could reasonably be expected to cause the loss of tax-qualified status of any Plan that is intended to be qualified under Section 401(a) of the Internal Revenue Code.

(b) There are no pending or, to the knowledge of any Responsible Officer of any Note Party, threatened claims, actions or lawsuits, or action by any Governmental Authority, with respect to any Plan that could reasonably be expected to have a Material Adverse Effect. There has been

no prohibited transaction or violation of the fiduciary responsibility rules with respect to any Plan that has resulted or could reasonably be expected to result in a Material Adverse Effect.

(c) Except as could not reasonably be expected to have a Material Adverse Effect, (i) no ERISA Event has occurred and neither Parent nor any ERISA Affiliate is aware of any fact, event or circumstance that could reasonably be expected to constitute or result in an ERISA Event with respect to any Pension Plan, (ii) Parent and each ERISA Affiliate has met all applicable requirements under the Pension Funding Rules in respect of each Pension Plan, and no waiver of the minimum funding standards under the Pension Funding Rules has been applied for or obtained, (iii) as of the most recent valuation date for any Pension Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Internal Revenue Code) is sixty percent (60%) or higher and neither Parent nor any ERISA Affiliate knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage for any such plan to drop below sixty percent (60%) as of the next valuation date, (iv) neither Parent nor any ERISA Affiliate has incurred any liability to the PBGC other than for the payment of premiums, and there are no premium payments which have become due that are unpaid, (v) neither Parent nor any ERISA Affiliate has engaged in a transaction that could be subject to Section 4069 or Section 4212(c) of ERISA, and (vi) no Pension Plan has been terminated by the PBGC, and no event or circumstance has occurred or exists that could reasonably be expected to cause the PBGC to institute proceedings under Title IV of ERISA to terminate any Pension Plan.

(d) Neither Parent nor any ERISA Affiliate has established or otherwise has any liability with respect to a “welfare plan”, as such term is defined in Section 3(1) of ERISA, that either provides post-employment welfare benefits other than as required by Section 4980B of the Internal Revenue Code (or similar state law) or is a health or life insurance plan that is not fully insured by a third party insurance company.

#### 6.13 Subsidiaries and Capitalization.

Set forth on Schedule 6.13 to the Disclosure Letter is a complete and accurate list as of the Closing Date of each Subsidiary of any Note Party, together with (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by any Note Party or any Subsidiary and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto.

#### 6.14 Margin Regulations; Investment Company Act.

(a) No Note Party is engaged and no Note Party will engage, principally or as one of its important activities, in the business of purchasing or carrying margin stock (within the meaning of Regulation U issued by the FRB), or extending credit for the purpose of purchasing or carrying margin stock. Following the application of the proceeds of each issuance and purchase of Notes, not more than 25% of the value of the assets (either of Parent only or of Parent and its Subsidiaries on a consolidated basis) will be margin stock.

(b) No Note Party or any Subsidiary is or is required to be registered as an “investment company” under the Investment Company Act of 1940.

## 6.15 Disclosure.

Each Note Party has disclosed to the Purchasers all agreements, instruments and corporate or other restrictions to which it or any of its Subsidiaries is subject, and all other matters known to it, that, in each case of the foregoing, either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. No report, financial statement, certificate or other written information (other than financial projections, estimates and other forward-looking information, and information of a general economic or industry specific nature) furnished by or on behalf of any Note Party to any Purchaser in connection with the transactions contemplated hereby and the negotiation of this Agreement or delivered hereunder or under any other Note Document (in each case, as modified or supplemented by other information so furnished, and when taken as a whole) contains, when furnished, any material misstatement of fact or omits to state any fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, that, with respect to financial projections, estimates, budgets or other forward-looking information, the Note Parties represent only that such information was prepared in good faith based upon assumptions believed by the Note Parties to be reasonable at the time such information was prepared (it being understood that such information is as to future events and is not to be viewed as facts, is subject to significant uncertainties and contingencies, many of which are beyond the control of the Parent and its Subsidiaries, that no assurance can be given that any particular projection, estimate or forecast will be realized and that actual results during the period or periods covered by any such projections, estimate, budgets or forecasts may differ significantly from the projected results and such differences may be material).

## 6.16 Compliance with Laws.

Each Note Party and each Subsidiary is in compliance with the requirements of all Laws and all judgments, orders, writs, injunctions and decrees applicable to it or to its properties, except in such instances in which (a) such requirement of Law or judgment, order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted or (b) the failure to comply therewith could not reasonably be expected to have a Material Adverse Effect.

## 6.17 Intellectual Property; Licenses, Etc.

(a) Schedule 6.17(a) to the Disclosure Letter sets forth a complete and accurate list of the following IP Rights as of the Closing Date: (i) all Copyrights and all Trademarks of any Note Party, that are registered, or in respect of which an application for registration has been filed or recorded, with the United States Patent and Trademark Office or the United States Copyright Office or with any other Governmental Authority (or comparable organization or office established in any country or pursuant to an international treaty or similar international agreement for the filing, recordation or registration of interests in intellectual property), together with relevant identifying information with respect to such Copyrights and Trademarks, (ii) all Patents of any Note Party that are issued, or in respect of which an application has been filed or recorded, with the United States Patent and Trademark Office or with any other Governmental Authority (or comparable organization or office established in any country or pursuant to an international treaty or similar international agreement for the filing, recordation or registration of interests in intellectual property), together with relevant identifying information with respect to such Patents, and (iii) each Copyright License, each Patent License and each Trademark License of any Note Party that is, in the case of this clause (iii), material to the Businesses, taken as a whole.

(b) All Material IP Rights are in full force and effect, and have not expired, lapsed or been forfeited, cancelled or abandoned. Each of Parent and the Subsidiaries, have, since taking title

to the Material IP Rights, performed all acts and have paid all required annuities, fees, costs, expenses and taxes necessary to maintain the Material IP Rights in full force and effect or have caused others to do the same. All documents filed or recorded with a patent office or other relevant intellectual property registry for registration, recordation or issuance of Material IP Rights have been duly and properly filed and recorded, except where the failure to do so could not reasonably be expected to affect the validity or enforceability of such Material IP Rights. Except for rejections issued by a Governmental Authority in the ordinary course of prosecuting Patent or Trademark applications, none of the Material IP Rights are subject to any pending or outstanding injunction, directive, order, judgment, or other disposition of dispute that materially adversely restricts, or when any such pending dispute is concluded would reasonably be expected to materially adversely restrict the use, transfer, registration, licensing or other exploitation of any such Material IP Rights, or otherwise materially adversely affects the validity, use, right to use, registrability, or enforceability of such Material IP Rights. Except as otherwise described on Schedule 6.17 to the Disclosure Letter or for rejections issued by a Governmental Authority in the ordinary course of prosecuting Patent or Trademark applications, to the knowledge of any Responsible Officer of any Note Party, no action or proceeding is pending that could result in any of the foregoing.

(c) Parent or a Subsidiary owns or has a valid license to all Material IP Rights, free and clear of any and all Liens other than Permitted Liens. To the extent any of the Material IP Rights were authored, developed, conceived or created, in whole or in part, for or on behalf of Parent or a Subsidiary by any Person, then Parent or such Subsidiary, as applicable, has entered into a written agreement with such Person in which such Person has assigned all right, title and interest in and to such Material IP Rights to Parent or such Subsidiary, except where the failure to do so could not reasonably be expected to affect the validity, enforceability or ownership by Parent or such Subsidiary of such Material IP Rights. Each of Parent and each Subsidiary is the sole and exclusive owner of all right, title and interest in and to all such Material IP Rights that are owned by it, subject only to Permitted Liens.

(d) As of the Closing Date, except as described in Schedule 6.17(d) to the Disclosure Letter, and except for software that is commercially available to the public, no Note Party is a party to, nor is bound by, any inbound license or other similar agreement in respect of Material IP Rights, the breach or termination of which could reasonably be expected to cause a Material Adverse Effect, or that prohibits or otherwise restricts the Note Parties from granting a security interest in the applicable Note Party's interest in such license or agreement or any other property.

(e) (i) To the knowledge of any Responsible Officer of any Note Party, except as described in Schedule 6.17(e) to the Disclosure Letter, no Third Party is committing an act of Infringement of any Material IP Rights, and (ii) no Note Party has given notice to any Third Party alleging that such Third Party is committing an act of Infringement of any Material IP Rights, except in each case of clauses (i) and (ii), as of any Bringdown Date, where such Infringement could not reasonably be expected to have a Material Adverse Effect.

(f) With respect to each Copyright License, Trademark License and Patent License in respect of Material IP Rights listed on Schedule 6.17(a) to the Disclosure Letter, such agreement (i) is in full force and effect and is binding upon and enforceable against Parent and the Subsidiaries party thereto and to the knowledge of any Responsible Officer of any Note Party, all other parties thereto in accordance with its terms, (ii) as of the Closing Date, has not been amended or otherwise modified and (iii)(x) is not as of the Closing Date currently subject to any material default or breach by the Parent or any Subsidiary thereunder or to the knowledge of any Responsible Officer of any

Note Party, by any other party thereto, and (y) is not as of any Bringdown Date currently subject to any material default or breach by the Parent or any Subsidiary thereunder or to the knowledge of any Responsible Officer of any Note Party, by any other party thereto, where such default or breach could reasonably be expected to result in the termination of such agreement or the loss of the material benefits to or material rights of a Note Party or Subsidiary thereunder.

(g) Except as set forth on Schedule 6.17(g) to the Disclosure Letter, no written claim, and no other claim known to any Responsible Officer of a Note Party has been made by a Third Party that alleges that the Material IP Rights, or the conduct or operation of the business of Parent or the Subsidiaries, including the development, manufacture, use, sale or other commercialization of any Product, Infringes on any IP Rights of that Third Party, except as of any Bringdown Date, to the extent such Infringement could not reasonably be expected to have a Material Adverse Effect.

(h) Parent and the Subsidiaries have used commercially reasonable efforts and precautions to protect their interests in, and the value and confidentiality of their respective Confidential Information and Trade Secrets, including any source code for Proprietary Software, except to the extent such failure to maintain or protect could not reasonably be expected to have a Material Adverse Effect.

#### 6.18 Solvency.

(a) the US Issuer and the US Notes Guarantors are Solvent, on a consolidated basis , and (b) Parent and its Subsidiaries are Solvent, on a consolidated basis.

#### 6.19 Perfection of Security Interests in the Collateral.

The Collateral Documents create valid security interests in, and Liens on, the Collateral purported to be covered thereby, which security interests and Liens will be, upon the timely and proper filings, deliveries, notations and other actions contemplated in the Collateral Documents, perfected security interests and Liens (to the extent that such security interests and Liens can be perfected by such filings, deliveries, notations and other actions), prior to all other Liens other than Permitted Liens.

#### 6.20 Business Locations.

Set forth on Schedule 6.20(a) to the Disclosure Letter is a list of all real property that is owned or leased by the Note Parties as of the Closing Date (with (x) a description of each real property that is Excluded Property and (y) a designation of whether such real property is owned or leased). Set forth on Schedule 6.20(b) to the Disclosure Letter is the tax payer identification number and organizational identification number of each Note Party as of the Closing Date. The exact legal name and jurisdiction of organization of (a) each Issuer is as set forth on the signature pages hereto and (b) each Guarantor is (i) as set forth on the signature pages hereto, (ii) as set forth on the signature pages to the Joinder Agreement pursuant to which such Guarantor became a party hereto, or (iii) as may otherwise be disclosed by the Note Parties to the Collateral Agent in accordance with Section 8.12(c). Except as set forth on Schedule 6.20(c) to the Disclosure Letter, no Note Party has during the five years preceding the Closing Date (i) changed its legal name, (ii) changed its jurisdiction of organization, or (iii) been party to a merger, amalgamation, consolidation or other change in structure.

## 6.21 Sanctions Concerns; Anti-Corruption Laws; PATRIOT Act.

(a) Sanctions Concerns. No Note Party, nor any Subsidiary, nor, to the knowledge of any Responsible Officer of any Note Party, any director, officer, employee, agent, Affiliate or representative thereof, is an individual or entity that is, or is owned (at a 50% or greater level individually or in the aggregate) or controlled by any individual or entity that is (i) currently the subject or target of any Sanctions, (ii) included on OFAC's List of Specially Designated Nationals, HMT's Consolidated List of Financial Sanctions Targets and the Investment Ban List, or any similar list enforced by any other relevant sanctions authority or (iii) located, organized or resident in a Designated Jurisdiction.

(b) Anti-Corruption Laws. The Note Parties and their Subsidiaries have conducted their business in compliance in all material respects with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other applicable jurisdictions, and have instituted and maintained policies and procedures designed to promote and achieve compliance with such Laws.

(c) PATRIOT Act. To the extent applicable, each Note Party and each Subsidiary is in compliance, in all material respects, with (i) the Trading with the Enemy Act, as amended, and each of the foreign assets control regulations of the United States Treasury Department (31 CFR, Subtitle B, Chapter V, as amended) and any other enabling legislation or executive order relating thereto and (ii) the PATRIOT Act.

## 6.22 Limited Offering of Notes.

None of the Note Parties nor anyone acting on their behalf has offered or will offer to sell the Notes to, or solicit offers with respect thereto from, or enter into any preliminary conversations or negotiations relating thereto with, any Person other than the Purchasers, so as to require the issuance and sale of the Notes to be registered under the Securities Act or applicable securities laws of any other jurisdiction. None of the Note Parties nor anyone acting on their behalf has engaged, directly or indirectly, in any form of general solicitation or general advertising with respect to the offering of the Notes (as those terms are used in Regulation D) or otherwise in any manner involving a public offering within the meaning of Section 4(a)(2) of the Securities Act. Assuming the accuracy and completeness of the representations and warranties of the Purchasers set forth in Article VI-A below, the offer and sale of the Notes are exempt from registration under the Securities Act and any applicable securities laws of any other jurisdiction.

## 6.23 Registration Rights; Issuance Taxes.

(a) No Issuer is under any requirement to register under the Securities Act, or the Trust Indenture Act of 1939, as amended, any of its presently outstanding securities or any of its securities that may subsequently be issued.

(b) As of the Closing Date and if applicable, the Delayed Draw Notes Closing Date, all taxes imposed on the Issuers in connection with the issuance, sale and delivery of the Notes have been or will be fully paid, and all Laws imposing such taxes have been or will be fully satisfied by the Issuers.



## 6.24 Material Contracts.

Except for the Organization Documents and other agreements set forth on Schedule 6.24, as of the Closing Date there are no (i) commercial manufacturing or supply agreements relating to XHANCE or any other Material Product, (ii) agreements constituting clause (b) of the definition of Permitted Licenses or (iii) agreements constituting clauses (c) or (d) of the definition of Permitted Licenses involving XHANCE, in each case (i) and (ii) above to which Parent or any Subsidiary is a party requiring payment, or under which Parent or any Subsidiary is expected to pay, more than \$500,000 in any year (solely for purposes of this representation and as of the Closing Date) and \$2,000,000 in any year (for all other purposes), or other agreements or instruments to which Parent or any Subsidiary is a party and the breach, nonperformance or cancellation of which, or the failure of which to renew, could reasonably be expected to have a Material Adverse Effect (collectively with the Organization Documents, the "Material Contracts"). The consummation of the transactions contemplated by the Note Documents will not give rise to a right of termination in favor of any party to any Material Contract.

## 6.25 Regulatory Compliance.

(a) The Note Parties represent and warrant:

(i) that (x) Parent and its Subsidiaries have obtained all Required Permits, or have contracted with third parties holding Required Permits to obtain any and all rights, in each case necessary for the conduct of the Businesses or for compliance with all applicable Laws and (y) all such Required Permits or rights thereto are in full force and effect, except in each case of clause (x) or (y) where the failure to do so could not reasonably be expected to result in a Material Adverse Effect;

(ii) that Parent and its Subsidiaries have not received any written communication or to the knowledge of any Responsible Officer of any Note Party, any other communication, from any Governmental Authority regarding, and, to the knowledge of any Responsible Officer of a Note Party, there are no such notices being contemplated by a Governmental Authority regarding, (A) any adverse change in, limitation or modification of, any Required Permit, or any failure to comply with any Laws or any term or requirement of any Required Permit, in each case, that could reasonably be expected to result in a Material Adverse Effect or (B)(x) as of the Closing Date, any revocation, withdrawal, suspension, cancellation, or termination of any Required Permit and (y) as of any Bringdown Date, any revocation, withdrawal, suspension, cancellation, or termination of any Required Permit, in each case, that could reasonably be expected to result in a Material Adverse Effect;

(iii) that none of the officers, directors, employees, agents, or Affiliates of Parent or any Subsidiary or, to the knowledge of any Responsible Officer of a Note Party, any other Person involved in the development of (including seeking regulatory approval for) (A) as of the Closing Date, any Product and (B) as of any Bringdown Date, any Material Product, has been debarred pursuant to 21 U.S.C. Section 335a;

(iv) that none of the officers, directors, employees, agents, or Affiliates of Parent or any Subsidiary or, to the knowledge of any Responsible Officer of a Note Party, any consultant or independent contractor engaged by the Note Parties for services related to the development of (A) as of the Closing Date, a Product and (B) as of any Bringdown Date, a Material Product, has made an untrue statement of material fact or fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA, committed

an act, or failed to make a statement, in each case that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities,” set forth in 56 Fed. Reg. 46191 (September 10, 1991);

(v) that all applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests for a Required Permit from the FDA or other Governmental Authority by or on behalf of Parent or any Subsidiary, their Businesses and Material Products, when submitted to the FDA or other Governmental Authority, were true, complete and correct in all material respects as of the date of submission, and any necessary or required material updates, changes, corrections or modifications to such applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions have been properly and timely submitted to the FDA or other Governmental Authority. The Required Permits issued by the FDA and other Governmental Authorities for the Material Products are, to the knowledge of any Responsible Officer of any Note Party, valid and supported by proper research, design, testing, analysis and disclosure;

(vi) that all preclinical and clinical trials that have been conducted and/or are being conducted by or on behalf of Parent and its Subsidiaries for the Material Products, including those trials for which results and data have been submitted to any Governmental Authority, including the FDA, are being or have been conducted in compliance in all material respects with applicable protocols, procedures and controls and Laws, including, as applicable, current Good Laboratory Practices and Good Clinical Practices, as those terms are defined by the FDA. Neither Parent nor any Subsidiary has received any written notice from FDA relating to the imposition of a full or partial clinical hold, as that term is defined by FDA on any such ongoing clinical trial that could reasonably be expected to result in a Material Adverse Effect;

(vii) that neither Parent nor any Subsidiary has received any written notice or to the knowledge of any Responsible Officer of any Note Party, any other notice, that any Governmental Authority, including without limitation the FDA, the Office of the Inspector General of HHS or the United States Department of Justice has commenced or to the knowledge of any Responsible Officer of any Note Party, threatened to initiate any action against Parent or a Subsidiary or their respective officers, directors, employees, shareholders, agents or Affiliates, or to the knowledge of any Responsible Officer of a Note Party, their licensees, manufacturers and contractors with respect to the Products, seeking to enjoin the conduct of business at any facility owned or used by any of them (including the Facilities) or for any material civil penalty, injunction, seizure or criminal action, in each case, that could reasonably be expected to have a Material Adverse Effect;

(viii) that neither Parent nor any Subsidiary has received from the FDA a Warning Letter, Form FDA-483, Untitled Letter, other written correspondence or notice setting forth allegedly objectionable observations or alleged violations of Laws enforced by the FDA, or any comparable correspondence from any state or local authority with regard to any Product or the manufacture, testing, processing, packaging, promotion, sale, distribution, or holding thereof, or any comparable correspondence from any foreign counterpart of the FDA, or any comparable correspondence from any foreign counterpart of any state or local

authority with regard to (A) as of the Closing Date, any Product and (B) as of any Bringdown Date, any Material Product or the manufacture, testing, processing, packing, promotion, sale, distribution or holding thereof, that in each case, could reasonably be expected to (x) have a material adverse effect on the ability of the Parent and its Subsidiaries, taken as a whole, to develop or commercially exploit any Material Product or (y) have a Material Adverse Effect; and

(ix) (A) that neither Parent nor any Subsidiary has engaged in any Recalls, field notifications, warnings, “dear doctor” letters, investigator notices, safety alerts or other notice of action, including as a result of any Risk Evaluation and Mitigation Strategy proposed by the FDA, relating to an alleged lack of safety or regulatory compliance of the Material Products issued by Parent or any Subsidiary (“Safety Notices”), that in each case solely as of any Bringdown Date, (x) could reasonably be expected to have a material adverse effect on the ability of the Parent and its Subsidiaries, taken as a whole, to develop or commercially exploit any Material Product or (y) could reasonably be expected to prevent the commercialization of XHANCE or any other Material Product for six or more months, (B) no Responsible Officer of any Note Party has knowledge of any complaints with respect to (1) as of the Closing Date, the Products and (2) as of any Bringdown Date, the Material Products which, if true, could reasonably be expected to have a Material Adverse Effect, and (C) no Responsible Officer of any Note Party has knowledge of any facts that would be reasonably likely to result in (1) a Safety Notice with respect to (x) as of the Closing Date, the Products and (y) as of any Bringdown Date, the Material Products, (2) a change in the labeling of any of the Material Products, or (3) a termination or suspension of development and testing of any of (x) as of the Closing Date, the Products and (y) as of any Bringdown Date, the Material Products, that in each case of this clause (C) could reasonably be expected to (i) have a material adverse effect on the ability of the Parent and its Subsidiaries, taken as a whole, to develop or commercially exploit such Product or (ii) have a Material Adverse Effect.

(b) With respect to the Products, the Note Parties represent and warrant that:

(i) all Products are listed on Schedule 1.01(b) to the Disclosure Letter and the Issuers have delivered to the Purchasers on or prior to the Closing Date copies of all Required Permits relating to any Material Products issued or outstanding as of the Closing Date;

(ii) no material portion of the Material Products are adulterated or misbranded within the meaning of the FDCA, except for such adulterations or misbrandings that could not reasonably be expected to have (x) a material adverse effect on the ability of the Parent and its Subsidiaries, taken as a whole, to develop or commercially exploit such Material Products or (y) have a Material Adverse Effect;

(iii) each Product is not an article prohibited from introduction into interstate commerce under any provisions of the FDCA or PHSA, except where such introduction of a prohibited Product could not reasonably be expected to have a Material Adverse Effect;

(iv) with respect to each Material Product, (a) each such Material Product has been tested, manufactured, imported, held, owned, warehoused, promoted, sold, labeled, furnished, distributed and marketed by or on behalf of Parent and its Subsidiaries in accordance with applicable Required Permits and Laws, including current Good

Manufacturing Practices, (b) all reports, notices, or other submissions required to be submitted to Governmental Authorities under applicable Law have been timely submitted, and (c) all records required to be maintained under applicable Law have been and are being lawfully maintained, except in each case where a failure to do so could not reasonably be expected to have a Material Adverse Effect;

(v) without limiting the generality of Section 6.25(a)(i) and (ii) above, with respect to any Material Product being developed, tested or manufactured by or on behalf of Parent and its Subsidiaries, Parent and its Subsidiaries and any applicable third parties, have received, and such Material Product shall be the subject of, all Required Permits necessary in connection with the development, testing or manufacture of such Material Product currently being conducted by or on behalf of Parent or such Subsidiary, and, neither Parent nor any Subsidiary nor to the knowledge of any Responsible Officer of any Note Party, any third party, has received any notice from any applicable Government Authority, specifically including the FDA, (A) that such Government Authority is conducting an investigation or review of Parent's or its Subsidiaries' or any applicable third party's manufacturing facilities and processes for such Material Product that has found deficiencies or violations of Laws or the Required Permits related to the manufacture of such Material Product, that in each case of the clause (A), could reasonably be expected to result in a Material Adverse Effect, or (B) that any such Required Permit has been revoked or withdrawn or that any such Governmental Authority has issued an order or recommendation stating that the development, testing or manufacturing of such Material Product by or on behalf of Parent or its Subsidiaries should cease;

(vi) without limiting the generality of Section 6.25(a)(i) and (ii) above, with respect to any Material Product marketed, sold or commercialized by or on behalf of Parent or any of its Subsidiaries, Parent and its Subsidiaries, and any applicable third parties have received, and such Material Product is the subject of, all Required Permits necessary in connection with the marketing, sale and commercialization of such Material Product as currently being marketed, sold or commercialized by or on behalf of Parent and its Subsidiaries, and neither Parent nor any Subsidiary nor to the knowledge of any Responsible Officer of any Note Party, any third party, has received any notice from any applicable Governmental Authority, specifically including the FDA, (A) that such Governmental Authority is conducting a non-routine investigation or review of any such Required Permit that, if it finds deficiencies or violations of Laws or a Required Permit, could reasonably be expected to result in a Material Adverse Effect or (B) that any such Required Permit has been revoked or withdrawn or that any such Governmental Authority has issued any order or recommendation stating that the marketing, sale or commercialization of such Material Product cease or that such Material Product be withdrawn from the marketplace; and

(vii) neither Parent nor any Subsidiary has experienced any material failures in the commercial manufacturing of any Material Product such that the amount of such Material Product commercially manufactured in accordance with specifications thereof in any two-month period decreased significantly with respect to the quantities of such Material Product produced in the prior two-month period, other than any such failures in the commercial manufacturing of such Material Product as would not reasonably be expected to result in an interruption of the supply of such Material Product.

6.26 Labor Matters.

There are no existing or threatened strikes, lockouts or other labor disputes involving Parent or any Subsidiary that singly or in the aggregate could reasonably be expected to have a Material Adverse Effect. Except as could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, hours worked by and payment made to employees of Parent and its Subsidiaries are not in violation of the Fair Labor Standards Act or any other applicable law, rule or regulation dealing with such matters.

6.27 EEA Financial Institution.

No Note Party or any of their Subsidiaries is an EEA Financial Institution.

6.28 Ranking of Notes.

The Indebtedness represented by the Notes and the other Obligations under the applicable Note Documents of each Note Party is intended to constitute senior secured Indebtedness, and accordingly is, and shall be, at all times while the Notes and the other Obligations remain outstanding or the Purchasers have any outstanding Delayed Draw Note Commitments hereunder, *pari passu* or senior in right of payment with all Indebtedness (if any) of such Note Party.

6.29 Guaranty by OptiNose UK

Each Note Party incorporated or existing under the laws of England and Wales has received sufficient corporate benefit in connection with the transactions contemplated by this Agreement and the other Note Documents such that its provision of the guaranty contemplated by this Agreement and none of the security provided by the English Security Documents is a transaction at an undervalue.

ARTICLE VI-A.

REPRESENTATIONS OF THE PURCHASERS.

Each Purchaser represents and warrants to the Issuers that:

(a) such Purchaser is an “accredited investor” within the meaning of Rule 501(a) of Regulation D under the Securities Act and the Notes to be acquired by it pursuant to this Agreement are being acquired for its own account and not with a view to any distribution thereof or with any present intention of offering or selling any of the Notes in a transaction that would violate the Securities Act or the securities laws of any state of the United States or any other applicable jurisdiction;

(b) such Purchaser has such knowledge and experience in financial and business matters so as to be capable of evaluating the merits and risks of its investment in the Notes and such Purchaser is capable of bearing the economic risks of such investment and acknowledges that the Notes as of the date hereof, have not been registered under the Securities Act or the securities laws of any state or other jurisdiction; and

(c) each Purchaser acknowledges that the Issuers and, for purposes of the opinions to be delivered to the Purchasers pursuant hereto, counsel to the Issuers and their Affiliates will rely upon the accuracy and truth of the foregoing representations and in this Article VI-A and hereby consents to such reliance.

## ARTICLE VII

### AFFIRMATIVE COVENANTS

So long as any Purchaser shall have any Delayed Draw Commitment hereunder, or any Note or other Obligation hereunder shall remain unpaid or unsatisfied (other than contingent indemnification obligations for which no claim has been asserted), the Note Parties shall and shall cause each Subsidiary to:

#### 7.01 Financial Statements.

Deliver to the Collateral Agent and each Purchaser:

(a) as soon as available, and in any event within ninety-five (95) days after the end of each fiscal year of Parent (or, if earlier, when required to be filed with the SEC), a consolidated balance sheet of Parent and its Subsidiaries as at the end of such fiscal year, and the related consolidated statements of income or operations, changes in shareholders' equity and cash flows for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all in reasonable detail and prepared in accordance with GAAP, audited and accompanied by a report and opinion of Ernst & Young LLP or another independent certified public accountant of nationally recognized standing reasonably acceptable to the Required Purchasers, which report and opinion shall be unqualified (except for qualifications relating to changes in accounting principles or practices reflecting changes in GAAP and required or approved by Parent's independent public accountants) and prepared in accordance with generally accepted auditing standards. For purposes of clarity, [a "going concern" statement or explanatory note shall not be a qualification for purposes hereof](#); and

(b) as soon as available, and in any event within fifty (50) days after the end of each of the first three fiscal quarters of each fiscal year of Parent (or, if earlier, when required to be filed with the SEC), a consolidated balance sheet of Parent and its Subsidiaries as at the end of such fiscal quarter, and the related consolidated statements of income or operations, changes in shareholders' equity and cash flows for such fiscal quarter and for the portion of Parent's fiscal year then ended, setting forth in each case in comparative form the figures for the corresponding fiscal quarter of the previous fiscal year and the corresponding portion of the previous fiscal year, all in reasonable detail and certified by a Responsible Officer of Parent as fairly presenting in all material respects the financial condition, results of operations, shareholders' equity and cash flows of Parent and its Subsidiaries in accordance with GAAP, subject only to normal year-end audit adjustments and the absence of footnotes.

#### 7.02 Certificates; Other Information.

Deliver to the Collateral Agent and each Purchaser:

(a) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), a duly completed Compliance Certificate signed by the chief executive officer, chief financial officer, chief operating officer or vice president of finance of Parent, certifying compliance with the covenants set forth in Section 8.16 and setting forth calculations of (i) from and after the Delayed Draw Note Closing Date, Consolidated Revenues (General) for the four fiscal quarter period covered thereby and Debt to Revenue Ratio (General) as of the last day of such period and (ii) during a Springing Covenant Compliance Period, Consolidated Revenues (Product) for the four fiscal

quarter period covered thereby (including calculation of each clause of the definition thereof) and Debt to Revenue Ratio (Product) as of the last day of such period;

(b) as soon as practicable, and in any event not later than fifty(50) days after the commencement of each fiscal year of Parent, an annual business plan and budget of Parent and its Subsidiaries for the then current fiscal year containing, among other things, projections for each quarter of such fiscal year;

(c) promptly after the same are available, copies of each annual report, proxy or financial statement or other report or communication (other than ministerial or administrative in nature) sent to the equityholders of any Note Party, and copies of all annual, regular, periodic and special reports and registration statements which a Note Party may file or be required to file with the SEC under Section 13 or 15(d) of the Securities Exchange Act of 1934, and not otherwise required to be delivered to the Collateral Agent pursuant hereto;

(d) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), a certificate of a Responsible Officer of Parent containing information regarding the amount of all Dispositions and Involuntary Dispositions, in each case, the Net Cash Proceeds of which exceed \$1,000,000, Debt Issuances, all Extraordinary Receipts the Net Cash Proceeds of which exceed \$1,000,000 and Acquisitions that occurred during the period covered by such financial statements;

(e) promptly after any request by the Collateral Agent or any Purchaser, copies of any detailed audit reports, management letters or recommendations submitted to the Board of Directors (or the audit committee of the Board of Directors) of Parent by independent accountants in connection with the accounts or books of Parent or any Subsidiary, or any audit of any of them;

(f) promptly after the furnishing thereof, copies of any statement or report (other than ministerial or administrative in nature) furnished to any holder of debt securities of any Note Party or any Subsidiary pursuant to the terms of any indenture, loan or credit or similar agreement with an aggregate principal amount outstanding in excess of the Threshold Amount and not otherwise required to be furnished to the Purchasers pursuant to Section 7.01 or any other clause of this Section 7.02;

(g) promptly, and in any event within five (5) Business Days after receipt thereof by any Note Party or any Subsidiary thereof, copies of any initial notice or other initial written correspondence received from the SEC (or comparable agency in any applicable non-U.S. jurisdiction) concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of any Note Party or any Subsidiary thereof;

(h) promptly, such additional information regarding the business, financial or corporate affairs of any Note Party or any Subsidiary, or compliance with the terms of the Note Documents, as the Collateral Agent or any Purchaser may from time to time reasonably request; and

(i) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), a certificate of a Responsible Officer of Parent (i) listing (A) all applications with either the United States Copyright Office, the United States Patent and Trademark Office or upon the reasonable request of the Collateral Agent, in each case, such comparable Governmental Authority in Norway, England or in any other jurisdiction by any Note Party, if any, for Copyrights, Patents or Trademarks made since the date of the prior certificate (or, in the case of the first such

certificate, the Closing Date), (B) all issuances of registrations or letters with either the United States Copyright Office, the United States Patent and Trademark Office or, upon the reasonable request of the Collateral Agent, in each case, such comparable Governmental Authority in Norway, England or in any other jurisdiction on existing applications by any Note Party for Copyrights, Patents and Trademarks received since the date of the prior certificate (or, in the case of the first such certificate, the Closing Date), and C) all Trademark Licenses, Copyright Licenses and Patent Licenses in respect of Material IP Rights entered into by any Note Party since the date of the prior certificate (or, in the case of the first such certificate, the Closing Date), and (ii) with respect to any insurance coverage of any Note Party or any Subsidiary that was renewed, replaced or modified during the period covered by such financial statements, such updated information with respect to such insurance coverage as is required to be included on Schedule 6.10 to the Disclosure Letter.

Documents required to be delivered pursuant to Section 7.01(a) or (b) or Section 7.02 may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date (i) on which Parent posts such documents, or provides a link thereto on Parent's website on the Internet at the website address listed on Schedule 12.02, or (ii) on which such documents are posted on Parent's behalf on an Internet or intranet website, if any, to which each Purchaser and the Collateral Agent have access (whether a commercial, third-party website or whether sponsored by the Collateral Agent); provided, that: Parent shall notify the Collateral Agent and each Purchaser (by facsimile or electronic mail) of the posting of any such documents and if requested by the Collateral Agent, provide to the Collateral Agent by electronic mail electronic versions (i.e., soft copies) of such documents. The Collateral Agent shall have no obligation to request the delivery of or to maintain paper copies of the documents referred to above, and in any event shall have no responsibility to monitor compliance by Parent with any such request for delivery by a Purchaser, and each Purchaser shall be solely responsible for requesting delivery to it or maintaining its copies of such documents.

### 7.03 Notices.

(a) Promptly (and in any event, within five (5) Business Days) upon any Responsible Officer of any Note Party obtaining knowledge thereof, notify the Collateral Agent and each Purchaser of the occurrence of any Default.

(b) Promptly (and in any event, within five (5) Business Days) upon any Responsible Officer of any Note Party obtaining knowledge thereof, notify the Collateral Agent and each Purchaser of any matter that has resulted or could reasonably be expected to result in a Material Adverse Effect.

(c) Promptly (and in any event, within ten (10) Business Days) upon any Responsible Officer of any Note Party obtaining knowledge thereof, notify the Collateral Agent and each Purchaser of the occurrence of any ERISA Event.

(d) Promptly (and in any event, on the next Reporting Date) notify the Collateral Agent and each Purchaser of any material change in accounting policies or financial reporting practices by Parent or any Subsidiary.

(e) (i) Promptly (and in any event, within five (5) Business Days) notify the Collateral Agent and each Purchaser of any material litigation, arbitration or governmental investigation or proceeding not previously disclosed by Parent which has been instituted or, to the knowledge of any Responsible Officer of any Note Party, is threatened against Parent or any other Note Party or to which any of the properties of any thereof is subject and (ii) promptly (and in any event, on the next



Reporting Date) notify the Collateral Agent and each Purchaser of any other litigation, arbitration or governmental investigation or proceeding not previously disclosed by Parent which has been instituted or, to the knowledge of any Responsible Officer of any Note Party, is threatened against Parent or any other Note Party or to which any of the properties of any thereof is subject, which could reasonably be expected to result in losses and/or expenses in excess of the Threshold Amount.

(f) Promptly (and in any event, on the next Reporting Date), notify the Collateral Agent and each Purchaser after (i) any Note Party enters into a new Material Contract or (ii) an existing Material Contract is materially amended or terminated.

(g) Promptly (and in any event, within ten (10) Business Days of any Responsible Officer of any Note Party learning thereof) notify the Collateral Agent and each Purchaser of (i) any Governmental Authority, including but not limited to the FDA, is conducting or has conducted (A) an investigation of any of the Facilities of any Note Party or any Subsidiary thereof and/or manufacturing processes for any Material Product that has found material deficiencies or material violations of Laws and/or the Required Permits related to such Material Product, or (B) a non-routine investigation or review of any Required Permit (other than routine reviews in the ordinary course of business associated with the renewal of a Required Permit, routine pre-approval inspections and similar FDA or other Governmental Authority visits and which could not reasonably be expected to result in a Material Adverse Effect), (ii) that any Governmental Authority, including but not limited to the FDA, or any institutional review board or ethics committee has issued an order or recommendation that development, testing, manufacturing, marketing, sale and/or provision of any Material Product should cease, be suspended, or be interrupted, (iii) if a Material Product has been approved for marketing and sale, if (A) any marketing or sales of such Material Product should cease or be interrupted, (B) such Material Product should be withdrawn from the marketplace, or (C) the FDA should provide written notice ordering or recommending any such cessation, interruption, or withdrawal, (iv) any Required Permit has been revoked, withdrawn, suspended, cancelled, materially limited, terminated or materially modified, (v) adverse clinical test results with respect to any Material Product has occurred, (vi) that Parent or any Subsidiary has conducted, including at the request of the FDA, any Recall or other forms of retrieval from any market of any Material Product (other than a Market Withdrawal or retrieval or discrete batches or lots that are not material in amount or quantity and are not made in conjunction with a larger Recall), or (vii) any failures in the manufacturing of any Material Product such that the amount of such Material Product successfully manufactured in accordance with specifications thereof and the required payments to be made by or to the applicable Note Party or Subsidiary therefor in any two-month period shall decrease significantly with respect to the quantities of such Material Product and payments produced in the prior two-month period, except for such failures not reasonably expected to have a material adverse effect on Product supply levels (each event described in the foregoing clauses (i) through (vii), a “Regulatory Reporting Event”); provided, that, if after the Closing Date, Parent or any Subsidiary wishes to manufacture, sell, develop, test or market any new Product, the Issuers shall promptly (but in any event no later than the next Reporting Date) provide to the Purchasers a copy of an updated Schedule 1.01(b) to the Disclosure Letter and copies of all Required Permits relating to any such new Product that is a Material Product and/or Parent’s or the applicable Subsidiary’s manufacture, sale, development, testing or marketing thereof issued or outstanding as of the date of such notice.

Each notice pursuant to this Section 7.03(a) through (e) and (g) shall be accompanied by a statement of a Responsible Officer of Parent setting forth details of the occurrence referred to therein and stating what action the applicable Note Party has taken and proposes to take with respect thereto. Each notice pursuant to Section 7.03(a) shall describe with particularity any and all provisions of this Agreement and any other

Note Document that have been breached. With respect to any Regulatory Reporting Event, the Note Parties shall provide to the Collateral Agent and the Purchasers such further information (including copies of such documentation) as the Collateral Agent or any Purchaser shall reasonably request with respect to such Regulatory Reporting Event.

#### 7.04 Payment of Obligations.

Pay and discharge, as the same shall become due and payable, (a) all national, federal and state income and other material tax liabilities, assessments and governmental charges or levies upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted and adequate reserves in accordance with GAAP are being maintained by the applicable Note Party or Subsidiary and (b) all lawful claims which, if unpaid, would by law become a Lien upon its property (other than Permitted Liens).

#### 7.05 Preservation of Existence, Etc.

(a) Preserve, renew and maintain in full force and effect its legal existence under the Laws of the jurisdiction of its organization except in a transaction permitted by Section 8.04 or Section 8.05.

(b) Preserve, renew and maintain in full force and effect its good standing under the Laws of the jurisdiction of its organization, except to the extent the failure to do so could not reasonably be expected to have a Material Adverse Effect.

(c) Take all reasonable action to maintain all rights, privileges, permits, licenses and franchises necessary or desirable in the normal conduct of its business, except to the extent that the failure to do so could not reasonably be expected to have a Material Adverse Effect.

(d) Preserve or renew all of its registered IP Rights or IP Rights in respect of which an application for registration has been filed or recorded with the United States Copyright Office or the United States Patent and Trademark Office, the non-preservation or non-renewal of which could reasonably be expected to have a Material Adverse Effect.

#### 7.06 Maintenance of Properties.

(a) Maintain, preserve and protect all of its material properties and equipment necessary in the operation of its business in good working order and condition (ordinary wear and tear and casualty and condemnation events excepted), except where the failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(b) Make all necessary repairs thereto and renewals and replacements thereof, except where the failure to do so could not reasonably be expected to have a Material Adverse Effect.

(c) Use the standard of care typical in the industry in the operation and maintenance of its facilities.

#### 7.07 Maintenance of Insurance.

(a) Maintain with financially sound and reputable insurance companies not Affiliates of Parent, insurance with respect to its properties and business against loss or damage of the kinds

customarily insured against by Persons engaged in the same or similar business, of such types and in such amounts as are customarily carried under similar circumstances by such other Persons.

(b) Without limiting the foregoing, (i) maintain, if available, fully paid flood hazard insurance on all real property that is located in a special flood hazard area and that constitutes Collateral, on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise required by the Collateral Agent or (in relation to Collateral or insurance subject to a Lien created pursuant to the English Debenture, maintain insurance in accordance with the English Debenture), (ii) furnish to the Collateral Agent evidence of the renewal (and payment of renewal premiums therefor) of all such policies prior to the expiration or lapse thereof, and (iii) furnish to the Collateral Agent prompt written notice of any redesignation of any such improved real property into or out of a special flood hazard area.

(c) Cause the Collateral Agent and its successors and/or assigns to be named as Purchaser's loss payee, assignee, chargee or mortgagee as its interest may appear, with respect to any such insurance providing property coverage and/or additional insured with respect to any such insurance providing general liability coverage, and cause each provider of such required insurance to agree, by endorsement upon the policy or policies issued by it, that it will give the Collateral Agent thirty (30) days (or such lesser amount as the Collateral Agent may agree to in its sole discretion) prior written notice before any such policy or policies shall be materially altered or canceled. So long as no Event of Default shall have occurred and be continuing, subject to Section 2.07(b), Parent and its Subsidiaries may retain all or any portion of the proceeds of any insurance of Parent and its Subsidiaries (and the Collateral Agent shall promptly remit to Parent or the applicable Subsidiary any proceeds with respect to such insurance received by the Collateral Agent).

#### 7.08 Compliance with Laws.

Comply with the requirements of all Laws and all orders, writs, injunctions and decrees applicable to it or to its business or property, except in such instances in which (a) such requirement of Law or order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted, or (b) the failure to comply therewith could not reasonably be expected to have a Material Adverse Effect.

#### 7.09 Books and Records.

(a) Maintain proper books of record and account, in which full, true and correct entries in conformity in all material respects with GAAP consistently applied shall be made of all financial transactions and matters involving the assets and business of such Note Party or such Subsidiary, as the case may be.

(b) Maintain such books of record and account in material conformity with all applicable requirements of any Governmental Authority having regulatory jurisdiction over such Note Party or such Subsidiary, as the case may be.

#### 7.10 Inspection Rights.

Permit representatives and independent contractors of the Collateral Agent and each Purchaser to visit and inspect any of its properties, to examine its corporate, financial and operating records, and make copies thereof or abstracts therefrom, and to discuss its affairs, finances and accounts with its directors, officers, and independent public accountants (so long as a representative of the Note Parties is provided a reasonable opportunity to participate in any such discussion with accountants), all at the expense of the

Issuers and at such reasonable times during normal business hours and as often as may be desired, upon reasonable advance notice to the Issuers; provided, however, the Issuers shall only be required to reimburse the Collateral Agent (but not any Purchaser) for its reasonable out-of-pocket costs and expenses in connection with one such visit and inspection in any fiscal year; provided, further, however, when an Event of Default exists, the Collateral Agent or any Purchaser (or any of their respective representatives or independent contractors) may do any of the foregoing at the expense of the Issuers at any time during normal business hours, as often as desired and without advance notice. All such visits and examinations pursuant to this Section 7.10 shall comply with the Parent's or such Subsidiary's policies and protocols for safety for visitors to its facilities, including visits to any manufacturing areas. Notwithstanding anything to the contrary in this Section 7.10 or any other provision of the Note Documents, none of the Parent nor any of its Subsidiaries will be required to disclose, permit the inspection, examination or making copies or abstracts of, or discussion of, any document, information or other matter that (a) constitutes non-financial trade secrets or non-financial proprietary information, (b) in respect of which disclosure to the Collateral Agent or a Purchaser (or its respective representatives or contractors) is prohibited by law or (c) is subject to attorney-client or similar privilege or constitutes attorney work product.

#### 7.11 Use of Proceeds.

Use the proceeds of the Notes (a) solely for the Initial Notes, to repay or refinance existing intercompany Indebtedness of Parent and its Subsidiaries, (b) to support the launch and commercialization of XHANCE and (c) for other general corporate purposes, provided, that, in no event shall the proceeds of the Notes be used in contravention of any Note Document.

#### 7.12 Additional Subsidiaries.

Prior to or upon the acquisition or formation of any Subsidiary:

(a) notify the Purchasers thereof in writing, together with the (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by Parent or any Subsidiary and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto;

(b) (i) if such Subsidiary (other than a Foreign Subsidiary Holding Company or an Immaterial Subsidiary) is a Domestic Subsidiary that is not an Excluded Subsidiary, cause such Person to become a Norwegian Notes Guarantor and a US Notes Guarantor by executing and delivering to the Purchasers a Joinder Agreement or such other documents as the Required Purchasers shall reasonably request for such purpose, and (ii) if such Subsidiary (other than an Immaterial Subsidiary) is a Foreign Subsidiary or is a Foreign Subsidiary Holding Company, in each case, that is not an Excluded Subsidiary, cause such Person to become a Norwegian Notes Guarantor by executing and delivering to the Purchasers a Joinder Agreement or such other documents as the Required Purchasers shall reasonably request for such purpose, and in each case (i) and (ii), deliver to the Collateral Agent documents of the types referred to in Sections 5.01(f) and (g) and if requested by the Required Purchasers, favorable opinions of counsel to such Person (which shall cover, among other things, the legality, validity, binding effect and enforceability of the documentation referred to in clause (i) or (ii), as applicable), all in form, content and scope reasonably satisfactory to the Required Purchasers.

### 7.13 ERISA Compliance.

Do, and cause each of its ERISA Affiliates to do, each of the following: (a) maintain each Plan, both in form and operation, in compliance in all material respects with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state law, (b) cause each Plan that is intended to be qualified under Section 401(a) of the Internal Revenue Code to maintain such qualification, and (c) make all required contributions to any Plan subject to Section 412, Section 430 or Section 431 of the Internal Revenue Code, in each case (a) through (c) except as could not reasonably be expected to have a Material Adverse Effect.

### 7.14 Pledged Assets.

(a) Equity Interests. (i) To secure the Norwegian Notes Obligations, cause 100% of the issued and outstanding Equity Interests of each direct Subsidiary owned by a Note Party and (ii) to secure the US Notes Obligations, cause (x) 100% of the issued and outstanding Equity Interests of each Domestic Subsidiary (other than any Foreign Subsidiary Holding Company) directly owned by Parent, US Issuer or any other US Notes Guarantor and (y) 65% (or such greater percentage that, due to a change in an applicable Law after the Closing Date, (A) could not reasonably be expected to cause the undistributed earnings of such Foreign Subsidiary or such Foreign Subsidiary Holding Company as determined for United States federal income tax purposes to be treated as a deemed dividend to such Foreign Subsidiary's or such Foreign Subsidiary Holding Company's United States parent and (B) could not reasonably be expected to cause any adverse tax consequences) of the issued and outstanding Equity Interests entitled to vote (within the meaning of Treas. Reg. Section 1.956-2(c)(2)) and 100% of the issued and outstanding Equity Interests not entitled to vote (within the meaning of Treas. Reg. Section 1.956-2(c)(2)) in each Foreign Subsidiary and each Foreign Subsidiary Holding Company, in each case, directly owned by Parent, US Issuer or any other US Notes Guarantor, in each case of (i) and (ii), to be subject at all times, subject to Section 7.12(b), to a first priority, perfected Lien in favor of the Collateral Agent, for the benefit of the Purchasers, pursuant to the terms and conditions of the Collateral Documents, subject to Permitted Liens and to the extent not constituting Excluded Property, together with opinions of counsel (if requested by the Collateral Agent in connection with the entering into of a Collateral Document in connection with any such pledge) and any filings and deliveries necessary in connection therewith to perfect the security interests therein, all in form and substance reasonably satisfactory to the Collateral Agent and the Required Purchasers.

(b) Other Property. (i) Cause all property (other than Excluded Property) of the Norwegian Issuer and each Norwegian Notes Guarantor to be subject at all times to first priority, perfected and, in the case of owned real property, title insured Liens (provided that, in the case of owned real property located outside of the United States, title insurance shall be required only to the extent consistent with customary practice in the jurisdiction where such real property is located) in favor of the Collateral Agent to secure the Norwegian Notes Obligations pursuant to (and subject to the limitations, timing requirements and exceptions set forth in) the Collateral Documents or, with respect to any such property acquired subsequent to the Closing Date (with respect to which (x) the Collateral Agent's Lien does not automatically attach under then-existing Collateral Documents or (y) the then-existing Collateral Documents do not automatically create a Lien in favor of the Collateral Agent), such other additional security documents as the Collateral Agent or Required Purchasers shall reasonably request (subject to Permitted Liens) and (ii) cause all property (other than Excluded Property) of the US Issuer and each US Notes Guarantor to be subject at all times to first priority, perfected and, in the case of owned real property, title insured Liens in favor of the Collateral Agent to secure the US Notes Obligations pursuant to (and subject to the limitations, timing requirements

and exceptions set forth in) the Collateral Documents or, with respect to any such property acquired subsequent to the Closing Date (with respect to which (x) the Collateral Agent's Lien does not automatically attach under then-existing Collateral Documents or (y) the then-existing Collateral Documents do not automatically create a Lien in favor of the Collateral Agent), such other additional security documents as the Collateral Agent shall reasonably request (subject to Permitted Liens), and in each case (i) and (ii), in connection with the foregoing, deliver to the Collateral Agent such other documentation as the Collateral Agent may request including filings and deliveries necessary to perfect such Liens, Organization Documents, resolutions, Real Property Security Documents, and favorable opinions of counsel to such Person (if requested by the Collateral Agent or Required Purchasers in connection with the entering into of a Collateral Document in connection with the granting of any such security interest), all in form, content and scope reasonably satisfactory to the Collateral Agent and the Required Purchasers (provided that, in the case of owned real property located outside of the United States, real estate title insurance policies and other deliverables specific to such owned real property shall be required only to the extent consistent with customary practice in the jurisdiction where such real property is located). Notwithstanding anything to the contrary in the Note Documents, the Note Parties shall have sixty (60) days (or such longer period as the Required Purchasers shall agree in their sole discretion) to comply with this Section 7.14(b) with respect to any owned real property acquired after the Closing Date (such period to be measured from the date of acquisition of such real property).

#### 7.15 Compliance with Material Contracts.

Comply with each Material Contract of such Person, except as could not reasonably be expected to have a Material Adverse Effect.

#### 7.16 Deposit Accounts.

(a) Prior to or upon the acquisition or establishment of any Deposit Account (other than any Excluded Account) by any Note Party, provide written notice thereof to the Collateral Agent; provided that the Note Parties shall provide written notice to the Collateral Agent of the acquisition or establishment of any Excluded Account on or before the first Reporting Date to occur after the acquisition or establishment thereof.

(b) Cause all Deposit Accounts of the Note Parties (other than Excluded Accounts) at all times to be subject to Deposit Account Control Agreements, in each case in form and substance reasonably satisfactory to the Collateral Agent (it being understood that the Note Parties shall have ninety (90) days after the acquisition or establishment of a Deposit Account (or such longer period as the Collateral Agent shall agree in its sole discretion) to comply with this Section 7.16(b) with respect to any such Deposit Account acquired or established after the Closing Date in connection with a Permitted Acquisition or other Investment permitted by Section 8.02 (such period to be measured from the date of acquisition or establishment)).

#### 7.17 Products and Required Permits.

Without limiting the generality of Section 7.08, in connection with the development, testing, manufacture, marketing or sale of each and any Material Product by Parent or any Subsidiary, Parent or such Subsidiary shall comply in all material respects with all Required Permits, except where such non-compliance could not reasonably be expected to result in (i) the revocation or termination of such Required Permit or (ii) a Material Adverse Effect.

#### 7.18 Consent of Licensors.

Promptly (but in any event no later than the next Reporting Date) after entering into or becoming bound by any license or agreement (other than over-the-counter software that is commercially available to the public) after the date hereof, the failure, breach or termination of which could reasonably be expected to have a Material Adverse Effect, the Note Parties shall (a) provide written notice to the Purchasers of the material terms of such license or agreement, all of which shall constitute "Information" pursuant to Section 12.07, regardless of whether marked confidential, and (b) in good faith take such commercially reasonable actions as the Collateral Agent or Required Purchasers may reasonably request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for (i) the applicable Note Party's interest in such licenses or contract rights to be deemed Collateral and for the Collateral Agent to have a security interest in it that might otherwise be restricted by the terms of the applicable license or agreement, whether now existing or entered into in the future and (ii) the Collateral Agent to have the ability in the event of a liquidation of any of the Collateral to dispose of such Collateral in accordance with the Collateral Agent's rights and remedies under this Agreement and the other Note Documents, subject to such Collateral remaining subject to such license or other agreement notwithstanding such disposal; provided, that, the failure to obtain any such consent or waiver shall not by itself constitute a Default.

#### 7.19 Anti-Corruption Laws.

Conduct its business in compliance in all material respects with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions which are applicable to such Person and maintain policies and procedures designed to promote and achieve compliance with such Laws.

#### 7.20 Post-Closing Deliverables.

Notwithstanding anything to the contrary herein or in the Note Documents (it being understood that to the extent that the existence of any of the following post-closing obligations that is not overdue would otherwise cause any representation, warranty, covenant, default or event of default in this Agreement or any other Note Document to be in breach, the Collateral Agent and the Purchasers hereby waive such breach for the period from the Closing Date until the first date on which such condition is required to be fulfilled (giving effect to any extensions thereof) pursuant to this Section 7.20), the Note Parties shall deliver or cause to be delivered the following items to the Collateral Agent no later than the dates set forth below (or such later date agreed to by the Collateral Agent in its sole discretion), and each such item shall be in form and substance reasonably satisfactory to the Collateral Agent:

(a) No later than thirty (30) days after the Closing Date, insurance certificates and endorsements as required by and in compliance with Section 7.07;

(b) No later than ninety (90) days after the Closing Date, Deposit Account Control Agreements as required by and in compliance with Section 7.16(b) for all Deposit Accounts in existence as of the Closing Date; and

(c) Use all reasonable efforts to deliver Collateral Access Agreements for each applicable property as required by the definition of "Collateral Access Agreement" and otherwise under the Note Documents within ninety (90) days after the Closing Date or such later date as may be determined by the Required Purchasers.

## ARTICLE VIII

### NEGATIVE COVENANTS

So long as any Purchaser shall have any Delayed Draw Note Commitment hereunder, any Note or other Obligation hereunder shall remain unpaid or unsatisfied (other than contingent indemnification obligations for which no claim has been asserted), no Note Party shall, nor shall it permit any Subsidiary to, directly or indirectly:

#### 8.01 Liens.

Create, incur, assume or suffer to exist any Lien upon any of its property, assets or revenues, whether now owned or hereafter acquired, other than the following:

(a) Liens pursuant to any Note Document;

(b) Liens existing on the date hereof and listed on Schedule 8.01 to the Disclosure Letter;

(c) Liens (other than Liens imposed under ERISA) for taxes, assessments or governmental charges or levies not yet delinquent or which are being contested in good faith and by appropriate proceedings diligently conducted, if adequate reserves with respect thereto are maintained on the books of the applicable Person in accordance with GAAP;

(d) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law or pursuant to customary reservations or retentions of title arising in the ordinary course of business, provided, that, such Liens secure only amounts (i) not yet due and payable, (ii) if due, not overdue by more than thirty (30) days, or (iii) that if overdue by more than thirty (30) days are being contested in good faith by appropriate proceedings for which adequate reserves determined in accordance with GAAP have been established;

(e) pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation, other than any Lien imposed by ERISA;

(f) deposits to secure the performance of bids, trade contracts and leases (other than Indebtedness), statutory obligations, surety and appeal bonds, indemnity and performance bonds and other obligations of a like nature incurred in the ordinary course of business;

(g) easements, rights-of-way, restrictions and other similar encumbrances affecting real property which do not in any case materially detract from the value of the property subject thereto or materially interfere with the ordinary conduct of the business of the applicable Person and Liens disclosed on any Mortgage that are reasonably acceptable to Collateral Agent;

(h) Liens securing judgments for the payment of money (or appeal or other surety bonds relating to such judgments) not constituting an Event of Default under Section 9.01(h);

(i) (x) Liens securing Indebtedness permitted under Section 8.03(e)(x); provided, that: (i) such Liens do not at any time encumber any property other than the property financed by such



Indebtedness, (ii) the Indebtedness secured thereby does not exceed the cost (negotiated on an arm's length basis) of the property being acquired on the date of acquisition and (iii) such Liens attach to such property concurrently with or within ninety (90) days after the acquisition thereof and (y) Liens securing Indebtedness permitted under Section 8.03(e)(y) on any assets or property prior to the acquisition thereof and not created in contemplation of or in connection with such acquisition or Investment; provided, that, such Liens do not at any time encumber any assets or property other than the assets or property financed by such Indebtedness and such Liens do not apply to any other assets or property of Parent or any Subsidiary;

(j) licenses, sublicenses, leases or subleases (other than relating to intellectual property) granted to others in the ordinary course of business not interfering in any material respect with the business of any Note Party or any of its Subsidiaries;

(k) any interest of title of a lessor under, and Liens arising from UCC financing statements (or equivalent filings, registrations or agreements in foreign jurisdictions) relating to, leases permitted by this Agreement and the filing of UCC financing statements as a precautionary measure with respect thereto;

(l) Liens arising in the ordinary course of business by virtue of any contractual, statutory or common law provision relating to banker's Liens, rights of setoff or similar rights and remedies covering deposit or securities accounts (including funds or other assets credited thereto) or other funds maintained with a depository institution or securities intermediary, in each case incurred in the ordinary course of business;

(m) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code on items in the course of collection;

(n) Liens of sellers of goods to Parent and any of its Subsidiaries arising under Article 2 of the Uniform Commercial Code or similar provisions of applicable law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(o) Permitted Licenses;

(p) Liens on cash collateral in an aggregate principal amount not to exceed \$2,000,000 outstanding at any one time pledged to secure Indebtedness (i) in respect of corporate credit cards, purchase cards or bank card products permitted pursuant to Section 8.03(f) and (ii) of the type permitted by Section 8.03(i);

(q) Liens in favor of customs and revenue authorities arising as a matter of law, in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods;

(r) pledges and deposits in the ordinary course of business securing liability to insurance carriers providing property, casualty or liability insurance to Parent or any Subsidiary (including obligations in respect of letters of credit or bank guarantees for the benefit of such insurance carriers);

(s) rights of first refusal, voting, redemption, transfer or other restrictions (including call provisions and buy-sell provisions) with respect to the Equity Interests of any Joint Venture or other Persons that are not Subsidiaries;

(t) any Lien arising under conditional sale, title retention, consignment or similar arrangements for the sale of goods in the ordinary course of business; provided that such Lien attaches only to the goods subject to such sale, title retention, consignment or similar arrangement;

(u) to the extent constituting a Lien, cash escrow arrangements securing indemnification obligations associated with a Permitted Acquisition or any other Investment permitted under Section 8.02;

(v) Liens solely on cash earnest money deposits made by the Parent or any of its Subsidiaries in connection with any letter of intent or purchase agreement for a Permitted Acquisition or any other Investment permitted under Section 8.02;

(w) Liens on cash and Cash Equivalents securing Indebtedness permitted under Section 8.03(h), in an aggregate principal amount not to exceed \$6,250,000 outstanding at any one time; and

(x) other Liens securing Indebtedness or other obligations, in an aggregate amount not to exceed \$250,000 outstanding at any one time.

## 8.02 Investments.

Make any Investments, except:

(a) Investments held by a Note Party or a Subsidiary in the form of cash or Cash Equivalents;

(b) Investments existing as of the Closing Date and set forth in Schedule 8.02 to the Disclosure Letter;

(c) Investments in any Person that is a Note Party prior to giving effect to such Investment;

(d) Investments by any Subsidiary of Parent that is not a Note Party in any other Subsidiary of Parent that is not a Note Party;

(e) Investments consisting of extensions of credit in the nature of accounts receivable or notes receivable arising from the grant of trade credit in the ordinary course of business;

(f) Permitted Acquisitions and earnest money deposits in connection therewith and Investments acquired as a result of a Permitted Acquisition to the extent that such Investments were not made in contemplation of or in connection with such Permitted Acquisition and were in existence prior to the date of such Permitted Acquisition;

(g) (i) loans and advances to officers, directors and employees of Parent and/or its Subsidiaries in an aggregate amount not to exceed \$1,000,000 at any time outstanding, for travel, entertainment, relocation and analogous ordinary business purposes and (ii) Investments in an aggregate amount not to exceed \$1,000,000 consisting of non-cash loans to employees, officers, or directors relating to the purchase of equity securities of Parent or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Parent's board of directors;

(h) Investments (including Indebtedness obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of the non-cash portion of the sales consideration received by Parent or any of its Subsidiaries in connection with any Disposition permitted under Section 8.05;

(j) Investments consisting of security deposits with utilities, landlords and other like Persons made in the ordinary course of business;

(k) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business;

(l) (i) Joint Ventures or strategic alliances consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support, and (ii) other Joint Ventures; provided that any capital contribution or other Investment in any such Joint Ventures by Parent and its Subsidiaries in reliance on this Section 8.02(l) shall be limited to the entering into a Permitted License with such Joint Venture;

(m) Investments in respect of obligations under Swap Contracts permitted under Section 8.03;

(n) to the extent constituting Investments, Guarantees of Indebtedness, which Guarantees are expressly permitted under Section 8.03;

(o) to the extent constituting Investments, Investments in the form of Permitted Bond Hedge Transactions and Permitted Warrant Transactions, in each case, entered into in connection with Permitted Convertible Bond Indebtedness permitted by Section 8.03(q); and

(p) other Investments not exceeding \$1,500,000 in the aggregate in any fiscal year, provided that the portion of such amount that is not used by Parent or its Subsidiaries in any fiscal year shall be carried forward and shall increase such amounts available for succeeding fiscal years.

### 8.03 Indebtedness.

Create, incur, assume or suffer to exist any Indebtedness, except:

(a) Indebtedness under the Note Documents;

(b) Indebtedness of Parent and its Subsidiaries existing on the Closing Date and described on Schedule 8.03 to the Disclosure Letter;

(c) intercompany Indebtedness permitted under Section 8.02;

(d) obligations (contingent or otherwise) of Parent or any Subsidiary existing or arising under any Swap Contract, provided, that, such obligations are (or were) entered into by such Person in the ordinary course of business for the purpose of directly mitigating risks associated with liabilities, commitments, investments, assets, or property held or reasonably anticipated by such Person, or changes in the value of securities issued by such Person, and not for purposes of speculation or taking a “market view”;

(e) (x) purchase money Indebtedness (including obligations in respect of Capital Leases or Synthetic Leases) hereafter incurred by Parent or any of its Subsidiaries to finance the purchase of fixed assets, and renewals, refinancings and extensions thereof, provided, that, (i) the total of all such Indebtedness incurred in reliance on this clause (x) for all such Persons taken together, together with the total of all Indebtedness assumed by Parent and its Subsidiaries in reliance on clause (y) of this Section 8.03(e), shall not exceed an aggregate principal amount of \$3,500,000 at any one time outstanding, (ii) such Indebtedness when incurred shall not exceed the purchase price of the asset(s) financed, and (iii) no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing (other than by an amount equal to unpaid interest and premium thereon, and any underwriting discounts, fees, commissions and expenses associated with such refinancing) and (y) purchase money Indebtedness (including obligations in respect of Capital Leases or Synthetic Leases) assumed in connection with a Permitted Acquisition or other Investment permitted by Section 8.02, that was incurred to finance the purchase of fixed assets, and renewals, refinancings and extensions thereof; provided, that, (i) the total of all such Indebtedness assumed in reliance on this clause (y) for all such Persons taken together, together with the total of all Indebtedness incurred by Parent and its Subsidiaries in reliance on clause (x) of this Section 8.03(e), shall not exceed an aggregate principal amount of \$3,500,000 at any one time outstanding, (ii) no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing (other than by an amount equal to unpaid interest and premium thereon, and any underwriting discounts, fees, commissions and expenses associated with such refinancing) and (iii) such Indebtedness shall not have been incurred in contemplation of or in connection with such Permitted Acquisition or other Investment;

(f) Indebtedness in respect of obligations relating to corporate credit cards, purchase cards or bank card products, not to exceed \$2,000,000 in the aggregate at any one time outstanding;

(g) Guarantees of Indebtedness otherwise permitted under this Section 8.03;

(h) Indebtedness with respect to outstanding letters of credit, banker's acceptances or similar instruments posted in the ordinary course of business, provided the outstanding principal amount of such Indebtedness shall not exceed \$6,250,000 in the aggregate at any time;

(i) Indebtedness in respect of any agreement providing for treasury, depository, or cash management services, including in connection with any automated clearing house transfers of funds or any similar transactions, securities settlements, foreign exchange contracts, assumed settlement, netting services, overdraft protections and other cash management, intercompany cash pooling and similar arrangements, in each case in the ordinary course of business;

(j) advances or deposits in the ordinary course of business from customers, vendors or partners and not constituting Indebtedness for borrowed money;

(k) workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations, in each case incurred in the ordinary course of Parent's or its Subsidiaries' business;

(l) Indebtedness and related guarantees incurred solely as a result of endorsing negotiable instruments in the ordinary course of business;

(m) Indebtedness constituting Earn Out Obligations or obligations in respect of working capital adjustment requirements under the agreements used to consummate a Permitted Acquisition or other Investment permitted under Section 8.02;

(n) other unsecured Indebtedness in an aggregate amount not to exceed \$2,000,000 at any one time outstanding;

(o) Indebtedness in respect of (i) surety and appeal bonds, performance bonds, bid bonds, appeal bonds, completion guarantees and similar obligations incurred in the ordinary course of business and (ii) customary indemnification obligations to purchasers in connection with Dispositions permitted by Section 8.05;

(p) Indebtedness owed to any Person in respect of the purchase price for property, casualty, liability, or other insurance to any Note Party or to any of their Subsidiaries, or to a premium finance company with respect only to such insurance premiums; and

(q) Permitted Convertible Bond Indebtedness, provided that the aggregate principal amount of Indebtedness incurred pursuant to this clause (q), when multiplied by the per annum cash interest rate applicable to such Indebtedness, shall not exceed \$6,750,000 at any time outstanding.

#### 8.04 Fundamental Changes.

Merge, dissolve, liquidate, consolidate with or into another Person, or Dispose of (whether in one transaction or in a series of transactions) all or substantially all of its assets (whether now owned or hereafter acquired) to or in favor of any Person; provided, that, notwithstanding the foregoing provisions of this Section 8.04 but subject to the terms of Sections 7.12 and 7.14, (a) Parent or any Issuer may merge or consolidate with any Subsidiary that is not an Issuer, provided that Parent or the applicable Issuer shall be the continuing or surviving entity, (b) any Note Party (other than Parent and the Issuers) may merge or consolidate with any other Note Party (other than Parent and the Issuers), (c) any Subsidiary that is not a Note Party may be merged or consolidated with or into any Note Party, provided that the continuing or surviving Person shall be such Note Party or concurrently therewith becomes a Note Party, (d) any Subsidiary that is not a Note Party may be merged or consolidated with or into any other Subsidiary that is not a Note Party, (e) any Subsidiary may dissolve, liquidate or wind up its affairs at any time provided that such dissolution, liquidation or winding up could not reasonably be expected to have a Material Adverse Effect and all of its assets and business are transferred to a Note Party or, solely in the case of a Subsidiary that is not a Note Party, another Subsidiary that is not a Note Party prior to or concurrently with such dissolution, liquidation or winding up, and (f) in connection with any Permitted Acquisition or other Investment permitted under Section 8.02, Parent or any Subsidiary of Parent may merge into or consolidate with any other Person or permit any other Person to merge into or consolidate with it, so long as (i) the Person surviving such merger with any Subsidiary shall be a direct or indirect Wholly-Owned Subsidiary of Parent, (ii) in the case of any such merger to which Parent or an Issuer is a party, Parent or such Issuer, as applicable, is the surviving Person, and (iii) in the case of any such merger to which a Note Party (other than Parent or an Issuer) is a party, the surviving Person is such Note Party or concurrently therewith becomes a Note Party; provided that in the case of (a) through (d) and (f) above, no entity organized in any political subdivision of the United States may merge or consolidate with and into, or be merged or consolidated with or into, an entity organized in a jurisdiction other than another political subdivision of the United States.

## 8.05 Dispositions.

Make any Disposition (which for the avoidance of doubt shall not include any Permitted Transfer) unless (a) the consideration paid in connection therewith shall be at least 75% cash or Cash Equivalents paid contemporaneous with consummation of the transaction and shall be in an amount not less than the fair market value (as reasonably determined by Parent in good faith) of the property disposed of, (b) no Default or Event of Default shall have occurred and be continuing both immediately prior to and after giving effect to such Disposition, (c) such transaction does not involve the sale or other disposition of a minority equity interest in any Subsidiary, (d) such transaction does not involve a sale, transfer, license (other than Permitted License) or other disposition of XHANCE or any rights related thereto in the United States or any state or political subdivision thereof and (e) the aggregate fair market value of all of the assets sold or otherwise disposed of in such Disposition together with the aggregate fair market value of all assets sold or otherwise disposed of by Parent and its Subsidiaries in all such transactions occurring during the term of this Agreement does not exceed \$5,000,000.

## 8.06 Restricted Payments.

Declare or make, directly or indirectly, any Restricted Payment, except that:

(a) each Subsidiary that is a Note Party may make Restricted Payments to any Note Party, and (ii) each Subsidiary that is not a Note Party may make Restricted Payments to a Note Party and to another Subsidiary that is not a Note Party and pro rata Restricted Payments to minority stockholders of any such Subsidiary;

(b) Parent and each Subsidiary may declare and make dividend payments or other distributions payable solely in the Qualified Capital Stock of such Person (including in connection with the conversion of Permitted Convertible Bond Indebtedness or Equity Interests of the Parent);

(c) (i) Parent may make cashless repurchases of Equity Interests deemed to occur upon exercise of stock options or warrants of such Equity Interests to represent a portion of the exercise price of such options or warrants and (ii) to the extent constituting a Restricted Payment Parent may acquire (or withhold) its Equity Interests pursuant to any employee stock option or similar plan in satisfaction of withholding or similar taxes payable by any present or former officer, employee, director or member of management and the Parent may make deemed repurchases in connection with the exercise of stock options;

(d) Parent may make payments of cash in lieu of fractional shares of Equity Interests arising out of stock dividends, splits or combinations in connection with exercises or conversions of options, warrants and other convertible securities;

(e) [Reserved];

(f) Parent and each Subsidiary may make payments in respect of the repurchase of Equity Interests from former officers, directors, employees, consultants or other holders of Equity Interests of Parent and its Subsidiaries in connection with the termination of such Persons' services or pursuant to stock repurchase plans or agreements, employee stock option agreements, restricted stock agreements, equity incentive plans or other similar agreements or plans, not to exceed an aggregate amount of \$1,000,000 in any fiscal year (it being agreed that, to the extent constituting an Investment permitted by Section 8.02(g)(ii), the amount of any Indebtedness of such Persons owing to Parent or any Subsidiary forgiven in connection with such Restricted Payment shall be

excluded from any determination pursuant to this clause (f)); provided that the portion of such basket that is not used by Parent or its Subsidiaries in any fiscal year shall be carried-forward and shall increase such basket for succeeding fiscal years;

(g) Parent and each Subsidiary may effect the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(h) Parent and each Subsidiary may make any payment of premium to a counterparty under a Permitted Bond Hedge Transaction in accordance with the definition thereof;

(i) Parent and each Subsidiary may make payments to redeem or repurchase the Equity Interests held by any minority shareholder in any Joint Venture or Subsidiary that is not a Wholly-Owned Subsidiary, in each case, to the extent such payment is an Investment permitted under Section 8.02(p) and the amount of such payment does not exceed the amount then-available under Section 8.02(p); and

(j) Parent and each Subsidiary may make any payment or delivery in connection with a Permitted Warrant Transaction by (i) delivery of shares of the Parent's common stock upon net share settlement thereof and any related purchase of such common stock required to be made in connection with such delivery, (ii) set-off or payment of an early termination payment or similar payment thereunder, in each case, in the Parent's common stock upon any early termination thereof or (iii) in the event of cash settlement upon settlement, any payment of a cash settlement or equivalent amount.

#### 8.07 Change in Nature of Business.

Engage in any material line of business substantially different from those lines of business conducted by Parent and its Subsidiaries on the Closing Date or any business reasonably related or incidental thereto or which constitutes a reasonable extension or expansion thereof.

#### 8.08 Transactions with Affiliates and Insiders.

Enter into or permit to exist any transaction or series of transactions with any officer, director or Affiliate of such Person other than (a) transactions among Note Parties or among Subsidiaries that are not Note Parties, (b) transfers of cash and assets to any Note Party, (c) intercompany transactions expressly permitted by Section 8.02, Section 8.03, Section 8.04, Section 8.05 or Section 8.06, (d) normal and reasonable compensation (including performance, discretionary, retention, relocation, transaction and other special bonuses and payment, severance payments and payments pursuant to employment agreements) and other benefits (including retirement, health, stock option and other benefit plans, life insurance, disability insurance and other equity (or equity-linked) awards) and reimbursement of expenses of officers and directors in the ordinary course of business, (e) except as otherwise specifically limited in this Agreement, other transactions which are entered into in such Person's business on terms and conditions substantially as favorable to such Person as would be obtainable by it in a comparable arms-length transaction with a Person other than an officer, director or Affiliate, (f) transactions set forth on Schedule 8.08 to the Disclosure Letter and (g) transactions including consideration of less than \$10,000.

#### 8.09 Burdensome Agreements.

Enter into, or permit to exist, any Contractual Obligation that (a) encumbers or restricts the ability of any such Person to (i) make Restricted Payments to any Note Party, (ii) pay any Indebtedness or other obligations owed to any Note Party, (iii) make loans or advances to any Note Party, (iv) transfer any of its property to any Note Party, (v) pledge its property pursuant to the Note Documents or any renewals, refinancings, exchanges, refundings or extension thereof, or (vi) act as a Note Party pursuant to the Note Documents or any renewals, refinancings, exchanges, refundings or extension thereof, except (in respect of any of the matters referred to in clauses (i) through (vi) above) for (1) this Agreement and the other Note Documents, (2) any document or instrument governing Indebtedness incurred pursuant to Section 8.03(e), provided, that, any such restriction contained therein relates only to the asset or assets constructed or acquired in connection therewith, (3) any Permitted Lien or any document or instrument governing any Permitted Lien, provided, that, any such restriction contained therein relates only to the asset or assets subject to such Permitted Lien, (4) customary restrictions and conditions contained in any agreement relating to the sale of any property permitted under Section 8.05 pending the consummation of such sale, (5) customary provisions regarding confidentiality or restricting assignment, pledges or transfer of any Permitted License or any agreement entered into in the ordinary course of business, (6) customary provisions in joint venture agreements and other similar agreements applicable to, and agreements evidencing Indebtedness of, Joint Ventures permitted under Section 8.02 and applicable solely to the assets of such Joint Venture and the Equity Interests in such Joint Venture, so long as such provisions and restrictions remain in effect, (7) restrictions or encumbrances in any agreement in effect at the time any Person becomes a Subsidiary that is not a Wholly-Owned Subsidiary, so long as (x) such agreement was not entered into in contemplation of such Person becoming a Subsidiary, (y) such restrictions or encumbrances do not extend beyond such Subsidiary or its assets, and (z) such restrictions or encumbrances only exist for so long as such Subsidiary is not required to become a Note Party pursuant to the terms hereof or (8) restrictions of the type described in clause (iv) above in any agreement evidencing Permitted Convertible Bond Indebtedness that restricts the merger or consolidation of, or the sale of all or substantially all of the assets of, the Parent.

#### 8.10 Use of Proceeds.

Use the proceeds of any Note, whether directly or indirectly, and whether immediately, incidentally or ultimately, to purchase or carry margin stock (within the meaning of Regulation U of the FRB) or to extend credit to others for the purpose of purchasing or carrying margin stock or to refund indebtedness originally incurred for such purpose.

#### 8.11 Prepayment of Junior Indebtedness.

Make (or give any notice with respect thereto) any voluntary or optional payment or prepayment or redemption or acquisition for value of (including without limitation, by way of depositing money or securities with the trustee with respect thereto before due for the purpose of paying when due), refund, refinance or exchange of any Junior Debt of any Note Party or any Subsidiary (other than (a) intercompany Indebtedness of Parent and its Subsidiaries permitted by Section 8.03, (b) unsecured Indebtedness incurred in reliance on Section 8.03(f) or Section 8.03(i), (c) any prepayment, redemption or conversion of any Permitted Convertible Bond Indebtedness that is made or settled in Qualified Capital Stock of Parent or, in respect of any fractional shares to be issued, in cash, or (d) any prepayment or redemption of any Permitted Convertible Bond Indebtedness pursuant to an exchange for other Permitted Convertible Bond Indebtedness or with the proceeds from the substantially contemporaneous incurrence of any Permitted Convertible Bond Indebtedness) or make any payment in violation of any subordination provision applicable to such Junior Debt.



8.12 Organization Documents; Fiscal Year; Legal Name, Jurisdiction of Formation and Form of Entity.

- (a) Amend, modify or change its Organization Documents in a manner materially adverse to the Purchasers.
- (b) Change its fiscal year without the written consent of the Collateral Agent.
- (c) Without providing ten (10) days prior written notice to the Collateral Agent, change its name, jurisdiction of organization or form of organization.

8.13 Ownership of Subsidiaries.

Notwithstanding any other provisions of this Agreement to the contrary, (a) permit any Person (other than any Note Party or any Wholly-Owned Subsidiary of Parent) to own any Equity Interests of any Subsidiary of any Note Party in existence as of the Closing Date, except to qualify directors where required by applicable law or to satisfy other requirements of applicable law with respect to the ownership of Equity Interests of Foreign Subsidiaries, (b) permit any Note Party or any Subsidiary to issue or have outstanding any shares of Disqualified Capital Stock or (c) create, incur, assume or suffer to exist any Lien on any Equity Interests of any Subsidiary of any Note Party, except for Permitted Liens.

8.14 Sale Leasebacks.

Enter into any Sale and Leaseback Transaction.

8.15 Sanctions; Anti-Corruption Laws.

(a) Directly or indirectly, use the proceeds of any Note, or lend, contribute or otherwise make available such proceeds of any Note to any Person, to fund any activities of or business with any Person, or in any Designated Jurisdiction, that, at the time of such funding, is the subject of Sanctions such that funding is prohibited by applicable Sanctions, or in any other manner that will result in a violation by any Person (including any Person participating in the transactions hereunder, whether as a Purchaser, Collateral Agent or otherwise) of Sanctions.

(b) Directly or indirectly, use the proceeds of any Note for any purpose which would breach the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions..

8.16 Financial Covenants.

(a) Permit cash and Cash Equivalents of the Note Parties held in Deposit Accounts for which the Collateral Agent shall have received a Deposit Account Control Agreement at any time to be less than \$10,000,000; provided, that solely until the date that is ninety (90) days after the Closing Date (or such longer period as Collateral Agent shall agree in its sole discretion), or if earlier, the date when all required Deposit Account Control Agreements under Section 7.20(b) have been executed and delivered, the Note Parties shall not be required to maintain such amount required by this clause (a) in Deposit Accounts for which the Collateral Agent has received Deposit Account Control Agreements but may rather maintain such amount in Deposit Accounts for which the Collateral Agent has not received a Deposit Account Control Agreement.

(b) (i) At any time after Delayed Draw Notes have been issued and purchased, permit the Debt to Revenue Ratio (General) to be greater than the ratio set forth opposite the period in the table below:

| <b>During Period</b>   | <b>Maximum Debt to Revenue Ratio (General)</b>   |
|--|--|
| From and after Delayed Draw Note Closing Date until the penultimate day of the fiscal quarter in which the Delayed Draw Note Closing Date occurs                 | 6.50:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the last day of the fiscal quarter in which the Delayed Draw Note Closing Date occurs until the penultimate day of the immediately following fiscal quarter | 6.00:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                      | 5.50:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                      | 5.00:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                      | 4.50:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                      | 4.00:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                      | 3.50:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |
| At all times thereafter  | 3.00:1.00 (or if a lower ratio applies for such period pursuant to clause (ii) below during which period the Springing Covenant Compliance Period is in effect, then such lower ratio) |

(ii) At any time during a Springing Covenant Compliance Period, permit the Debt to Revenue Ratio (Product) to be greater than the ratio set forth opposite the period in the table below:

| During Period  | Maximum Debt to Revenue Ratio (Product)  |
|--|--|
| From and after the first Springing Covenant Trigger Date to occur until the penultimate day of the fiscal quarter in which such Springing Covenant Trigger Date occurs           | 6.50:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the last day of the fiscal quarter in which the first Springing Covenant Trigger Date to occur occurs until the penultimate day of the immediately following fiscal quarter | 6.00:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                                      | 5.50:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                                      | 5.00:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                                      | 4.50:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                                      | 4.00:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| From the immediately following day after the end of such prior period until the penultimate day of the immediately following fiscal quarter                                      | 3.50:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |
| At all times thereafter  | 3.00:1.00 (or if a lower ratio applies for such period pursuant to clause (i) above if the Delayed Draw Notes have been issued and purchased, then such lower ratio) |

## ARTICLE IX

### EVENTS OF DEFAULT AND REMEDIES

#### 9.01 Events of Default.

Any of the following shall constitute an Event of Default:

(a) Non-Payment. Any Issuer or any other Note Party fails to pay (i) when and as required to be paid herein, any amount of principal of any Note, or (ii) within three Business Days after the same becomes due, any interest on any Note, or any fee due hereunder, or (iii) within five Business Days after the same becomes due, any other amount payable hereunder or under any other Note Document; or

(b) Specific Covenants. Any Note Party fails to perform or observe any term, covenant or agreement contained in any of (i) Section 7.01, 7.02(a), (b), (d), (e), (h) or (i), 7.03(a), 7.05(a) (solely as to any Note Party), 7.10, 7.11, 7.12, 7.14(a), 7.16, 7.20 or Article VIII or (ii) Section

7.02(c), (f), or (g), and such failure specified in this clause (ii) continues for fifteen days after the earlier of the date on which (i) a Responsible Officer of any Note Party becomes aware of such failure and (ii) written notice thereof shall have been given to any Note Party by the Collateral Agent or any Purchaser; or

(c) Other Defaults. Any Note Party fails to perform or observe any other covenant or agreement (not specified in subsection (a) or (b) above) contained in any Note Document on its part to be performed or observed and such failure continues for thirty days after the earlier of the date on which (i) a Responsible Officer of any Note Party becomes aware of such failure and (ii) written notice thereof shall have been given to any Note Party by the Collateral Agent or any Purchaser; or

(d) Representations and Warranties. Any representation, warranty or certification made or deemed made by or on behalf of the Issuers or any other Note Party herein, in any other Note Document, or in any document delivered in connection herewith or therewith shall be incorrect or misleading in any material respect when made or deemed made; or

(e) Cross-Default. (i) Any Note Party or any Subsidiary (A) fails to make any payment when due (whether by scheduled maturity, required prepayment, acceleration, demand, or otherwise, and subject to any applicable grace periods) in respect of any Indebtedness (other than Indebtedness hereunder and Indebtedness under Swap Contracts) having an aggregate principal amount (including undrawn committed or available amounts and including amounts owing to all creditors under any combined or syndicated credit arrangement) of more than the Threshold Amount, or (B) fails to observe or perform any other agreement or condition relating to any such Indebtedness or contained in any instrument or agreement evidencing, securing or relating thereto, or any other event occurs, the effect of which default or other event is to cause, or to permit the holder or holders of such Indebtedness (or a trustee or agent on behalf of such holder or holders or beneficiary or beneficiaries) to cause, with the giving of notice if required, such Indebtedness to be demanded or to become due or to be repurchased, prepaid, defeased or redeemed (automatically or otherwise), or an offer to repurchase, prepay, defease or redeem such Indebtedness to be made, prior to its stated maturity; provided, that, clause (i)(B) above shall not apply to (x) secured Indebtedness that becomes due as a result of the sale or transfer of the property or assets securing such Indebtedness, if such sale or transfer is permitted hereunder and under the documents governing such Indebtedness and (y) the conversion of Permitted Convertible Bond Indebtedness permitted pursuant to Section 8.11(c) or (ii) there occurs under any Swap Contract (other than a Permitted Bond Hedge Transaction or Permitted Warrant Transaction) an Early Termination Date (as defined in such Swap Contract) resulting from any event of default under such Swap Contract as to which Parent or any Subsidiary is the Defaulting Party (as defined in such Swap Contract) and the Swap Termination Value owed by Parent or such Subsidiary as a result thereof is greater than the Threshold Amount; or

(f) Insolvency Proceedings, Etc. Any Note Party or any of its Subsidiaries institutes or consents to the institution of any proceeding under any Debtor Relief Law, or makes an assignment for the benefit of creditors; or applies for or consents to the appointment of any receiver, trustee, custodian, conservator, liquidator, administrator, rehabilitator or similar officer for it or for all or any material part of its property; or any receiver, trustee, custodian, conservator, liquidator, administrator, rehabilitator or similar officer is appointed without the application or consent of such Person and the appointment continues undischarged or unstayed for sixty calendar days; or any proceeding under any Debtor Relief Law relating to any such Person or to all or any material part of its property is instituted without the consent of such Person and continues undismissed or unstayed for sixty calendar days, or an order for relief is entered in any such proceeding; or

(g) Inability to Pay Debts; Attachment. (i) Any Note Party or any of its Subsidiaries becomes unable or admits in writing its inability or fails generally to pay its debts as they become due, or (ii) any writ or warrant of attachment or execution or similar process is issued or levied against all or any material part of the property of any such Person and is not released, vacated or fully bonded within thirty days after its issue or levy; or

(h) Judgments. There is entered against any Note Party or any Subsidiary one or more final judgments or orders for the payment of money in an aggregate amount exceeding the Threshold Amount (to the extent not covered by independent third-party insurance as to which the insurer does not dispute coverage) or (ii) any one or more non-monetary final judgments that have, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect and, in either case, (A) enforcement proceedings are commenced by any creditor upon such judgment or order or (B) such judgment or order shall not have been vacated or discharged or stayed or bonded pending appeal within thirty (30) calendar days from entry; or

(i) ERISA. (i) An ERISA Event occurs with respect to a Pension Plan or Multiemployer Plan which has resulted or could reasonably be expected to result in liability of any Note Party under Title IV of ERISA to the Pension Plan, Multiemployer Plan or the PBGC in an aggregate amount in excess of the Threshold Amount, or (ii) Parent or any ERISA Affiliate fails to pay when due, after the expiration of any applicable grace period, any installment payment with respect to its withdrawal liability under Section 4201 of ERISA under a Multiemployer Plan in an aggregate amount in excess of the Threshold Amount; or

(j) Invalidity of Note Documents. Any Note Document, at any time after its execution and delivery and for any reason other than as expressly permitted hereunder or thereunder, ceases to be in full force and effect; or any Note Party or any Permitted Holder contests in any manner the validity or enforceability of any Note Document; or any Note Party denies that it has any or further liability or obligation under any Note Document, or purports to revoke, terminate or rescind any Note Document; or

(k) Material Adverse Effect. There occurs any circumstance or circumstances that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect; or

(l) Change of Control. There occurs any Change of Control;

(m) Invalidity of Subordination Provisions. Any subordination provision in any document or instrument governing Indebtedness that is purported to be subordinated to the Obligations or any subordination provision in any subordination agreement that relates to any Indebtedness that is to be subordinated to the Obligations, or any subordination provision in any guaranty by any Note Party of any such Indebtedness, shall cease to be in full force and effect, or any Person (including the holder of any such Indebtedness) shall contest in any manner the validity, binding nature or enforceability of any such provision; or

(n) Regulatory Events. (i) The FDA shall revoke, withdrawal, cancel or terminate marketing approval of XHANCE in the U.S. and such action remains undischarged or unstayed for more than 60 days; or (ii)(1) any Governmental Authority (including the FDA) shall revoke, withdrawal, cancel, terminate, suspend, materially limit or materially modify any Required Permit relating to XHANCE, (2) the marketing of XHANCE is voluntarily suspended by any Note Party or Subsidiary or (3) any Note Party or any Subsidiary shall initiate any recall of XHANCE or any

Safety Notice is issued in connection therewith (each of the foregoing clauses (1), (2) and (3), a “Regulatory Event”), and, the occurrence of the Regulatory Event is (x) reasonably expected to prevent the marketing of XHANCE in the U.S. for more than six months; or (y) reasonably expected to result in the Note Parties failure to comply with the financial covenants in Section 8.16(a) and, solely if such covenants (or subsection thereof) is in effect immediately prior to such Regulatory Event, Section 8.16(b), during the twelve-month period following such Regulatory Event; or

(o) Permitted Bond Hedge Transactions and Permitted Warrant Transactions. There occurs under any Permitted Bond Hedge Transaction or Permitted Warrant Transaction an Early Termination Date (as defined therein) resulting from any event of default thereunder as to which Parent or any Subsidiary is the Defaulting Party (as defined therein) and the net termination value owed by Parent or such Subsidiary as a result thereof is greater than the Threshold Amount, and such termination value is required to be paid in cash and may not be settled by the delivery of common stock of Parent.

## 9.02 Remedies Upon Event of Default.

If any Event of Default occurs and is continuing, the Required Purchasers may take any or all of the following actions:

(a) declare the Delayed Draw Note Commitments of each Purchaser to be terminated, whereupon such commitments and obligation shall be terminated;

(b) declare the unpaid principal amount of all outstanding Notes, all interest accrued and unpaid thereon, prepayment premium thereto (if any) and all other amounts owing or payable hereunder or under any other Note Document to be immediately due and payable, without presentment, demand, protest or other notice of any kind, all of which are hereby expressly waived by the Note Parties; and

(c) exercise, or instruct the Collateral Agent to exercise (and the Collateral Agent shall exercise upon such instruction), all rights and remedies available to the Collateral Agent or the Purchasers under the Note Documents;

provided, however, that upon the occurrence of an Event of Default under Section 9.01(f), the obligation of each Purchaser to purchase Notes shall automatically terminate, the unpaid principal amount of all outstanding Notes and all interest, prepayment premium and other amounts as aforesaid shall automatically become due and payable, in each case without further act of the Collateral Agent or any Purchaser.

If the Obligations are accelerated for any reason, the prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.10(b) will also be due and payable as though such Obligations were voluntarily prepaid and, in each case, shall constitute part of the Obligations, in view of the impracticability and extreme difficulty of ascertaining actual damages and by mutual agreement of the parties as to a reasonable calculation of each Purchaser’s lost profits as a result thereof. Any prepayment premium required by Section 2.07(e) and any exit fee required by Section 2.10(b) payable pursuant to the preceding sentence shall be presumed to be the liquidated damages sustained by each Purchaser as the result of the early termination and the Issuers agree that it is reasonable under the circumstances currently existing. The prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.10(b) shall also be payable, in each case, in the event that the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE ISSUERS EXPRESSLY WAIVE THE

PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING PREPAYMENT PREMIUM AND EXIT FEE IN CONNECTION WITH ANY SUCH ACCELERATION. The Issuers expressly agree that (i) the prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.10(b) are reasonable and are the product of an arm's length transaction between sophisticated business people, ably represented by counsel, (ii) the prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.06(b) shall each be payable notwithstanding the then prevailing market rates at the time payment is made, (iii) there has been a course of conduct between the Purchasers and the Issuers giving specific consideration in this transaction for such agreement to pay the prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.10(b), and (iv) the Issuers shall be estopped hereafter from claiming differently than as agreed to in this paragraph. The Issuers expressly acknowledge that their agreement to pay the prepayment premium required by Section 2.07(e) and the exit fee required by Section 2.10(b) as herein described is a material inducement to the Purchasers to purchase the Notes hereunder. Purchasers agree that in connection with any foreclosure or other exercise of rights under this Agreement or any other Note Document with respect to IP Rights, the rights of the licensees under Permitted Licenses will not be terminated, limited or otherwise adversely affected so long as no default exists under the Permitted License that would permit the licensor to terminate such Permitted License (commonly known as a non-disturbance).

### 9.03 Application of Funds.

(a) After the exercise of remedies provided for in Section 9.02 (or after the Notes issued by the Norwegian Issuer have automatically become immediately due and payable as set forth in the proviso to Section 9.02), any amounts received by any Purchaser or the Collateral Agent on account of the Norwegian Notes Obligations shall be applied by the Collateral Agent in the following order:

First, to payment of that portion of the Norwegian Notes Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Collateral Agent and amounts payable under Article III) payable to the Collateral Agent in its capacity as such;

Second, to payment of that portion of the Norwegian Notes Obligations constituting fees, indemnities and other amounts (other than principal and interest) payable to the Purchasers (including fees, charges and disbursements of counsel to the respective Purchasers) arising under the Note Documents and amounts payable under Article III, ratably among them in proportion to the respective amounts described in this clause Second payable to them;

Third, to payment of that portion of the Norwegian Notes Obligations constituting accrued and unpaid interest on and prepayment premium and exit fees with respect to the Notes issued by the Norwegian Issuer, ratably among the Purchasers in proportion to the respective amounts described in this clause Third held by them;

Fourth, to payment of that portion of the Norwegian Notes Obligations constituting accrued and unpaid principal of the Notes issued by the Norwegian Issuer, ratably among the Purchasers in proportion to the respective amounts described in this clause Fourth held by them; and

Last, the balance, if any, after all of the Norwegian Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been indefeasibly paid in full, to the Norwegian Issuer or as otherwise required by Law.

(b) After the exercise of remedies provided for in Section 9.02 (or after the Notes issued by the US Issuer have automatically become immediately due and payable as set forth in the proviso to Section 9.02), any amounts received by any Purchaser or the Collateral Agent on account of the US Notes Obligations shall be applied by the Collateral Agent in the following order:

First, to payment of that portion of the US Notes Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Collateral Agent and amounts payable under Article III) payable to the Collateral Agent in its capacity as such;

Second, to payment of that portion of the US Notes Obligations constituting fees, indemnities and other amounts (other than principal and interest) payable to the Purchasers (including fees, charges and disbursements of counsel to the respective Purchasers) arising under the Note Documents and amounts payable under Article III, ratably among them in proportion to the respective amounts described in this clause Second payable to them;

Third, to payment of that portion of the US Notes Obligations constituting accrued and unpaid interest on and prepayment premium and exit fees with respect to the Notes issued by the US Issuer, ratably among the Purchasers in proportion to the respective amounts described in this clause Third held by them;

Fourth, to payment of that portion of the US Notes Obligations constituting accrued and unpaid principal of the Notes issued by the US Issuer, ratably among the Purchasers in proportion to the respective amounts described in this clause Fourth held by them; and

Last, the balance, if any, after all of the US Notes Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been indefeasibly paid in full, to the US Issuer or as otherwise required by Law.

## ARTICLE X

### LIBOR AND OTHER PROVISIONS

#### 10.01 Increased Costs, Etc.

The Issuers agree to reimburse the Purchasers for any increase in the cost to the Purchasers of, or any reduction in the amount of any sum receivable by the Purchasers in respect of, the Purchasers' Delayed Draw Note Commitments and the purchase or maintaining of the Notes hereunder that may arise in connection with any Change in Law, except for such changes with respect to increased capital costs and taxes which are governed by Section 10.02 and Article III, respectively. The Collateral Agent shall notify the Issuers in writing of the occurrence of any such event, stating the reasons therefor and the additional amount required fully to compensate the Purchasers for such increased cost or reduced amount. Such additional amounts shall be payable by the Issuers directly to the Purchasers within five days of its receipt of such notice, and such notice shall, in the absence of manifest error, be conclusive and binding on the Issuers; provided that the Issuers shall not be required to compensate the Purchasers pursuant to this Section for any increased costs or reductions incurred more than 180 days prior to the date that such Purchaser notifies the Issuers of the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof.



## 10.02 Increased Capital Cost.

If any Change in Law affects or would affect the amount of capital required or expected to be maintained by any Purchaser or any Person controlling such Purchaser, and such Purchaser determines (in good faith but in its sole and absolute discretion) that the rate of return on its or such controlling Person's capital as a consequence of the Delayed Draw Note Commitments or the Notes purchased by it hereunder is reduced to a level below that which such Purchaser or such controlling Person could have achieved but for the occurrence of any such circumstance, then upon notice from time to time by such Purchaser to the Issuers, the Issuers shall within five days following receipt of such notice pay directly to such Purchaser additional amounts sufficient to compensate such Purchaser or such controlling Person for such reduction in rate of return; provided that the Issuers shall not be required to compensate the Purchasers pursuant to this Section for any increased costs or reductions incurred more than 180 days prior to the date that such Purchaser notifies the Issuers of the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof. A statement of such Purchaser as to any such additional amount or amounts shall, in the absence of manifest error, be conclusive and binding on the Issuers. In determining such amount, such Purchaser may use any method of averaging and attribution that it (in its sole and absolute discretion) shall deem applicable.

## 10.03 LIBOR Not Determinable.

(a) If prior to the commencement of any Interest Period:

- (i) the Collateral Agent determines (which determination shall be conclusive absent manifest error) that adequate and reasonable means do not exist for ascertaining LIBOR for such Interest Period; or
- (ii) the Collateral Agent is advised by the Required Purchasers that LIBOR for such Interest Period will not adequately and fairly reflect the cost to such Purchasers of purchasing or maintaining their Notes for such Interest Period;

then the Collateral Agent shall give notice thereof to the Issuers and the Purchasers by telephone or telecopy as promptly as practicable thereafter. In the event of any such determination, until the Collateral Agent has advised the Issuers that the circumstances giving rise to such notice no longer exist, LIBOR shall be determined by the Collateral Agent in its sole discretion.

(b) If at any time the Collateral Agent determines (which determination shall be conclusive absent manifest error) that (i) the circumstances set forth in clause (a)(i) have arisen and such circumstances are unlikely to be temporary or (ii) the circumstances set forth in clause (a)(i) have not arisen but the supervisor for the administrator of the three-month London Interbank Offered Rate or a Governmental Authority having jurisdiction over the Collateral Agent has made a public statement identifying a specific date after which the three-month London Interbank Offered Rate shall no longer be used for determining interest rates for loans, then the Collateral Agent and the Issuers shall endeavor to establish an alternate rate of interest to the three-month London Interbank Offered Rate that gives due consideration to the then prevailing market convention for determining a rate of interest for loans in the United States at such time, and shall enter into an amendment to this Agreement to reflect such alternate rate of interest and such other related changes to this Agreement as may be applicable. Notwithstanding anything to the contrary in Section 12.01, such amendment shall become effective without any further action or consent of any other party to this

Agreement so long as the Collateral Agent shall not have received, within five (5) Business Days of the date notice of such alternate rate of interest is provided to the Purchasers, a written notice from the Required Purchasers stating that such Required Purchasers object to such amendment.

10.04 Mitigation of Obligations; Replacement of Purchasers.

(a) If any Purchaser requests compensation under Section 10.01 or 10.02, or any Issuer is required to pay any Indemnified Taxes or additional amounts to any Purchaser, or any Governmental Authority for the account of any Purchaser pursuant to Section 3.01, then at the request of such Issuer, such Purchaser shall use commercially reasonable efforts to designate a different lending office for purchasing its Notes hereunder or to assign its rights and obligations hereunder to another of its offices, branches or affiliates, if, in the judgment of such Purchaser such designation or assignment (i) would eliminate or reduce amounts payable pursuant to Section 3.01, 10.01 and 10.02, as the case may be, in the future, and (ii) in each case, would not subject such Purchaser to any unreimbursed cost or expense and would not otherwise be disadvantageous to such Purchaser. The Issuers hereby agree to pay all reasonable and documented out-of-pocket costs and expenses incurred by any Purchaser in connection with any such designation or assignment.

(b) Replacement of Purchasers. If any Purchaser requests compensation under Section 10.01 or 10.02, or if any Issuer is required to pay any Indemnified Taxes or additional amounts to any Purchaser or any Governmental Authority for the account of any Purchaser pursuant to Section 3.01, and, in each case, such Purchaser has declined or is unable to designate a different lending office in accordance with Section 10.04(a), the Issuer may replace such Purchaser in accordance with Section 12.13.

ARTICLE XI

COLLATERAL AGENT

11.01 Appointment and Authority.

(a) Each of the Purchasers hereby irrevocably appoints Athyrium Opportunities III Acquisition LP to act on its behalf as the Collateral Agent hereunder and under the other Note Documents and authorizes the Collateral Agent to take such actions on its behalf and to exercise such powers as are delegated to the Collateral Agent by the terms hereof or thereof, and to act as the agent of such Purchaser for purposes of acquiring, holding and enforcing any and all Liens on Collateral granted by any of the Note Parties to secure any of the Obligations, together with such powers and discretion as are incidental thereto. Except for the rights of the Issuers under Sections 11.06 and 11.09, the provisions of this Article are solely for the benefit of the Collateral Agent and the Purchasers, and neither the Issuers nor any other Note Party shall have rights as a third party beneficiary of any of such provisions. It is understood and agreed that the use of the term “agent” herein or in any other Note Documents (or any other similar term) with reference to the Collateral Agent is not intended to connote any fiduciary or other implied (or express) obligations arising under agency doctrine of any applicable Law. Instead such term is used as a matter of market custom, and is intended to create or reflect only an administrative relationship between contracting parties.

(b) In this connection, the Collateral Agent and any co-agents, sub-agents and attorneys-in-fact appointed by the Collateral Agent pursuant to Section 11.05 for purposes of holding or enforcing any Lien on the Collateral (or any portion thereof) granted under the Collateral Documents,

or for exercising any rights and remedies thereunder at the direction of the Collateral Agent), shall be entitled to the benefits of all provisions of this Article XI and Article XII, as though such co-agents, sub-agents and attorneys-in-fact were the “collateral agent” under the Note Documents) as if set forth in full herein with respect thereto.

#### 11.02 Rights as a Purchaser.

The Person serving as the Collateral Agent hereunder shall have the same rights and powers in its capacity as a Purchaser as any other Purchaser and may exercise the same as though it were not the Collateral Agent and the term “Purchaser” or “Purchasers” shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Collateral Agent hereunder in its individual capacity. Such Person and its Affiliates may accept deposits from, lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with any Note Party or any Subsidiary or other Affiliate thereof as if such Person were not the Collateral Agent hereunder and without any duty to account therefor to the Purchasers.

#### 11.03 Exculpatory Provisions.

The Collateral Agent shall not have any duties or obligations except those expressly set forth herein and in the other Note Documents, and its duties hereunder shall be administrative in nature. Without limiting the generality of the foregoing, the Collateral Agent:

(a) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default has occurred and is continuing;

(b) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Note Documents that the Collateral Agent is required to exercise as directed in writing by the Required Purchasers (or such other number or percentage of the Purchasers as shall be expressly provided for herein or in the other Note Documents), provided, that, the Collateral Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Collateral Agent to liability or that is contrary to any Note Document or applicable law, including for the avoidance of doubt any action that may be in violation of the automatic stay under any Debtor Relief Law; and

(c) shall not, except as expressly set forth herein and in the other Note Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to any Note Party or any of its Affiliates that is communicated to or obtained by the Person serving as the Collateral Agent or any of its Affiliates in any capacity.

The Collateral Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Purchasers (or such other number or percentage of the Purchasers as shall be necessary, or as the Collateral Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 12.01 and Section 9.02) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment. The Collateral Agent shall be deemed not to have knowledge of any Default unless and until notice describing such Default is given in writing to the Collateral Agent by an Issuer, or a Purchaser.

The Collateral Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Note Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder

or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Note Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Article V or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Collateral Agent.

#### 11.04 Reliance by Collateral Agent.

The Collateral Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, Internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Collateral Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. In determining compliance with any condition hereunder to the purchase of any Note, that by its terms must be fulfilled to the satisfaction of a Purchaser, the Collateral Agent may presume that such condition is satisfactory to such Purchaser unless the Collateral Agent shall have received notice to the contrary from such Purchaser prior to the purchase of such Note. The Collateral Agent may consult with legal counsel (who may be counsel for the Note Parties), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.

#### 11.05 Delegation of Duties.

The Collateral Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Note Document by or through any one or more sub-agents appointed by the Collateral Agent. The Collateral Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Article shall apply to any such sub-agent and to the Related Parties of the Collateral Agent and any such sub-agent, and shall apply to their respective activities in connection with the syndication of the credit facilities provided for herein as well as activities as Collateral Agent. The Collateral Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and non-appealable judgment that the Collateral Agent acted with gross negligence or willful misconduct in the selection of such sub-agents.

#### 11.06 Resignation of Collateral Agent.

The Collateral Agent may resign as Collateral Agent at any time by giving thirty (30) days advance written notice thereof to the Purchasers and the Issuers and, thereafter, the retiring (or retired) or terminated Collateral Agent shall be discharged from its duties and obligations hereunder. Upon any such resignation, the Required Purchasers shall have the right, subject to the approval of the Issuers (so long as no Event of Default has occurred and is continuing; such approval not to be unreasonably withheld), to appoint a successor Collateral Agent. If no successor Collateral Agent shall have been so appointed by the Required Purchasers, been approved (so long as no Event of Default has occurred and is continuing) by the Issuers or have accepted such appointment within thirty (30) days after the Collateral Agent's giving of notice of resignation, then the Collateral Agent may, on behalf of the Purchasers, appoint a successor Collateral Agent reasonably acceptable to the Issuers (so long as no Default or Event of Default has occurred and is continuing). Upon the acceptance of any appointment as Collateral Agent hereunder by a successor Collateral Agent, such successor Collateral Agent shall thereupon succeed to and become vested with all rights, powers, privileges

and duties of the retiring (or retired) or terminated Collateral Agent. After any retiring Collateral Agent's resignation hereunder as Collateral Agent, the provisions of this Agreement shall continue in effect for its benefit in respect of any actions taken or omitted to be taken by it while it was acting as Collateral Agent. If no successor has accepted appointment as Collateral Agent by the date which is thirty (30) days following a retiring Collateral Agent's notice of resignation or notice of Collateral Agent's removal, the retiring Collateral Agent's resignation shall nevertheless thereupon become effective and the Required Purchasers shall perform all of the duties of the Collateral Agent hereunder until such time, if any, as the Required Purchasers appoint a successor agent as provided for above. In the event that a new Collateral Agent is appointed and such Collateral Agent is not an Affiliate of the holders of a majority in interest of the Notes, then the Issuers shall agree to pay to such Collateral Agent the fees and expenses (such fees to be payable annually in advance) that such Collateral Agent may reasonably request in connection with its appointment and service.

#### 11.07 Non-Reliance on Collateral Agent and Other Purchasers.

Each Purchaser acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Purchaser or any of their Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement. Each Purchaser also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Purchaser or any of their Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Note Document or any related agreement or any document furnished hereunder or thereunder.

#### 11.08 Collateral Agent May File Proofs of Claim.

In case of the pendency of any receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition or other judicial proceeding relative to any Note Party, the Collateral Agent (irrespective of whether the principal of any Note shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Collateral Agent shall have made any demand on the Issuers) shall be entitled and empowered, by intervention in such proceeding or otherwise:

(a) to file and prove a claim for the whole amount of the principal and interest owing and unpaid in respect of the Notes and all other Obligations that are owing and unpaid and to file such other documents as may be necessary or advisable in order to have the claims of the Purchasers and the Collateral Agent (including any claim for the reasonable compensation, expenses, disbursements and advances of the Purchasers and the Collateral Agent and their respective agents and counsel and all other amounts due the Purchasers and the Collateral Agent under Section 12.04) allowed in such judicial proceeding; and

(b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, assignee, trustee, liquidator, sequestrator or other similar official in any such judicial proceeding is hereby authorized by each Purchaser to make such payments to the Collateral Agent and, in the event that the Collateral Agent shall consent to the making of such payments directly to the Purchasers, to pay to the Collateral Agent any amount due for the reasonable compensation, expenses, disbursements and advances of the Collateral Agent and its agents and counsel, and any other amounts due the Collateral Agent under Section 12.04.

Nothing contained herein shall be deemed to authorize the Collateral Agent to authorize or consent to or accept or adopt on behalf of any Purchaser any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Purchaser or to authorize the Collateral Agent to vote in respect of the claim of any Purchaser in any such proceeding.

#### 11.09 Collateral and Guaranty Matters.

The Purchasers irrevocably authorize the Collateral Agent and Collateral Agent agrees at the request of the Issuers,

(a) to release any Lien on any Collateral granted to or held by the Collateral Agent under any Note Document (i) upon payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Note Documents, (ii) that is sold or otherwise disposed of to a Person other than a Note Party or Subsidiary as part of or in connection with any sale or other Disposition permitted hereunder or under any other Note Document or any Involuntary Disposition, or (iii) as approved in accordance with Section 12.01;

(b) to release or subordinate any Lien on any property granted to or held by the Collateral Agent under any Note Document to the holder of any Lien on such property that is permitted by Section 8.01(i); and

(c) to release any Guarantor from its obligations under the Guaranty (i) if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Note Documents or (ii) upon termination of all unused Delayed Draw Note Commitments and payment in full of all Obligations (other than contingent indemnification obligations for such no claim has been asserted) under the Note Documents.

Upon request by the Collateral Agent at any time, the Required Purchasers will confirm in writing the Collateral Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor from its obligations under the Guaranty, pursuant to this Section 11.09.

The Collateral Agent shall not be responsible for or have a duty to ascertain or inquire into any representation or warranty regarding the existence, value or collectability of the Collateral, the existence, priority or perfection of the Collateral Agent's Lien thereon, or any certificate prepared by any Note Party in connection therewith, nor shall the Collateral Agent be responsible or liable to the Purchasers for any failure to monitor or maintain any portion of the Collateral.

In connection with any termination, release or subordination pursuant to this Section 11.09, Collateral Agent shall promptly, upon the request of any Note Party, (x) execute and deliver to such Note Party, at such Note Party's expense, all documents that such Note Party shall reasonably request to evidence such termination, release or subordination, and (y) deliver to the Note Parties, at the expense of the Note Parties, any portion of such Collateral so released in possession of the Collateral Agent.

## ARTICLE XII

### MISCELLANEOUS

#### 12.01 Amendments, Etc.

No amendment or waiver of any provision of this Agreement or any other Note Document, and no consent to any departure by any Issuer or any other Note Party therefrom, shall be effective unless in writing signed by the Required Purchasers and the Issuers or the applicable Note Party, as the case may be, and acknowledged by the Collateral Agent and each such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; provided, further, that:

(a) no such amendment, waiver or consent shall:

(i) extend or increase the Delayed Draw Note Commitment of a Purchaser (or reinstate any Delayed Draw Note Commitment terminated pursuant to Section 9.02) without the written consent of such Purchaser whose Delayed Draw Note Commitment is being extended or increased (it being understood and agreed that a waiver of any condition precedent set forth in Section 5.02 or 5.03 or of any Default or a mandatory reduction in Delayed Draw Note Commitments is not considered an extension or increase in Delayed Draw Note Commitments of any Purchaser);

(ii) postpone any date fixed by this Agreement or any other Note Document for any payment of principal (excluding mandatory prepayments), interest, prepayment premiums, fees or other amounts due to the Purchasers (or any of them) or any scheduled or mandatory reduction of the Delayed Draw Note Commitments hereunder or under any other Note Document without the written consent of each Purchaser entitled to receive such payment or whose Delayed Draw Note Commitments are to be reduced;

(iii) reduce the principal of, the rate of interest specified herein on or the prepayment premium specified herein for any Note, or any fees or other amounts payable hereunder or under any other Note Document without the written consent of each Purchaser entitled to receive such payment of principal, interest, fees or other amounts; provided, however, that, only the consent of the Required Purchasers shall be necessary to amend the definition of "Default Rate" or to waive any obligation of the Issuers to pay interest at the Default Rate;

(iv) change any provision of this Section 12.01(a) or the definition of "Required Purchasers" without the written consent of each Purchaser directly affected thereby;

(v) except in connection with a Disposition permitted under Section 8.05, release all or substantially all of the Collateral without the written consent of each Purchaser directly affected thereby, except to the extent the release of any Collateral is permitted pursuant to Section 11.09 (in which case such release may be made by the Collateral Agent);

(vi) release the Issuers or, except in connection with a merger, amalgamation or consolidation permitted under Section 8.04 or a Disposition permitted under Section 8.05, all or substantially all of the Guarantors without the written consent of each Purchaser directly affected thereby, except to the extent the release of any Guarantor is permitted pursuant to Section 11.10 (in which case such release may be made by the Collateral Agent);

(b) unless also signed by the Collateral Agent, no amendment, waiver or consent shall affect the rights or duties of the Collateral Agent under this Agreement or any other Note Document;

(c) any amendment or waiver pursuant to this Section 12.01 shall apply equally to all holders of the Notes and shall be binding upon them, upon each future holder of the Notes and upon the Note Parties, and shall amend the Notes, in each case whether or not a notation thereof shall have been placed on any such Note. Any such waiver shall be effective only in the specific instance and for the purpose for which given;

(d) notwithstanding any other provision contained in this Section 12.01 or elsewhere in this Agreement to the contrary, Notes which at any time are held by the Issuers or by any of their Affiliates shall not be deemed outstanding for purposes of any vote, consent, approval, waiver or other action required or permitted to be taken by the holders of Notes, or by any of them, under the provisions of this Section 12.01 or Section 9.02 of this Agreement, and neither the Issuers nor any of their Affiliates shall be entitled to exercise any right as a Purchaser or holder of Notes with respect to any such vote, consent, approval or waiver or to take or participate in taking any such action at any time; and

(e) Neither the Issuers nor any of their Affiliates will, directly or indirectly, pay or cause to be paid any remuneration, whether by way of supplemental or additional interest, fee or otherwise, to any Purchaser as consideration for or as an inducement to the entering into by any Purchaser of any amendment, waiver or consent with respect to any of the terms and provisions of this Agreement or the other Note Documents, unless such remuneration is concurrently offered, on the same terms, ratably to all of holders of Notes which agree to such amendment, waiver or consent.

provided, however, that, notwithstanding anything to the contrary herein, (i) no Defaulting Purchaser shall have any right to approve or disapprove any amendment, waiver or consent hereunder (and any amendment, waiver or consent which by its terms requires the consent of all Purchasers or each affected Purchaser may be effected with the consent of the applicable Purchasers other than Defaulting Purchasers), except that (x) the undrawn Delayed Draw Note Commitment of any Defaulting Purchaser may not be increased or extended without the consent of such Purchaser and (y) any waiver, amendment or modification requiring the consent of all Purchasers or each affected Purchaser that by its terms affects any Defaulting Purchaser more adversely than other affected Purchasers shall require the consent of such Defaulting Purchaser, (ii) each Purchaser is entitled to vote as such Purchaser sees fit on any bankruptcy reorganization plan that affects the Notes, and each Purchaser acknowledges that the provisions of Section 1126(c) of the Bankruptcy Code of the United States supersedes the unanimous consent provisions set forth herein and (iii) the Required Purchasers shall determine whether or not to allow an Issuer to use cash collateral in the context of a bankruptcy or insolvency proceeding and such determination shall be binding on all of the Purchasers.

Notwithstanding anything to the contrary herein, the Collateral Agent and the Issuers may amend or modify this Agreement and any other Note Document to (1) cure any factual or typographical error, omission, defect or inconsistency therein, or (2) grant a new Lien for the benefit of the Purchasers, extend an additional Lien over additional property for the benefit of the Purchasers or join additional Persons as Note Parties.

#### 12.02 Notices and Other Communications; E-mail and Facsimile Copies.

(a) Notices Generally. Except in the case of notices and other communications expressly permitted to be given by telephone (and except as provided in subsection (b) below), all notices and other communications provided for herein shall be in writing and shall be delivered by



hand or overnight courier service, mailed by certified or registered mail or sent by facsimile or electronic mail as follows, and all notices and other communications expressly permitted hereunder to be given by telephone shall be made to the applicable telephone number, in each case to the address, facsimile number, electronic mail address or telephone number specified for the Issuers, the other Note Parties (as of the Closing Date), and for the Purchasers (as of the Closing Date) and the Collateral Agent, as set forth on Schedule 12.02.

Notices and other communications sent by hand or overnight courier service, or mailed by certified or registered mail, shall be deemed to have been given when received; notices and other communications sent by facsimile shall be deemed to have been given when sent (except that, if not given during normal business hours for the recipient, shall be deemed to have been given at the opening of business on the next Business Day for the recipient). Notices and other communications delivered through electronic communications to the extent provided in subsection (b) below, shall be effective as provided in such subsection (b).

(b) Electronic Communications. Notices and other communications to the Collateral Agent or Purchasers hereunder may be furnished by electronic communication (including e-mail and Internet or intranet websites) pursuant to procedures approved by the Collateral Agent, provided, that, the foregoing shall not apply to notices to any Purchaser pursuant to Article II if such Purchaser has notified the Collateral Agent that it is incapable of receiving notices under such Article by electronic communication. Each of the Issuers, other Note Parties, the Collateral Agent and the Purchasers may each, in its discretion, agree to accept notices and other communications to it hereunder by electronic communications pursuant to procedures approved by it, provided, that, approval of such procedures may be limited to particular notices or communications.

Unless the applicable recipient otherwise prescribes, (i) notices and other communications sent to an e-mail address shall be deemed received upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested" function, as available, return e-mail or other written acknowledgement; provided that any notice or communication not so acknowledged shall be deemed received one (1) Business Day following delivery), and (ii) notices or communications posted to an Internet or intranet website shall be deemed received upon the deemed receipt by the intended recipient at its e-mail address as described in the foregoing clause (i) of notification that such notice or communication is available and identifying the website address therefor; provided, that, for both clauses (i) and (ii), if such notice, email or other communication is not sent during the normal business hours of the recipient, such notice, email or communication shall be deemed to have been sent at the opening of business on the next business day for the recipient.

(c) Change of Address, Etc. Each of the Issuers, other Note Parties, the Purchasers and the Collateral Agent may change its address, facsimile or telephone number for notices and other communications hereunder by notice to the other parties hereto.

(d) Reliance by Collateral Agent and Purchasers. The Collateral Agent and the Purchasers shall be entitled to rely and act upon any notices purportedly given by or on behalf of any Note Party even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Note Parties shall indemnify the Collateral Agent, each Purchaser and the Related Parties of each of them in accordance with Section 12.04 from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of a Note Party; provided that such indemnity

shall not, as to any Person be available to the extent that such losses, costs, expenses or liabilities are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from the gross negligence or willful misconduct of such Person. All telephonic notices to and other telephonic communications with the Collateral Agent may be recorded by the Collateral Agent (subject to contemporaneous notice from the Collateral Agent to such Person that the communication is being or will be recorded), and each of the parties hereto hereby consents to such recording.

#### 12.03 No Waiver; Cumulative Remedies; Enforcement.

No failure by any Purchaser or the Collateral Agent to exercise, and no delay by any such Person in exercising, any right, remedy, power or privilege hereunder or under any other Note Document shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided, and provided under each other Note Document, are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

#### 12.04 Expenses; Indemnity; and Damage Waiver.

(a) Costs and Expenses. The Note Parties shall pay (i) all reasonable and documented out-of-pocket expenses incurred by the Collateral Agent, each Purchaser and their respective Affiliates (limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Collateral Agent and the Purchasers (taken as a whole) and of a single local counsel to the Collateral Agent and the Purchasers (taken as a whole) in each relevant jurisdiction), in connection with (A) the preparation, negotiation, execution and delivery of this Agreement and the other Note Documents and (B) any amendments, modifications or waivers of the provisions hereof or thereof (whether or not the transactions contemplated hereby or thereby shall be consummated) or the administration of this Agreement and the other Note Documents and (ii) all reasonable and documented out-of-pocket expenses incurred by the Collateral Agent or any Purchaser (but limited in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Collateral Agent and the Purchasers (taken as a whole), and, of a single local counsel to the Collateral Agent and the Purchasers (taken as a whole) in each relevant jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs the Issuers of such conflict and thereafter retains its own counsel, of one additional primary firm of counsel for all such affected parties (taken as a whole) and one additional firm of counsel for all such affected parties (taken as a whole) in each relevant jurisdiction), in connection with the enforcement or protection of its rights (A) in connection with this Agreement and the other Note Documents, including its rights under this Section, or (B) in connection with the Notes made hereunder, including all such out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Notes. It is understood and agreed that the Note Parties shall not be required to pay costs, fees and expenses incurred prior to the Closing Date in connection with the preparation, negotiation, execution and delivery of this Agreement, the other Note Documents dated as of the Closing Date, and the issuance and purchase of the Initial Notes in excess of \$250,000.

#### (b) Indemnification by the Note Parties.

(i) The Note Parties shall indemnify the Collateral Agent (and any sub-agent thereof) and each Purchaser, and each Related Party of any of the foregoing Persons (each

such Person being called an “Indemnitee”) against, and hold each Indemnitee harmless from, any and all losses, claims, damages, liabilities and related expenses (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Indemnitees (taken as a whole), and, of a single local counsel to the Indemnitees (taken as a whole) in each relevant jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs the Issuers of such conflict and thereafter retains its own counsel, of one additional primary firm of counsel for all such affected parties (taken as a whole) and one additional firm of counsel for all such affected parties (taken as a whole) in each relevant jurisdiction), incurred by any Indemnitee or asserted against any Indemnitee by any Person (including the Issuers or any other Note Party) arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Note Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, or, in the case of the Collateral Agent (and any sub-agent thereof) and its Related Parties only, the administration of this Agreement and the other Note Documents, (ii) any Note or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of Hazardous Materials on or from any property owned or operated by a Note Party or any of its Subsidiaries, or any Environmental Liability related in any way to a Note Party or any of its Subsidiaries, or (iv) any actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by a third party or by any Issuer or any other Note Party, and regardless of whether any Indemnitee is a party thereto, in all cases, whether or not caused by or arising, in whole or in part, out of the comparative, contributory or sole negligence of the Indemnitee; provided, that, such indemnity shall not, as to any Indemnitee, be available to the extent that such losses, claims, damages, liabilities or related expenses (i) are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from (A) the gross negligence, or willful misconduct of such Indemnitee, or (B) a claim brought by any Note Party against an Indemnitee for material breach of such Indemnitee’s obligations hereunder or under any other Note Document, or (ii) arise solely from a dispute among the Indemnitees (except (1) when and to the extent that one of the Indemnitees party to such dispute was acting in its capacity or in fulfilling its role as Collateral Agent, or any similar role under this Agreement or any other Note Document or (2) any claims arising out of any act or omission of any of the Note Parties or any of their Affiliates) that does not involve any act or omission of the Note Parties or any of their respective Affiliates. This Section 12.04(b) shall not apply with respect to (x) Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any third party claim or any other non-Tax claim and (y) yield protection matters covered by Sections 10.01 and 10.02, which shall be governed exclusively by Sections 10.01 and 10.02.

(ii) Notwithstanding the foregoing in this Section 12.04(b), the Issuers shall not be liable for any settlement of any proceeding effected without the Issuers’ consent (which consent shall not be unreasonably withheld, delayed or conditioned), but if settled with the Issuers’ written consent, or if there is a judgment against an Indemnitee in any such proceeding, the Issuers shall indemnify and hold harmless each Indemnitee to the extent and in the manner set forth above. The Issuers shall not, without the prior written consent of an Indemnitee (which consent shall not be unreasonably withheld, conditioned or delayed), effect any settlement of any pending or threatened proceeding against such Indemnitee in

respect of which indemnity could have been sought hereunder by such Indemnitee unless (a) such settlement includes an unconditional release of such Indemnitee from all liability or claims that are the subject matter of, or arise out of, such proceeding and (b) such settlement does not include any statement as to, or any admission of fault, culpability, wrongdoing or a failure to act by or on behalf of such Indemnitee.

(c) Waiver of Consequential Damages, Etc. To the fullest extent permitted by applicable law, none of the Note Parties, the Collateral Agent, any Purchaser, any other party thereto or any Indemnitee shall assert, and each such Person hereby waives, and acknowledges that no other Person shall have, any claim against any other such Person, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) arising out of, in connection with, or as a result of, this Agreement, any other Note Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Note or the use of the proceeds thereof; provided, that, the foregoing shall in no event limit the indemnification obligations of the Note Parties under subsection (b) above to the extent such special, indirect, consequential or punitive damages are included in any third party claim in connection with which such Indemnitee is otherwise entitled to indemnification hereunder. No Indemnitee referred to in subsection (b) above shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Note Documents or the transactions contemplated hereby or thereby, other than any liability arising from the gross negligence, or willful misconduct of such Indemnitee as determined by a court of competent jurisdiction by final and nonappealable judgment.

(d) Payments. All amounts due under this Section shall be payable not later than ten Business Days after demand therefor.

(e) Survival. The agreements in this Section and the indemnity provisions of Section 12.02(d) shall survive the resignation of the Collateral Agent, the transfer of any Note, the replacement of any Purchaser, the termination of the Delayed Draw Note Commitments and the repayment, satisfaction or discharge of all the other Obligations.

#### 12.05 Marshalling; Payments Set Aside.

None of the Collateral Agent or the Purchasers shall be under any obligation to marshal any assets in favor of any Note Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any payment by or on behalf of any Note Party is made to the Collateral Agent or any Purchaser, or the Collateral Agent or any Purchaser exercises its right of setoff, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by the Collateral Agent or such Purchaser in its discretion) to be repaid to a trustee, receiver or any other party, in connection with any proceeding under any Debtor Relief Law or otherwise, then to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred.

#### 12.06 Successors and Assigns; Transfers.

(a) Successors and Assigns Generally. The provisions of this Agreement and the other Note Documents shall be binding upon and inure to the benefit of the parties hereto and thereto and

their respective successors and assigns permitted hereby, except that the Issuers and the other Note Parties may not assign or otherwise transfer any of their respective rights or obligations hereunder or thereunder without the prior written consent of the Purchasers and, except as otherwise set forth herein, so long as no Default or Event of Default has occurred and is continuing, no Purchaser may assign or otherwise transfer any of its rights or obligations hereunder except with the prior written consent of the Issuers. Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, and, to the extent expressly contemplated hereby, the Related Parties of each of the Collateral Agent and the Purchasers) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) Transfers by Purchasers. Each Purchaser shall be entitled to transfer, with the consent of the Issuers, such consent not to be unreasonably withheld or delayed (it being understood that the Issuers' consent may be withheld or delayed pending resolution of the amendments to the Note Documents contemplated by Section 12.06(i)) and not required for a transfer (x) to or in favor of any Affiliate of such Purchaser or any Approved Fund (or a limited partner or other investor in an Approved Fund, so long as after giving effect to such transfer, Athyrium Opportunities III Acquisition LP and its Approved Funds collectively constitute Required Purchasers) or (y) during the continuance of an Event of Default, (i) Notes, in an aggregate principal amount greater than or equal to \$1,000,000 thereof (*provided* that in the case of a transfer of Notes to or in favor of any Affiliate of such Purchaser or any Approved Fund (or a limited partner or other investor in an Approved Fund, so long as after giving effect to such transfer, Athyrium Opportunities III Acquisition LP and its Approved Funds collectively constitute Required Purchasers), no minimum shall apply); and (ii) Delayed Draw Note Commitments (with the consent of the Required Purchasers, which is not required for a transfer to or in favor of any Affiliate of such Purchaser or any or any Approved Fund (or a limited partner or other investor in an Approved Fund, so long as after giving effect to such transfer, (x) Athyrium Opportunities III Acquisition LP and its Approved Funds collectively constitute Required Purchasers and (y) the transferring Purchaser remains obligated to fund the amount of its transferred Delayed Draw Note Commitments if the transferee fails to fund when required to do so pursuant to the terms hereof); *provided* that in no event shall any equityholder of Parent (other than a Purchaser, its Affiliates or any Approved Fund (or a limited partner or other investor in an Approved Fund, so long as after giving effect to such transfer, Athyrium Opportunities III Acquisition LP and its Approved Funds collectively constitute Required Purchasers)) or any Subsidiary or any of their respective Affiliates purchase or be the recipient of a transfer of any Note without the prior written consent of the Required Purchasers; *provided, further*, that in no event shall a Defaulting Purchaser purchase or be the recipient of a transfer of any Note or Delayed Draw Note Commitment while such Purchaser is a Defaulting Purchaser; *provided, further*, so long as no Event of Default has occurred and is continuing, in no event shall any Competitor, any of its Subsidiaries or any of their respective Affiliates purchase or be the recipient of a transfer of any Note or Delayed Draw Note Commitment at any time. Each transferee pursuant to this Section 12.06(b) shall provide the Issuer and the Collateral Agent with (i) prompt written notice of any transfer that is effected and (ii) concurrently with any such transfer, an officer's certificate from an authorized Person of such transferee certifying to the matters contemplated by Article VI-A. All transfers pursuant to this Section 12.06(b) shall be made in accordance with all applicable requirements of the Securities Act of 1933 and any applicable securities laws of any U.S. state.

(c) Transfers by Defaulting Purchasers. In connection with any assignment of rights and obligations of any Defaulting Purchaser hereunder, no such assignment shall be effective unless and until, in addition to the other conditions thereto set forth herein, the parties to the assignment

shall make such additional payments to the Collateral Agent in an aggregate amount sufficient, upon distribution thereof as appropriate (which may be outright payment, purchases by the assignee of participations or subparticipations, or other compensating actions, including funding, with the consent of the Parent and the Collateral Agent, the applicable pro rata share of Notes previously issued but not purchased by the Defaulting Purchaser, to each of which the applicable assignee and assignor hereby irrevocably consent), to (x) pay and satisfy in full all payment liabilities then owed by such Defaulting Purchaser to the Collateral Agent or any Purchaser hereunder (and interest accrued thereon) and (y) purchase (and fund as appropriate) its full pro rata share of all Notes. Notwithstanding the foregoing, in the event that any assignment of rights and obligations of any Defaulting Purchaser hereunder shall become effective under applicable Law without compliance with the provisions of this paragraph, then the assignee of such interest shall be deemed to be a Defaulting Purchaser for all purposes of this Agreement until such compliance occurs.

(d) Transfer in Contravention of this Section Void. Any attempt to transfer any Note or portion thereof not in compliance with this Agreement shall be null and void and neither the Issuers nor any transfer agent shall give any effect in the Issuers' Note register to such attempted transfer.

(e) No Future Liability. Following the sale of any Note or portion thereof by the Purchasers to any subsequent Purchasers pursuant to the terms hereof, the Purchasers shall not be liable or responsible to the Issuers for any losses, damages or liabilities suffered or incurred by the Issuers, including any losses, damages or liabilities under the Securities Act, arising from or relating to any resale or transfer of any security previously sold by the Purchaser in compliance with this Section 12.06.

(f) Securities Register. Each Issuer will keep at its principal executive office a register, in which, subject to such reasonable regulations as it may prescribe, but at its expense, and such Issuer will provide for the registration and transfer of Notes. Whenever any Note shall be surrendered either at the principal executive office of such Issuer (or at the place of payment named in the Note), for transfer or exchange, accompanied, if so required by such Issuer, by a written instrument of transfer in form reasonably satisfactory to such Issuer duly executed by the holder thereof or by such holder's attorney duly authorized in writing, such Issuer will execute and deliver in exchange therefor a new Note or Notes, in such denominations as may be requested by such holder, of like tenor and in the same aggregate unpaid principal amount as the aggregate unpaid principal amount of the Note or Notes so surrendered. Any Note issued in exchange for any other Note or upon transfer thereof shall carry the rights to unpaid interest and interest to accrue which were carried by the Note so exchanged or transferred, and neither gain nor loss of interest shall result from any such transfer or exchange. Any transfer tax or governmental charge relating to such transaction shall be paid by the holder requesting the exchange. The entries in the register shall be conclusive and binding for all purposes, absent manifest error and such Issuer, the Purchasers and any of their respective agents may treat the Person in whose name any Note is registered as the sole and exclusive record and beneficial holder and owner of such Note for all purposes whatsoever. This Section 12.06(f) shall be construed so that such obligations are at all times maintained in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the Internal Revenue Code and any related regulations (and any other relevant or successor provisions of the Internal Revenue Code or such regulations).

(g) Lost, Stolen Damaged or Destroyed Notes. At the request of any holder of any Note, the applicable Issuer will issue and deliver at its expense, in replacement of any Note lost, stolen,

damaged or destroyed, upon surrender thereof, if mutilated, a new Note in the same aggregate unpaid principal amount, and otherwise of the same tenor, as the Note so lost, stolen, damaged or destroyed, duly executed by such Issuer. Such Issuer may condition the replacement of a Note reported by the holder thereof as lost, stolen, damaged or destroyed, upon the receipt from such holder of an indemnity and/or security reasonably satisfactory to such Issuer; *provided*, that if such holder shall be a Purchaser or any affiliate or nominee thereof, such Purchaser's unsecured agreement of indemnity shall be sufficient for purposes of this Section 12.06(g).

(h) Transfer of Delayed Draw Note Commitments. Subject to compliance with the other provisions of this Section 12.06, any transfer of Notes or Delayed Draw Note Commitments shall be effective upon the execution and delivery, by the transferor and the transferee (to the extent required by Section 12.06(b), with the consent of the Issuers and the Required Purchasers), pursuant to an Assignment and Assumption.

(i) Transfer to Non-Athyrium Affiliates. Prior to any transfer of Notes or Delayed Draw Note Commitments hereunder by a Purchaser to a Person that is not an Affiliate of Athyrium Opportunities II Acquisition LP or Athyrium Opportunities III Acquisition LP, the Purchasers, the Collateral Agent (or its prospective successor) and the Issuers shall negotiate in good faith to amend the Note Documents to provide for certain customary provisions contained in agreements evidencing secured debt held by multiple lenders or investors that are not Affiliates, including to permit the Issuers to make payments and deliver notices and other information hereunder solely to the Collateral Agent, acting on behalf of the Purchasers, and, if the Collateral Agent is also a Purchaser, permit the Collateral Agent to make certain additional determinations and take certain additional actions, including those with respect to Collateral, on behalf of the Purchasers, without their consent, not currently contemplated by the Note Documents to be made or taken by the Collateral Agent.

#### 12.07 Treatment of Certain Information; Confidentiality.

Each of the Collateral Agent and the Purchasers agrees to maintain the confidentiality of, and not disclose, the Information (as defined below), except that Information may be disclosed (a) to its Affiliates and to its Related Parties (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information prior to or upon such disclosure and instructed to keep such Information confidential and the Collateral Agent and Purchasers, as applicable, shall be responsible for any failure by such Related Parties to maintain the confidentiality thereof), (b) to the extent required or requested by any regulatory authority purporting to have jurisdiction over such Person or its Related Parties (including any self-regulatory authority, such as the National Association of Insurance Commissioners), in which case the disclosing party agrees, to the extent permitted by law, rule or regulation and reasonably practicable, to promptly inform the Issuers, except with respect to any audit or examination conducted by bank accountants or any regulatory authority, (c) to the extent required by applicable laws or regulations or by any subpoena or similar legal process; provided, that, (x) prior to any disclosure under this clause (c), the Collateral Agent or such Purchaser agrees to endeavor to provide the Issuers with prior notice thereof to the extent that the Collateral Agent or such Purchaser is permitted to provide such prior notice to the Issuers pursuant to the terms of applicable laws and regulations or such subpoena or legal process, as the case may be, and (y) any disclosure under this clause (c) pursuant to subpoena or similar legal process shall be limited solely to that portion of the Information as may be compelled by such subpoena or similar legal process, (d) to any other party hereto, (e) as may be reasonably necessary in connection with the exercise of any remedies hereunder or under any other Note Document or any action or proceeding relating to this Agreement or any other Note Document or the enforcement of rights hereunder or thereunder, (f) subject to

a written agreement containing provisions substantially the same as those of this Section, to (i) any assignee or transferee of, or any prospective assignee or transferee of, any of its rights and obligations under this Agreement or (ii) any actual or prospective party (or its Related Parties) to any swap, derivative or other transaction under which payments are to be made by reference to a Note Party and its obligations, this Agreement or payments hereunder, (g) on a confidential basis to (i) any rating agency in connection with rating the Issuers or their Subsidiaries or the credit facilities provided hereunder or (ii) the CUSIP Service Bureau or any similar agency in connection with the issuance and monitoring of CUSIP numbers or other market identifiers with respect to the credit facilities provided hereunder, (h) with the consent of the Issuers, (i) to the members of its investment committee (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and instructed to keep such Information confidential) or (j) to the extent such Information (x) becomes publicly available other than as a result of a breach of this Section or (y) becomes available to the Collateral Agent, any Purchaser or any of their respective Affiliates on a nonconfidential basis from a source other than the Note Parties who is not, to the knowledge of the Collateral Agent or such Purchaser, in breach of any obligation of confidentiality to any Note Party or Subsidiary with respect to such Information.

For purposes of this Section, “Information” means all information received from a Note Party or any Subsidiary relating to the Note Parties or any Subsidiary or any of their respective businesses, other than any such information that is available to the Collateral Agent or any Purchaser on a nonconfidential basis prior to disclosure by such Note Party or any Subsidiary. Any Person required to maintain the confidentiality of, and not disclose, Information as provided in this Section shall be considered to have complied with its obligation to do so if such Person has exercised the same degree of care to maintain the confidentiality of such Information as such Person would accord to its own confidential information.

#### 12.08 Set-off.

If an Event of Default shall have occurred and be continuing, each Purchaser and each of their respective Affiliates is hereby authorized at any time and from time to time, to the fullest extent permitted by applicable law, to set off and apply any and all deposits (general or special, time or demand, provisional or final, in whatever currency) at any time held and other obligations (in whatever currency) at any time owing by such Purchaser or any such Affiliate to or for the credit or the account of the Issuers or any other Note Party against any and all of the obligations of the Issuers or such Note Party now or hereafter existing under this Agreement or any other Note Document to such Purchaser or its Affiliates, irrespective of whether or not such Purchaser or Affiliate shall have made any demand under this Agreement or any other Note Document and although such obligations of the applicable Issuer or such Note Party may be contingent or unmatured or are owed to a branch office or Affiliate of such Purchaser different from the branch office or Affiliate holding such deposit or obligated on such indebtedness; provided, that, in the event that any Defaulting Purchaser shall exercise any such right of setoff, (x) all amounts so set off shall be paid over immediately to the Collateral Agent for further application in accordance with the provisions of Section 2.15 and, pending such payment, shall be segregated by such Defaulting Purchaser from its other funds and deemed held in trust for the benefit of the Collateral Agent and the Purchasers and (y) the Defaulting Purchaser shall provide promptly to the Collateral Agent a statement describing in reasonable detail the Obligations owing to such Defaulting Purchaser as to which it exercised such right of setoff. The rights of each Purchaser and their respective Affiliates under this Section are in addition to other rights and remedies (including other rights of setoff) that such Purchaser or their respective Affiliates may have. Each Purchaser agrees to notify the Issuers promptly after any such setoff and application, provided, that, the failure to give such notice shall not affect the validity of such setoff and application.



#### 12.09 Interest Rate Limitation.

Notwithstanding anything to the contrary contained in any Note Document, the interest paid or agreed to be paid under the Note Documents shall not exceed the maximum rate of non-usurious interest permitted by applicable Law (the “Maximum Rate”). If any Purchaser shall receive interest in an amount that exceeds the Maximum Rate, the excess interest shall be applied to the principal of the Notes or, if it exceeds such unpaid principal, refunded to the applicable Issuer. In determining whether the interest contracted for, charged, or received by the Collateral Agent or a Purchaser exceeds the Maximum Rate, such Person may, to the extent permitted by applicable Law, (a) characterize any payment that is not principal as an expense, fee, or premium rather than interest, (b) exclude voluntary prepayments and the effects thereof, and (c) amortize, prorate, allocate, and spread in equal or unequal parts the total amount of interest throughout the contemplated term of the Obligations hereunder.

#### 12.10 Counterparts; Integration; Effectiveness.

This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. This Agreement, the other Note Documents, the Purchasers or Collateral Agent, constitute the entire contract among the parties relating to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. “pdf” or “tif”) shall be effective as delivery of a manually executed counterpart of this Agreement.

#### 12.11 Survival of Representations and Warranties.

All representations and warranties made hereunder and in any other Note Document or other document delivered pursuant hereto or thereto or in connection herewith or therewith shall survive the execution and delivery hereof and thereof and shall continue in full force and effect as long as any Note or other Obligation (other than contingent indemnification obligations for which no claim has been asserted) hereunder shall remain unpaid or unsatisfied. Such representations and warranties have been or will be relied upon by the Collateral Agent and each Purchaser, regardless of any investigation made by the Collateral Agent or any Purchaser or on their behalf and notwithstanding that the Collateral Agent or any Purchaser may have had notice or knowledge of any Default at the time of any purchase of the Notes, and shall continue in full force and effect as long as any Note or any other Obligation (other than contingent indemnification obligations for which no claim has been asserted) hereunder shall remain unpaid or unsatisfied.

#### 12.12 Severability.

If any provision of this Agreement or the other Note Documents is held to be illegal, invalid or unenforceable, (a) the legality, validity and enforceability of the remaining provisions of this Agreement and the other Note Documents shall not be affected or impaired thereby and (b) the parties shall endeavor in good faith negotiations to replace the illegal, invalid or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the illegal, invalid or unenforceable provisions. The invalidity of a provision in a particular jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. Without limiting the foregoing provisions of this Section 12.12, if and to the extent that the enforceability of any provisions in this Agreement relating to Defaulting Purchasers shall be limited by Debtor Relief Laws, as determined in good faith by the Collateral Agent, then such provisions shall be deemed to be in effect only to the extent not so limited.

### 12.13 Replacement of Purchasers.

If any Issuer is entitled to replace a Purchaser pursuant to the provisions of Section 10.04, or if any Purchaser is a Defaulting Purchaser or a Non-Consenting Purchaser, then such Issuer may, at its sole expense and effort, upon written notice to such Purchaser and the Collateral Agent, require such Purchaser to assign and delegate, without recourse (in accordance with and subject to the restrictions contained in, and consents required by, Section 12.06), all of its interests, rights (other than its existing rights to payments pursuant to Section 3.01, 10.01 and 10.02) and obligations under this Agreement and the related Note Documents to an assignee that shall assume such obligations (which assignee may be another Purchaser, if a Purchaser accepts such assignment), provided, that:

(a) such Purchaser shall have received payment of an amount equal to one hundred percent (100%) of (x) the outstanding principal of its Notes, accrued interest thereon and all other amounts payable to it hereunder and under the other Note Documents (other than prepayment premium and exit fees) from the assignee (to the extent of such outstanding principal and accrued interest) or the Issuer (in the case of all other amounts) and (y) other than a Purchaser that is a Defaulting Purchaser pursuant to clause (a), (b) or (c) of the definition thereof, the prepayment premium required by Section 2.07(d) and the exit fee required by Section 2.10(b), in each case, from such Issuer, as if such assignment was a prepayment of one hundred percent (100%) of the outstanding principal amount of such assignor's Notes on the effective date of such assignment; and

(b) such assignment does not conflict with applicable Laws;

(c) in the case of any such assignment resulting from a claim for compensation under Section 10.01 or 10.02 or payments required to be made pursuant to Section 3.01, such assignment will result in a reduction in such compensation or payments thereafter; and

(d) in the case of any such assignment resulting from a Non-Consenting Purchaser's failure to consent to a proposed change, waiver, discharge or termination with respect to any Note Document, the applicable replacement bank, financial institution or fund consents to the proposed change, waiver, discharge or termination.

Notwithstanding anything to the contrary set forth herein, the failure by any Purchaser replaced pursuant to this Section 12.13 to execute and deliver an Assignment and Assumption shall not impair the validity of the removal of such Purchaser and the mandatory assignment of such Purchaser's Delayed Draw Commitments and outstanding Notes pursuant to this Section 12.13 shall nevertheless be effective without the execution by such Purchaser of an Assignment and Assumption.

A Purchaser shall not be required to make any such assignment or delegation if, prior thereto, as a result of a waiver by such Purchaser or otherwise, the circumstances entitling the applicable Issuer to require such assignment and delegation cease to apply.

### 12.14 Governing Law; Jurisdiction; Etc.

(a) GOVERNING LAW. THIS AGREEMENT AND THE OTHER NOTE DOCUMENTS (EXCEPT, AS TO ANY OTHER NOTE DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT (EXCEPT, AS

TO ANY OTHER NOTE DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

(b) SUBMISSION TO JURISDICTION. THE ISSUERS AND EACH OTHER NOTE PARTY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT THEY WILL NOT COMMENCE ANY ACTION, LITIGATION OR PROCEEDING OF ANY KIND OR DESCRIPTION, WHETHER IN LAW OR EQUITY, WHETHER IN CONTRACT OR IN TORT OR OTHERWISE, AGAINST THE COLLATERAL AGENT, ANY PURCHASER OR ANY RELATED PARTY OF THE FOREGOING IN ANY WAY RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT OR THE TRANSACTIONS RELATING HERETO OR THERETO, IN ANY OTHER FORUM OTHER THAN THE COURTS OF THE STATE OF NEW YORK AND ANY UNITED STATES DISTRICT COURT IN THE STATE OF NEW YORK, AND ANY APPELLATE COURT FROM ANY THEREOF LOCATED IN NEW YORK COUNTY, NEW YORK, AND EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY SUBMITS TO THE JURISDICTION OF SUCH COURTS AND AGREES THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION, LITIGATION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH NEW YORK STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. EACH OF THE PARTIES HERETO AGREES THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW. NOTHING IN THIS AGREEMENT OR IN ANY OTHER NOTE DOCUMENT SHALL AFFECT ANY RIGHT THAT THE COLLATERAL AGENT OR ANY PURCHASER MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT AGAINST THE ISSUERS OR ANY OTHER NOTE PARTY OR THEIR RESPECTIVE PROPERTIES IN THE COURTS OF ANY JURISDICTION.

(c) WAIVER OF VENUE. EACH PARTY HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY OBJECTION THAT ANY OF THEM MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT IN ANY COURT REFERRED TO IN PARAGRAPH (B) OF THIS SECTION. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(d) SERVICE OF PROCESS. EACH PARTY HERETO IRREVOCABLY CONSENTS TO SERVICE OF PROCESS IN THE MANNER PROVIDED FOR NOTICES IN SECTION 11.02. NOTHING IN THIS AGREEMENT WILL AFFECT THE RIGHT OF ANY PARTY HERETO TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY APPLICABLE LAW. THE NORWEGIAN ISSUER AND EACH OTHER NOTE PARTY NOT ORGANIZED IN THE UNITED STATES HEREBY IRREVOCABLY APPOINTS THE US ISSUER AS ITS AUTHORIZED AGENT UPON WHICH PROCESS MAY BE SERVED IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT, AND AGREES THAT SERVICE OF PROCESS UPON SUCH AGENT, AND WRITTEN NOTICE OF SAID SERVICE TO THE US ISSUER, BY THE PERSON SERVING THE SAME TO THE ADDRESS PROVIDED IN SCHEDULE 12.02, SHALL

CONSTITUTE EFFECTIVE SERVICE OF PROCESS ON THE NORWEGIAN ISSUER OR OTHER APPLICABLE NOTE PARTY IN ANY SUCH ACTION OR PROCEEDING.

12.15 Waiver of Right to Trial by Jury.

EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER NOTE DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE OTHER NOTE DOCUMENTS BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

12.16 Judgment Currency.

(a) If, for the purpose of obtaining judgment in any court, it is necessary to convert a sum owing hereunder in one currency into another currency, each party hereto agrees, to the fullest extent that it may effectively do so, that the rate of exchange used shall be that at which in accordance with normal banking procedures in the relevant jurisdiction the first currency could be purchased with such other currency on the Business Day immediately preceding the day on which final judgment is given.

(b) The obligations of any Note Party in respect of any sum due to any party hereto or any holder of the Obligations owing hereunder (the "Applicable Creditor") shall, notwithstanding any judgment in a currency (the "Judgment Currency") other than the currency in which such sum is stated to be due hereunder (the "Agreement Currency"), be discharged only to the extent that, on the Business Day following receipt by the Applicable Creditor of any sum adjudged to be so due in the Judgment Currency, the Applicable Creditor may in accordance with normal banking procedures in the relevant jurisdiction purchase the Agreement Currency with the Judgment Currency; if the amount of the Agreement Currency so purchased is less than the sum originally due to the Applicable Creditor in the Agreement Currency, each Note Party agrees, as a separate obligation and notwithstanding any such judgment, to indemnify the Applicable Creditor against such loss. The obligations of the Note Parties contained in this Section 12.16 shall survive the termination of this Agreement and the payment of all other amounts owing hereunder.

12.17 Electronic Execution of Assignments and Certain Other Documents.

The words "execute," "execution," "signed," "signature" and words of like import in any Assignment and Assumption or in any amendment or other modification hereof (including waivers and consents) shall be deemed to include electronic signatures, the electronic matching of terms and contract formations on electronic platforms approved by the Purchasers, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

#### 12.18 USA PATRIOT Act.

Each Purchaser that is subject to the Act (as hereinafter defined) and the Collateral Agent (for itself and not on behalf of any Purchaser) hereby notifies the Issuers and the other Note Parties that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the “Act”), it is required to obtain, verify and record information that identifies each Note Party, which information includes the name and address of each Note Party and other information that will allow such Purchaser or the Collateral Agent, as applicable, to identify each Note Party in accordance with the Act. The Issuers and other Note Parties agree to, promptly following a request by the Collateral Agent or any Purchaser, provide all such other documentation and information that the Collateral Agent or such Purchaser requests in order to comply with its ongoing obligations under applicable “know your customer” and anti-money laundering rules and regulations, including the Act.

#### 12.19 No Advisory or Fiduciary Relationship.

In connection with all aspects of each transaction contemplated hereby (including in connection with any amendment, waiver or other modification hereof or of any other Note Document), the Issuers acknowledge and agree, and acknowledge their Affiliates’ understanding, that: (a)(i) the arranging and other services regarding this Agreement provided by the Collateral Agent, Athyrium, and the Purchasers are arm’s-length commercial transactions between the Issuers and their Affiliates, on the one hand, and the Collateral Agent, Athyrium and the Purchasers on the other hand, (ii) the Issuers have consulted their own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate, and (iii) the Issuers are capable of evaluating, and understand and accept, the terms, risks and conditions of the transactions contemplated hereby and by the other Note Documents; (b)(i) the Collateral Agent, Athyrium and each Purchaser is and has been acting solely as a principal and, except as expressly agreed in writing by the relevant parties, has not been, is not and will not be acting as an advisor, agent or fiduciary, for the Issuers or any of their Affiliates or any other Person and (ii) neither the Collateral Agent nor any Purchaser has any obligation to the Issuers or any of their Affiliates with respect to the transactions contemplated hereby except those obligations expressly set forth herein and in the other Note Documents; and (c) the Collateral Agent, Athyrium and the Purchasers and their respective Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Issuers and their Affiliates, and neither the Collateral Agent, Athyrium nor any Purchaser has any obligation to disclose any of such interests to the Issuers or their Affiliates. To the fullest extent permitted by law, the Issuers hereby waive and release, any claims that they may have against the Collateral Agent, Athyrium or any Purchaser with respect to any breach or alleged breach of agency or fiduciary duty in connection with any aspect of any transaction contemplated hereby.

#### 12.20 Acknowledgement and Consent to Bail-In of EEA Financial Institutions.

Notwithstanding anything to the contrary in any Note Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Purchaser that is an EEA Financial Institution arising under any Note Document, to the extent such liability is unsecured, may be subject to the write-down and conversion powers of an EEA Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by (a) the application of any Write-Down and Conversion Powers by an EEA Resolution Authority to any such liabilities arising hereunder which may be payable to it by any Purchaser that is an EEA Financial Institution; and (b) the effects of any Bail-In Action on any such liability, including, if applicable: (i) a reduction in full or in part or cancellation of any such liability; (ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such EEA Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership

will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Note Document; or (iii) the variation of the terms of such liability in connection with the exercise of the write-down and conversion powers of any EEA Resolution Authority.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

ISSUERS:OPTINOSE AS,

a Norwegian private limited liability company

By: /s/ Helena Djupesland  
Name: Helena Djupesland  
Title: Member of the Board of Directors

By: /s/ Per Djupesland  
Name: Per Djupesland  
Title: Member of the Board of Directors

OPTINOSE

US, INC.,  
a Delaware corporation

By: /s/ Peter Miller  
Name: Peter Miller  
Title: Chief Executive Officer

GUARANTORS:OPTINOSE, INC.,

a Delaware corporation

By: /s/ Peter Miller  
Name: Peter Miller  
Title: Chief Executive Officer

OPTINOSE

UK LIMITED,  
a limited liability company organized under the laws of England and Wales

By: /s/ Helena Djupesland, on behalf of OptiNose UK Limited  
Name: Helena Djupesland  
Title: Director

[Signature Page to Note Purchase Agreement]

COLLATERAL AGENT:

ATHYRIUM OPPORTUNITIES III ACQUISITION LP,  
a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES  
ASSOCIATES III LP, its General Partner

By: ATHYRIUM OPPORTUNITIES  
ASSOCIATES III GP LLC, the General  
Partner of Athyrium Opportunities  
Associates III LP

By: /s/ Andrew C. Hyman  
Name: Andrew C. Hyman  
Title: Authorized Signatory

[Signature Page to Note Purchase Agreement]

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PURCHASERS:

ATHYRIUM

OPPORTUNITIES III ACQUISITION LP,  
a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES  
ASSOCIATES III LP, its General Partner

By: ATHYRIUM OPPORTUNITIES  
ASSOCIATES III GP LLC, the General  
Partner of Athyrium Opportunities  
Associates III LP

By: /s/ Andrew C. Hyman  
Name: Andrew C. Hyman  
Title: Authorized Signatory

[Signature Page to Note Purchase Agreement]

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**EXHIBIT A-1**

**INITIAL SENIOR SECURED NOTE**

**THIS SENIOR SECURED NOTE HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT, OR AN EXEMPTION FROM REGISTRATION, UNDER SAID ACT.**

**THIS INSTRUMENT AND THE RIGHTS AND OBLIGATIONS EVIDENCED HEREBY ARE GOVERNED BY THE TERMS AND CONDITIONS SET FORTH IN THAT CERTAIN NOTE PURCHASE AGREEMENT (THE “NOTE PURCHASE AGREEMENT”) DATED AS OF [•], 2017 AMONG OPTINOSE AS, A NORWEGIAN LIMITED LIABILITY COMPANY, OPTINOSE US, INC., A DELAWARE CORPORATION, OPTINOSE INC., A DELAWARE CORPORATION, THE OTHER GUARANTORS (AS DEFINED IN THE NOTE PURCHASE AGREEMENT) FROM TIME TO TIME PARTY THERETO, AND THE PURCHASERS SET FORTH IN THE NOTE PURCHASE AGREEMENT (EACH, A “PURCHASER” AND, COLLECTIVELY, THE “PURCHASERS”) AND ATHYRIUM OPPORTUNITIES III ACQUISITION LP, AS COLLATERAL AGENT; AND EACH HOLDER OF THIS INSTRUMENT, BY ITS ACCEPTANCE HEREOF, IRREVOCABLY AGREES TO BE BOUND BY THE PROVISIONS OF THE NOTE PURCHASE AGREEMENT. UNLESS OTHERWISE INDICATED, CAPITALIZED TERMS USED BUT NOT DEFINED HEREIN SHALL HAVE THE MEANINGS ASCRIBED TO SUCH TERMS IN THE NOTE PURCHASE AGREEMENT.**

[OPTINOSE AS][OPTINOSE US, INC.]

Senior Secured Note Due 2023  
(a "Note")

No. [ ]

[•]  
[•], 2017

[OptiNose AS, a Norwegian limited liability company][OptiNose US, Inc., a Delaware corporation], (together with its successors, the "Issuer"), for value received, hereby promises to pay to

ATHYRIUM OPPORTUNITIES III ACQUISITION LP

or its registered assigns  
in accordance with the below  
the principal amount of

[FIFTY MILLION DOLLARS AND ZERO CENTS][TWENTY FIVE MILLION DOLLARS AND ZERO CENTS]  
[\$50,000,000.00] [\$25,000,000.00]

and to pay interest from the Closing Date until paid in full at the rate per annum equal to LIBOR for such Interest Period plus 9.00%, computed on the basis of a 360-day year and actual days elapsed.

This Note shall at all times upon the occurrence and during the continuation of (a) an Event of Default under Section 9.01(a) (without regard to any grace periods) or Section 9.01(f) of the Note Purchase Agreement, or (b) any other Event of Default, if requested by the Required Purchasers, bear interest at an interest rate equal to LIBOR for such Interest Period plus 12.00% (the "Default Rate"), to the fullest extent permitted by applicable Laws.

Interest (including interest at the Default Rate) shall be payable on this Note quarterly in arrears on the 15th day of each March, June, September and December of each year (each, an "Interest Payment Date"), and at maturity (whether through the occurrence of the Maturity Date, by acceleration or otherwise) to the Purchaser holding this Note on such date, and shall be paid in cash in accordance with Section 2.09 of the Note Purchase Agreement.

Prepayment and repayment premiums and exit fees shall be due upon any repayment or prepayment of this Note, as applicable, pursuant to Section 2.07 of the Note Purchase Agreement.

Payments of the principal amount hereof, interest hereon, prepayment premium (if any), exit fee (if any) and all other amounts payable hereunder or under the Note Documents shall be made in Dollars, in immediately available funds not later than 2:00 p.m. on the date due, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Purchaser holding this Note may from time to time direct in writing. All payments

received by the Purchaser holding this Note after 2:00 p.m. shall be deemed received on the next succeeding Business Day and any applicable interest or fee shall continue to accrue. If any payment to be made by the Issuer shall come due on a day other than a Business Day, payment shall be made on the next following Business Day, and such extension of time shall be reflected in computing interest.

This Note is one of the Initial Notes in the aggregate original principal amount of [\$50,000,000][\$25,000,000], issued by the Issuer pursuant to the Note Purchase Agreement and this Note and the holder hereof are entitled, equally and ratably, with the holders of all other Notes outstanding under the Note Purchase Agreement to all the benefits provided for thereby or referred to therein, to which Note Purchase Agreement reference is hereby made for a statement thereof.

The obligations of the Issuer under this Note are guaranteed pursuant to the terms and provisions of Article IV of the Note Purchase Agreement, and the Collateral Documents executed in favor of the Collateral Agent, for the benefit of the Purchasers, to the extent described therein, by each of the applicable Note Parties and the other parties thereto.

This Note is subject to optional prepayment and mandatory prepayment prior to its expressed maturity date, at the times, on the terms and conditions and in the amounts set forth in the Note Purchase Agreement.

Upon the occurrence and during the continuation of any one or more of the Events of Default specified in the Note Purchase Agreement, all amounts then remaining unpaid on this Note may be declared to be or may automatically become immediately due and payable as provided in the Note Purchase Agreement.

This Note is registered on the books of the Issuer and, subject to the Note Purchase Agreement, is transferable only by surrender thereof at the principal executive office of the Issuer and accompanied by, if required by the Issuer, a written instrument of transfer reasonably satisfactory to the Issuer, duly executed by the registered holder of this Note or its attorney duly authorized in writing. Payment of or on account of principal, prepayment premium, if any, exit fee and interest on this Note shall be made only to or upon the order in writing of the registered holder.

\* \* \*

**THIS NOTE SHALL BE GOVERNED BY AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK.**

[OptiNose AS] [OptiNose US, Inc.]

By: \_\_\_\_\_

Name:

Title:

**EXHIBIT A-2**

**DELAYED DRAW SENIOR SECURED NOTE**

**THIS SENIOR SECURED NOTE HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT, OR AN EXEMPTION FROM REGISTRATION, UNDER SAID ACT.**

**THIS INSTRUMENT AND THE RIGHTS AND OBLIGATIONS EVIDENCED HEREBY ARE GOVERNED BY THE TERMS AND CONDITIONS SET FORTH IN THAT CERTAIN NOTE PURCHASE AGREEMENT (THE "NOTE PURCHASE AGREEMENT") DATED AS OF [•], 2017 AMONG OPTINOSE AS, A NORWEGIAN LIMITED LIABILITY COMPANY, OPTINOSE US, INC., A DELAWARE CORPORATION, OPTINOSE INC., A DELAWARE CORPORATION, THE OTHER GUARANTORS (AS DEFINED IN THE NOTE PURCHASE AGREEMENT) FROM TIME TO TIME PARTY THERETO, AND THE PURCHASERS SET FORTH IN THE NOTE PURCHASE AGREEMENT (EACH, A "PURCHASER" AND, COLLECTIVELY, THE "PURCHASERS") AND ATHYRIUM OPPORTUNITIES III ACQUISITION LP, AS COLLATERAL AGENT; AND EACH HOLDER OF THIS INSTRUMENT, BY ITS ACCEPTANCE HEREOF, IRREVOCABLY AGREES TO BE BOUND BY THE PROVISIONS OF THE NOTE PURCHASE AGREEMENT. UNLESS OTHERWISE INDICATED, CAPITALIZED TERMS USED BUT NOT DEFINED HEREIN SHALL HAVE THE MEANINGS ASCRIBED TO SUCH TERMS IN THE NOTE PURCHASE AGREEMENT.**

OPTINOSE US, INC.

Senior Secured Note Due 2023  
(a “Note”)

No. [ ]                      Yardley, PA  
   [•], 2019

OptiNose US, Inc., a Delaware corporation (together with its successors, the “Issuer”), for value received, hereby promises to pay to

ATHYRIUM OPPORTUNITIES III ACQUISITION LP

or its registered assigns  
in accordance with the below  
the principal amount of

TWENTY FIVE MILLION DOLLARS AND ZERO CENTS  
\$25,000,000.00

and to pay interest from the Closing Date until paid in full at the rate per annum equal to LIBOR for such Interest Period plus 9.00%, computed on the basis of a 360-day year and actual days elapsed.

This Note shall at all times upon the occurrence and during the continuation of (a) an Event of Default under Section 9.01(a) (without regard to any grace periods) or Section 9.01(f) of the Note Purchase Agreement, or (b) any other Event of Default, if requested by the Required Purchasers, bear interest at an interest rate equal to LIBOR for such Interest Period plus 12.00% (the “Default Rate”), to the fullest extent permitted by applicable Laws.

Interest (including interest at the Default Rate) shall be payable on this Note quarterly in arrears on the 15th day of each March, June, September and December of each year (each, an “Interest Payment Date”), and at maturity (whether through the occurrence of the Maturity Date, by acceleration or otherwise) to the Purchaser holding this Note on such date, and shall be paid in cash in accordance with Section 2.09 of the Note Purchase Agreement.

Prepayment and repayment premiums and exit fees shall be due upon any repayment or prepayment of this Note, as applicable, pursuant to Section 2.07 of the Note Purchase Agreement.

Payments of the principal amount hereof, interest hereon, prepayment premium (if any), exit fee (if any) and all other amounts payable hereunder or under the Note Documents shall be made in Dollars, in immediately available funds not later than 2:00 p.m. on the date due, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Purchaser holding this Note may from time to time direct in writing. All payments received by the Purchaser holding this Note after 2:00 p.m. shall be deemed received on the next

succeeding Business Day and any applicable interest or fee shall continue to accrue. If any payment to be made by the Issuer shall come due on a day other than a Business Day, payment shall be made on the next following Business Day, and such extension of time shall be reflected in computing interest.

This Note is one of the Delayed Draw Notes in the aggregate original principal amount of \$25,000,000, issued by the Issuer pursuant to the Note Purchase Agreement and this Note and the holder hereof are entitled, equally and ratably, with the holders of all other Notes outstanding under the Note Purchase Agreement to all the benefits provided for thereby or referred to therein, to which Note Purchase Agreement reference is hereby made for a statement thereof.

The obligations of the Issuer under this Note are guaranteed pursuant to the terms and provisions of Article IV of the Note Purchase Agreement, and the Collateral Documents executed in favor of the Collateral Agent, for the benefit of the Purchasers, to the extent described therein, by each of the applicable Note Parties and the other parties thereto.

This Note is subject to optional prepayment and mandatory prepayment prior to its expressed maturity date, at the times, on the terms and conditions and in the amounts set forth in the Note Purchase Agreement.

Upon the occurrence and during the continuation of any one or more of the Events of Default specified in the Note Purchase Agreement, all amounts then remaining unpaid on this Note may be declared to be or may automatically become immediately due and payable as provided in the Note Purchase Agreement.

This Note is registered on the books of the Issuer and, subject to the Note Purchase Agreement, is transferable only by surrender thereof at the principal executive office of the Issuer and accompanied by, if required by the Issuer, a written instrument of transfer reasonably satisfactory to the Issuer, duly executed by the registered holder of this Note or its attorney duly authorized in writing. Payment of or on account of principal, prepayment premium, if any, exit fee and interest on this Note shall be made only to or upon the order in writing of the registered holder.

\* \* \*

**THIS NOTE SHALL BE GOVERNED BY AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK.**

OPTINOSE US, INC.

By: \_\_\_\_\_

Name:

Title:



## EXHIBIT B

### FORM OF JOINDER AGREEMENT

THIS JOINDER AGREEMENT (this “Agreement”) dated as of \_\_\_\_\_, 20\_\_ is by and between \_\_\_\_\_, a \_\_\_\_\_ (the “New Subsidiary”), and ATHYRIUM OPPORTUNITIES III ACQUISITION LP, in its capacity as Collateral Agent under that certain Note Purchase Agreement dated as of [•], 2017 (as amended, modified, restated, supplemented or extended from time to time, the “Note Purchase Agreement”) among OptiNose AS, a Norwegian limited liability company (the “Norwegian Issuer”), OptiNose US, Inc., a Delaware corporation (the “US Issuer”; together with the Norwegian Issuer, the “Issuers” and each, an “Issuer”), OptiNose, Inc., a Delaware corporation, the other Guarantors from time to time party thereto, the Purchasers from time to time party thereto and Athyrium Opportunities III Acquisition LP, as Collateral Agent. Capitalized terms used herein and not otherwise defined herein shall have the meanings assigned to such terms in the Note Purchase Agreement.

The Note Parties are required by Section 7.12 of the Note Purchase Agreement to cause the New Subsidiary to become a “[Norwegian Notes Guarantor] [and US Notes Guarantor]” thereunder. Accordingly, the New Subsidiary hereby agrees as follows with the Collateral Agent, for the benefit of the Purchasers and the Collateral Agent:

1. The New Subsidiary hereby acknowledges, agrees and confirms that, by its execution of this Agreement, the New Subsidiary will be deemed to be a party to the Note Purchase Agreement and a “[Norwegian Notes Guarantor] [and US Notes Guarantor]” for all purposes of the Note Purchase Agreement, and shall have all of the obligations of a [Norwegian Notes Guarantor] [and US Notes Guarantor] thereunder as if it had executed the Note Purchase Agreement. The New Subsidiary hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions applicable to the [Norwegian Notes Guarantor] [and US Notes Guarantor] contained in the Note Purchase Agreement. Without limiting the generality of the foregoing terms of this paragraph 1, the New Subsidiary hereby jointly and severally together with the other [Norwegian Notes Guarantors] [and US Notes Guarantors], guarantees to each Purchaser, the Collateral Agent and each other holder of the [Norwegian Notes Obligations] [and US Notes Obligations], as provided in Article IV of the Note Purchase Agreement, the prompt payment of the [Norwegian Note Obligations] [and US Note Obligations] in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise) strictly in accordance with the terms thereof.

2. The New Subsidiary hereby acknowledges, agrees and confirms that, by its execution of this Agreement, the New Subsidiary will be deemed to be a party to the Security Agreement and a “[Norwegian Notes Grantor] [and US Notes Grantor]” for all purposes of the Security Agreement and shall have all the obligations of a [Norwegian Notes Grantor] [and US

Notes Grantor] thereunder as if it had executed the Security Agreement. The New Subsidiary hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions contained in the Security Agreement. Without limiting the generality of the foregoing terms of this paragraph 2, the New Subsidiary hereby grants to the Collateral Agent, for the benefit of the Secured Parties (as defined in the Security Agreement), a continuing security interest in any and all right, title and interest of the New Subsidiary in and to the Collateral of the New Subsidiary to secure the prompt payment and performance in full when due, whether by lapse of time, acceleration, mandatory prepayment or otherwise, of the [Norwegian Notes Obligations] [and US Notes Obligations].

3. The New Subsidiary hereby acknowledges, agrees and confirms that, by its execution of this Agreement, the New Subsidiary will be deemed to be a party to the Pledge Agreement and a “[Norwegian Notes Pledgor] [and US Notes Pledgor]” for all purposes of the Pledge Agreement, and shall have all the obligations of a [Norwegian Notes Pledgor] [and US Notes Pledgor] thereunder as if it had executed the Pledge Agreement. The New Subsidiary hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions contained in the Pledge Agreement. Without limiting the generality of the foregoing terms of this paragraph 3, the New Subsidiary hereby grants, pledges and assigns to the Collateral Agent, for the benefit of the Secured Parties (as defined in the Pledge Agreement), a continuing security interest in any and all right, title and interest of the New Subsidiary in and to the Equity Interests, if any, identified on Schedule 6 hereto, to the extent constituting Pledged Collateral, and all other Pledged Collateral (as defined in the Pledge Agreement) of the New Subsidiary to secure the prompt payment and performance in full when due, whether by lapse of time, acceleration, mandatory prepayment or otherwise, of the [Norwegian Notes Obligations] [and US Notes Obligations].

4. The New Subsidiary hereby represents and warrants to the Collateral Agent and the Purchasers that, as of the date hereof:

(a) The New Subsidiary’s exact legal name and jurisdiction of formation are as set forth on the signature pages hereto.

(b) The New Subsidiary’s taxpayer identification number and organization number are set forth on Schedule 1 hereto.

(c) Other than as set forth on Schedule 2 hereto, the New Subsidiary has not changed its legal name, changed its jurisdiction of formation, or been party to a merger, consolidation or other change in structure in the five years preceding the date hereof.

(d) Schedule 3 hereto includes (a) all of the Patents, Trademarks and Copyrights registered or pending registration with the United States Copyright Office and the United States Patent and Trademark Office and owned by the New Subsidiary, (b) all other Material IP Rights of the New Subsidiary, and (c) each Copyright License, each Patent License and each Trademark License of any Note Party that is, in the case of this clause (c), material to the Businesses, taken as a whole.

(e) Schedule 4 hereto includes all Commercial Tort Claims (as defined in the Security Agreement) before any Governmental Authority with a value in excess of \$100,000 by or in favor of the New Subsidiary.

(f) Schedule 5 hereto lists all real property that is owned or leased by the New Subsidiary as of the date hereof.

(g) Schedule 6 hereto includes each Subsidiary of the New Subsidiary, including (i) jurisdiction of formation, (ii) number of shares of each class of Equity Interests outstanding, (iii) the certificate number(s) of the certificates evidencing such Equity Interests and number and percentage of outstanding shares of each class owned by the New Subsidiary (directly or indirectly) of such Equity Interests and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto.

5. The address of the New Subsidiary for purposes of all notices and other communications is the address designated for all Note Parties on Schedule 12.02 to the Note Purchase Agreement or such other address as the New Subsidiary may from time to time notify the Collateral Agent in writing.

6. The New Subsidiary hereby waives acceptance by the Collateral Agent and the Purchasers of the guaranty by the New Subsidiary under Article IV of the Note Purchase Agreement upon the execution of this Agreement by the New Subsidiary.

7. This Agreement may be executed in multiple counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original but all of which when taken together shall constitute one contract. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

8. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

[Signature Page Follows]

IN WITNESS WHEREOF, the New Subsidiary has caused this Joinder Agreement to be duly executed by its authorized officer, and the Collateral Agent, for the benefit of itself and the Purchasers, has caused the same to be accepted by its authorized officer, as of the day and year first above written.

[NEW SUBSIDIARY]

By: \_\_\_\_\_

Name:

Title:

Acknowledged and accepted:

ATHYRIUM OPPORTUNITIES III ACQUISITION LP,  
as Collateral Agent

By: \_\_\_\_\_

Name:

Title:

Schedule 1

Taxpayer Identification Number; Organizational Number

## Schedule 2

Changes in Legal Name or Jurisdiction of Formation;  
Mergers, Consolidations and other Changes in Structure

## Schedule 3

### IP Rights

Schedule 4

Commercial Tort Claims



Schedule 5

Real Property

Schedule 6

Equity Interests

**EXHIBIT C**

**FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT**

This Assignment and Assumption Agreement (this “Assignment and Assumption Agreement”) is dated as of the Effective Date set forth below (the “Effective Date”) and is entered into by and between [Insert name of Assignor] (the “Assignor”) and [Insert name of Assignee] (the “Assignee”). Capitalized terms used but not defined herein have the meanings provided in the Note Purchase Agreement identified below, receipt of a copy of which is hereby acknowledged by the Assignee. The Standard Terms and Conditions set forth in Annex 1 attached hereto (the “Standard Terms and Conditions”) are hereby agreed to and incorporated herein by reference and made a part of this Assignment and Assumption Agreement as if set forth herein in full.

For an agreed consideration, the Assignor hereby irrevocably sells and assigns to the Assignee, and the Assignee hereby irrevocably purchases and assumes from the Assignor, subject to and in accordance with the Standard Terms and Conditions and the Note Purchase Agreement, as of the Effective Date inserted by the Collateral Agent as contemplated below (i) the aggregate principal amount of Notes and/or Delayed Draw Note Commitments identified below, (ii) the Assignor’s rights and obligations as a Purchaser under the Note Purchase Agreement and any other documents or instruments delivered pursuant thereto, to the extent related to the amount identified below of all of such outstanding rights and obligations of the Assignor of the aggregate principal amount of Notes and/or Delayed Draw Note Commitments identified below, and (iii) to the extent permitted to be assigned under applicable law, all claims, suits, causes of action and any other right of the Assignor (in its capacity as a Purchaser) against any Person, whether known or unknown, arising under or in connection with the Note Purchase Agreement, any other documents or instruments delivered pursuant thereto or the loan transactions governed thereby or in any way based on or related to any of the foregoing, including, but not limited to, contract claims, tort claims, malpractice claims, statutory claims and all other claims at law or in equity related to the rights and obligations sold and assigned pursuant to clauses (i) and (ii) above (the rights and obligations sold and assigned pursuant to clauses (i), (ii) and (iii) above being referred to herein collectively as, the “Assigned Interest”). Such sale and assignment is without recourse to the Assignor and, except as expressly provided in this Assignment and Assumption Agreement, without representation or warranty by the Assignor.

1. Assignor: \_\_\_\_\_  
Assignor [is][is not] a Defaulting Purchaser]
2. Assignee: \_\_\_\_\_  
[and is an Affiliate of [identify Purchaser]]
3. Issuer(s): [OptiNose AS, a Norwegian limited liability company][OptiNose US, Inc., a Delaware corporation]
- Note Purchase Agreement: Note Purchase Agreement dated as of [•], 2017 (as amended, modified, restated, supplemented or extended from time to time, the “Note Purchase Agreement”) among OptiNose AS, a Norwegian limited liability company (the “Norwegian Issuer”), OptiNose US, Inc., a Delaware corporation (the “US Issuer”; together with the Norwegian Issuer, the “Issuers” and each, an “Issuer”), the Guarantors from time to time party thereto, the Purchasers from time to time party thereto and the Required Purchasers Collateral Agent.
- 4.
5. Assigned Interest:

| Aggregate Principal Amount of Notes for all Purchasers | Amount of Notes Assigned <sup>1</sup> | Percentage Assigned of Notes | Issuer |
|--|---------------------------------------|------------------------------|--------|
|  |                                       |                              |        |
|  |                                       |                              |        |
|  |                                       |                              |        |

| Aggregate Amount of Delayed Draw Note Commitment for all Purchasers | Amount of Delayed Draw Note Commitment Assigned <sup>2</sup> | Percentage Assigned of Delayed Draw Note Commitment <sup>3</sup> |
|---|--|--|
|   |  |  |
|   |  |  |
|   |  |  |

6. Trade Date: \_\_\_\_\_
7. Effective Date: \_\_\_\_\_

<sup>1</sup> Amount to be greater than or equal to \$1,000,000 unless the Assignee is an Affiliate of the Purchaser or any limited partner or other investor in a fund managed by the Purchaser and through which the Purchaser holds Notes. Amount to be adjusted by the counterparties to take into account any payments or prepayments made between the Trade Date and the Effective Date.

<sup>2</sup> Amount to be adjusted by the counterparties to take into account any payments or prepayments made between the Trade Date and the Effective Date.

<sup>3</sup> Set forth, to at least 9 decimals, as a percentage of the Delayed Draw Note Commitment of all Purchasers thereunder.

The terms set forth in this Assignment and Assumption Agreement are hereby agreed to:

ASSIGNOR:

[NAME OF ASSIGNOR]

By: \_\_\_\_\_

Name:

Title:

ASSIGNEE:

[NAME OF ASSIGNEE]

By: \_\_\_\_\_

Name:

Title:

Consented to:

ATHYRIUM OPPORTUNITIES III ACQUISITION LP  
as Collateral Agent

By: \_\_\_\_\_

Name:

Title:

[Consented to:] To be added only if the consent of the Issuers is required by the terms of the Note Purchase Agreement.

OPTINOSE AS  
a Norwegian limited liability company

By:  
Name:  
Title:

OPTINOSE

OPTINOSE US, INC.,  
a Delaware corporation

By:  
Name:  
Title:

<sup>4</sup>To be added only if the consent of the Issuers is required by the terms of the Note Purchase Agreement.



## Annex 1 to Assignment and Assumption Agreement

### STANDARD TERMS AND CONDITIONS

#### 1. Representations and Warranties.

1.1. Assignor. The Assignor (a) represents and warrants that (i) it is the legal and beneficial owner of the Assigned Interest, (ii) the Assigned Interest is free and clear of any lien, encumbrance or other adverse claim, (iii) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption Agreement and to consummate the transactions contemplated hereby and (iv) it is [not] a Defaulting Purchaser; and (b) assumes no responsibility with respect to (i) any statements, warranties or representations made in or in connection with the Note Purchase Agreement or any other Note Document, (ii) the execution, legality, validity, enforceability, genuineness, sufficiency or value of the Note Documents or any collateral thereunder, (iii) the financial condition of the Issuers, any of their Subsidiaries or Affiliates or any other Person obligated in respect of any Note Document or (iv) the performance or observance by the Issuers, any of their Subsidiaries or Affiliates or any other Person of any of their respective obligations under any Note Document.

1.2. Assignee. The Assignee (a) represents and warrants that (i) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption Agreement and to consummate the transactions contemplated hereby and to become a Purchaser under the Note Purchase Agreement, (ii) it meets the requirements to be an assignee under Section 12.06(b) of the Note Purchase Agreement (subject to such consents, if any as may be required under Section 12.06(b) of the Note Purchase Agreement), (iii) from and after the Effective Date, it shall be bound by the provisions of the Note Purchase Agreement as a Purchaser thereunder and, to the extent of the Assigned Interest, shall have the obligations of a Purchaser thereunder, (iv) it is sophisticated with respect to decisions to acquire assets of the type represented by the Assigned Interest and either it, or the Person exercising discretion in making its decision to acquire the Assigned Interest, is experienced in acquiring assets of such type, and acknowledges that the Notes have not been registered under the Securities Act or the securities laws of any state or other jurisdiction, (v) each of the representations and warranties set out in Article VI-A of the Note Purchase Agreement are true and correct in respect of the Assignee, (vi) it has received a copy of the Note Purchase Agreement, and has received or has been accorded the opportunity to receive copies of the most recent financial statements delivered pursuant to Section 7.01 thereof, as applicable, and such other documents and information as it deems appropriate to make its own credit analysis and decision to enter into this Assignment and Assumption Agreement and to purchase the Assigned Interest, and (vii) it has, independently and without reliance upon the Collateral Agent or any other Purchaser and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Assignment and Assumption Agreement and to purchase the Assigned Interest; and (b) agrees that (i) it will, independently and without reliance on the Collateral Agent, the Assignor or any other Purchaser, and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking action under the

Note Documents, and (ii) it will perform in accordance with their terms all of the obligations which by the terms of the Note Documents are required to be performed by it as a Purchaser.

2. General Provisions. This Assignment and Assumption Agreement shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and assigns. This Assignment and Assumption Agreement may be executed in any number of counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute one instrument. Delivery of an executed counterpart of a signature page of this Assignment and Assumption Agreement by facsimile or other electronic imaging means (e.g. “pdf” or “tif”) shall be effective as delivery of a manually executed counterpart of this Assignment and Assumption Agreement. This Assignment and Assumption Agreement shall be governed by, and construed in accordance with, the law of the State of New York.

## OPTINOSE, INC.

## LIST OF SUBSIDIARIES

| Name              | Jurisdiction of Incorporation | Percent Owned |
|-------------------|-------------------------------|---------------|
| OptiNose US, Inc. | Delaware                      | 100%          |
| Optinose AS       | Norway                        | 100%          |
| Optinose UK, Ltd. | United Kingdom                | 100%          |

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-221047) pertaining to the Amended and Restated 2010 Stock Incentive Plan and the 2017 Employee Stock Purchase Plan of our report dated March 13, 2018, with respect to the consolidated financial statements of OptiNose, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2017.

/s/ Ernst & Young LLP  
Philadelphia, Pennsylvania  
March 13, 2018

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Peter K. Miller, certify that:

1. I have reviewed this Annual Report on Form 10-K of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2018

/s/ Peter K. Miller  
Peter K. Miller  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL  
OFFICER PURSUANT TO SECTION 302  
OF THE SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, certify that:

1. I have reviewed this Annual Report on Form 10-K of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2018

/s/ Keith A. Goldan  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE  
OFFICER PURSUANT TO 18 U.S.C  
SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter K. Miller, Chief Executive Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 13, 2018

/s/ Peter K. Miller  
Peter K. Miller  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL  
OFFICER PURSUANT TO U.S.C SECTION  
1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, Chief Financial Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
  
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 13, 2018

/s/ Keith A. Goldan  
Keith A. Goldan  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)