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, 2018

OR

o **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	**42-1771610**
(State of other jurisdiction of incorporation or organization)	(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:

Title of Each Class	**Name of each exchange on which registered**
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 o 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 o 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 o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No o

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, a 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 o	Accelerated filer ☒
Non-accelerated filer o (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 o No ☒

As of June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $682.4 million based on the last reported sale price of the registrant's common stock on June 30, 2018.

The number of shares of common stock outstanding at March 1, 2019 was 41,264,422 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 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, 2018.

	NOTE REGARDING FORWARD-LOOKING STATEMENTS	1
	MARKET, INDUSTRY AND OTHER DATA	2
	PART I	
ITEM 1.	BUSINESS	3
ITEM 1A.	RISK FACTORS	40
ITEM 1B.	UNRESOLVED STAFF COMMENTS	84
ITEM 2.	PROPERTIES	84
ITEM 3.	LEGAL PROCEEDINGS	84
ITEM 4.	MINE SAFETY DISCLOSURE	84
	PART II	
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	84
ITEM 6.	SELECTED CONSOLIDATED FINANCIAL DATA	85
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	85
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK	97
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	97
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	97
ITEM 9A.	CONTROLS AND PROCEDURES	97
ITEM 9B.	OTHER INFORMATION	99
	PART III	
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	99
ITEM 11.	EXECUTIVE COMPENSATION	99
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	99
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	99
ITEM 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES	99
	PART IV	
ITEM 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	99
	SIGNATURE PAGE	
	EXHIBIT INDEX	

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.

Trademark Notice

OPTINOSE® and XHANCE® are registered trademarks of Optinose in the United States. This Form 10-K contains references to our trademarks and to trademarks belonging to other entities. All other trademarks, trade names and service marks appearing in this Form 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®, our product candidates and Exhalation Delivery System (EDS) devices and technologies;
- our plan to internalize our contract sales team and deploy an additional 20 territory managers in “XHANCE naive” geographies to expand our reach among the ear, nose and throat and allergy specialist universe, and our expectation that doing so will grow the target audience for our sales team by approximately 25% to approximately 9,500 healthcare providers;
- our expectation to continue to secure broader market access over time, and our intention to eventually 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;
- our expectation to target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers;
- our analyses suggesting that XHANCE will have a comparatively low pharmacy budget impact;
- our clinical trial data suggesting that XHANCE may produce an offsetting benefit by helping reduce other healthcare resource utilization;
- our belief that 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;
- our believe that the current practice of postoperative intranasal steroid use could support XHANCE’s adoption as a maintenance therapy to improve outcomes following sinus surgery;
- planned product development activities, studies and clinical trials, including our plans to initiate a second phase 3b clinical trial of XHANCE in 2019 in pursuit of a follow-on indication for chronic sinusitis;
- our intention to execute a branded, multi-channel direct to consumer pilot in three cities targeting diagnosed and undiagnosed nasal polyp patients in 2019, and our anticipation to broaden the direct to consumer pilot to a national campaign in 2020 if the 2019 campaign is successful;
- our expectation that our GAAP operating expenses in 2019 will be between $135 - $142 million and that our non-cash stock-based compensation expense will be between $10 - $12 million;
- our expectation that our existing cash and cash equivalents will be sufficient to meet our debt service obligations under our Senior Secured Notes, and to carry out our planned development and commercial activities into the fourth quarter of 2020;
- our expectation that the average net revenue per prescription for XHANCE in the first quarter of 2019 will be between $155 - $175 and our expectation that the average net revenue per prescription will improve though 2019 and that the full-year 2019 average net revenue per prescription will be between $185 - $205;
- the size and growth potential of the markets for XHANCE and our product candidates, and our ability to service those markets;
- 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 (U.S.) 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.

MARKET, INDUSTRY AND OTHER DATA

This Form 10-K contains estimates, projections, market research and other information concerning our industry, our business, markets for XHANCE and our product candidates and the size of those markets, the prevalence of certain medical conditions, XHANCE market access and brand awareness, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, physician, patient and payor data. Unless otherwise expressly stated, we obtain this information 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 as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information.

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 (ENT) and allergy specialists. Our first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids (INS), which 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.

On September 18, 2017, the U.S. Food and Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through retail channels in April 2018.

Since the FDA approval of XHANCE, we have focused on executing our integrated launch plan and have made progress in each of these key strategic areas:

- Customer Model. We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENTs, allergists and “specialty-like” primary care physicians and have deployed a hybrid sales model that combines an internal sales leadership team with a fully-dedicated contract sales force to call on our target health care provider (HCP) customer universe. We prioritized approximately 80 territories within our sales force footprint to deploy in 2018 based upon pre-launch expectations regarding where we could achieve an estimated 65% commercial market access within each territory. The initial 80 territory managers were deployed in March 2018, actively engaging approximately 7,600 ENTs, allergists and "specialty like" primary care physician targets to promote XHANCE for the treatment of nasal polyps. During the first half of 2019, we plan to internalize our contract sales team and deploy an additional 20 territory managers in “XHANCE naive” geographies to expand our reach among our target physician audience. This is expected to grow the target audience for our sales team by approximately 25% to approximately 9,500 HCPs. We intend to eventually increase the size of our sales force to approximately 120 territory managers to expand our called on target audience to approximately 14,000 ENT, allergists and specialty-like primary care physicians. Additionally, we expect to target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers.

- XHANCE Patient Affordability Programs. In late August 2018, we implemented our current co-pay savings program. We believe this program, with an indefinite duration, provides an affordability solution for patients that physicians will support. The current program provides patient co-pay assistance including a first prescription at no out-of-pocket cost to patients ($0 co-pay) to commercially insured patients and low subsequent co-pays for refills. Our data suggests these programs are playing a role in building demand for XHANCE, particularly as they become more widely understood in the prescribing community.

- Market Access. In meeting with pharmacy benefit managers (PBMs) and health insurers/potential payors, we share what we believe is a compelling economic value proposition. Our analyses suggest 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 other healthcare resource utilization, most notably
the rate of endoscopic surgery and, therefore, surgery-related costs. For an insurance plan, this could represent potential for overall cost reduction in 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 trials, 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, including dupilumab, for which the submission of an Supplemental Biologics License Application (sBLA) was recently publicly announced.

Based on currently available third-party data and our internal analyses, we believe that greater than 75% of commercially insured lives are currently in a plan in which XHANCE is covered in a Tier 3 formulary position, and approximately 60% of commercially insured lives are in a plan that covers XHANCE in a “low hassle factor” position. However, payors may change coverage levels for XHANCE or controls such as step edits and prior authorization (PAs), positively or negatively, at any time. We use the term “hassle factor” to characterize the level of difficulty that physicians and patients must overcome to prescribe and fill XHANCE. We define a low “hassle factor” as Tier 3 unrestricted, Tier 3 single step edit, or Tier 3 with a simple PA requiring, for example, only the prior use of an over-the-counter or generic INS - although we acknowledge that any step edit or PA involves a level of burden for physicians and patients that could negatively impact XHANCE utilization. Our initial goal was for 75% of commercially insured lives to have access to XHANCE in a Tier 3 formulary position with a “low hassle factor" by the end of 2018. While at approximately 60% "low hassle factor" at December 31, 2018 we did not meet this goal, it remains an important concept for us as we seek to expand overall coverage for XHANCE.

We have also contracted with the Centers for Medicare and Medicaid Services for coverage of certain government insured lives and continue to expand XHANCE market access for other government-insured populations. As noted above, we have in place a co-pay assistance program for patients covered by commercial insurers and plan to continue to analyze affordability issues and assess patient affordability programs to appropriately support patient access to XHANCE for government insured patients.

- Infrastructure. We continue to develop our internal capabilities in a manner commensurate with having become a fully integrated and publicly traded commercial-stage specialty pharmaceutical company. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have also 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.

- XHANCE Prescriptions. Based on third-party prescription data as well as data from preferred pharmacy network partners, the total estimated number of XHANCE prescriptions in the second quarter, third quarter and fourth quarter 2018 were 8,611, 9,427, and 14,106, respectively, which represents 50% growth for prescriptions when comparing fourth quarter to third quarter. Estimated XHANCE prescriptions in December 2018 and January 2019 were 4,570 and 6,292, respectively, which represents 38% month-over-month growth. In addition, XHANCE prescriptions for the 4-week periods ended January 25 and February 22, 2019 were 5,156 and 7,186, respectively, which represents period-over-period growth of 39%.

XHANCE Development Update

In addition to XHANCE’s existing indication for the treatment of nasal polyps, in order to broaden our U.S. market opportunity we initiated a clinical research program in pursuit of a follow-on indication for the treatment of chronic sinusitis in the U.S. The program will comprise two phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018. We expect to initiate the second trial in 2019.

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 U.S. 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 U.S., 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 U.S. 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, 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 up to 80% of patients continue to have symptoms within two years of surgery. 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 (polyp grade 0), 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 (ESS) and balloon sinus dilation. 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. XHANCE had an adverse event profile generally comparable to the profile reported in similarly designed trials with conventional INS.

We believe XHANCE offers 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 comparable 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 on average $13,500 per procedure, and we expect that biologic monoclonal antibodies for the treatment of nasal polyps will cost approximately $37,000 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.

U.S. Market Opportunity

Our initial target market for XHANCE consists of ENT physicians, allergists and primary care physicians in the U.S. that most frequently prescribe INS. This group of approximately 5,000 primary care physicians, which we refer to as "specialty-like" 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 13 issued device and method of use patents expiring through 2034, three issued design patents expiring through 2030 and 10 patent applications that, if granted, would expire through 2034. The 13 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 Optinose 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 Optinose EDS devices 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 U.S.*** When we launched XHANCE in 2018, we initially deployed a specialty sales force of approximately 80 territory managers to call on a defined prescriber base of approximately 6,000 ENT and allergy specialists, as well as approximately 1,500 "specialty-like" primary care physicians, and filled territories were based on regions where we predicted comparatively favorable early market access. Based on results showing growth in prescription volume in the called-on audience and considering increases in market access during 2018 and planned efforts to further increase market access for XHANCE in 2019, we intend to incrementally increase the size of our sales force. In the first half of 2019 we expect to field territory managers in approximately 20 additional territories, increasing coverage to 100 of the approximately 120 territory nationwide structure that was initially established. The 120-territory structure was based on a target audience of approximately 14,000 specialists or "specialty-like" primary care physicians. Additionally, we expect to continue to target physicians through digital and non-personal promotion in areas where we do and do not have territory managers. We believe that approximately 15,000 targeted physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. With data suggesting that prescribing continues to be suitably responsive to promotion and as market access improves, we may continue to increase the size of our deployed sales team. In addition, in 2019 we intend to execute a branded direct-to-consumer pilot in three cities targeting diagnosed and undiagnosed nasal polyp patients.
- ***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 met with FDA and, in the fourth quarter of 2018, we initiated a Phase 3b clinical trial program in pursuit of that indication. 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 proprietary drugs or drug combinations 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 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 the use of an Optinose EDS to support development of central nervous system treatments, particularly those enabled by nose-to-brain drug delivery. We have engaged in early stage clinical development activities for OPN-300, which combines an Optinose EDS with oxytocin with potential applications including treatment of Prader-Willi syndrome and autism spectrum disorder. We have completed planned internal development activities for OPN-300 and may pursue external partnerships in the future for further development. In addition, in January 2019, we completed a licensing arrangement with Inexia Limited whereby we granted Inexia an exclusive license to our EDS devices and other intellectual property for the research, development and commercialization of products containing orexin receptor agonist and/or orexin receptor positive modulator molecules. Inexia has announced that specific target indications will be determined as the program advances, and is expected to include narcolepsy, a rare sleep disorder. The Inexia License Agreement has the potential to create value

in the form of milestones payments and royalties. We may evaluate other business development activities to capture additional value through the development of Optinose EDS devices outside of ENT and allergy.

- ***Expand XHANCE into international markets.*** We have engaged in initial assessment of potential development and commercialization of XHANCE in markets outside the U.S. and currently intend to remain opportunistic in pursuit of select international options. Upon receipt of additional data in the chronic sinusitis indication, we intend to more aggressively 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 U.S. 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 U.S. 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. It has been reported that 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 U.S., 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 U.S. 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 "specialty-like" primary care physicians, treat approximately 36% of all chronic rhinosinusitis patients in the U.S., 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 have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENTs,

allergists and “specialty-like” primary care physicians. If we obtain FDA approval for 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 U.S. 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. In lieu of prescription INS nasal sprays, physicians may recommend use of over-the-counter INS nasal sprays.
- ***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 U.S., 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 and cartilage 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.

In addition, SINUVA™ is a commercially available corticosteroid-eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. In the SINUVA clinical studies, patients were advised to use nasal steroid sprays and sinus rinses for the duration of the study.

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.

In addition, there are new small molecules, including fevipiprant, being developed for the treatment of nasal polyps, that are also believed to inhibit specific pathways of inflammation present in nasal polyps.

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 indicate that nasal polyp regrowth following surgery occurs in as high as 60% of cases within four years. In addition, it has been reported that up to 80% of patients continued to have symptoms within two years of surgery. 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 on average $13,500 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 $37,000 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 initiated a phase 3b clinical trial of XHANCE in the fourth quarter of 2018 for a follow-on indication for the treatment of chronic sinusitis and expect to initiate a second phase 3b trial in 2019. 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. As of February 8, 2019, 4,920 healthcare professionals have prescribed XHANCE as a result of our direct selling efforts targeting approximately 7,500 physicians and indirect promotional efforts.
- ***Fluticasone propionate is the most widely-prescribed INS in the U.S.*** 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 (polyp grade 0), 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.*** Prior to the XHANCE launch in 2018, we commissioned a market research study that 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 would 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.

  Informed by the above study and formal pricing research, at launch XHANCE was priced comparable to the only other branded intranasal steroid indicated for the treatment of nasal polyps, at their nasal polyp dose. 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. Greater than 75% of commercial plans cover XHANCE as of December 31, 2018. We believe we are on track to achieve similar levels of commercial market access as indicated from our pre-launch payor market research. We intend to contract with Commercial, Medicare Part D plans and Medicaid to accelerate physician adoption of XHANCE.
- ***Cost-Effective Solution.*** We launched XHANCE with a price 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 offers 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 Optinose EDS devices 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.

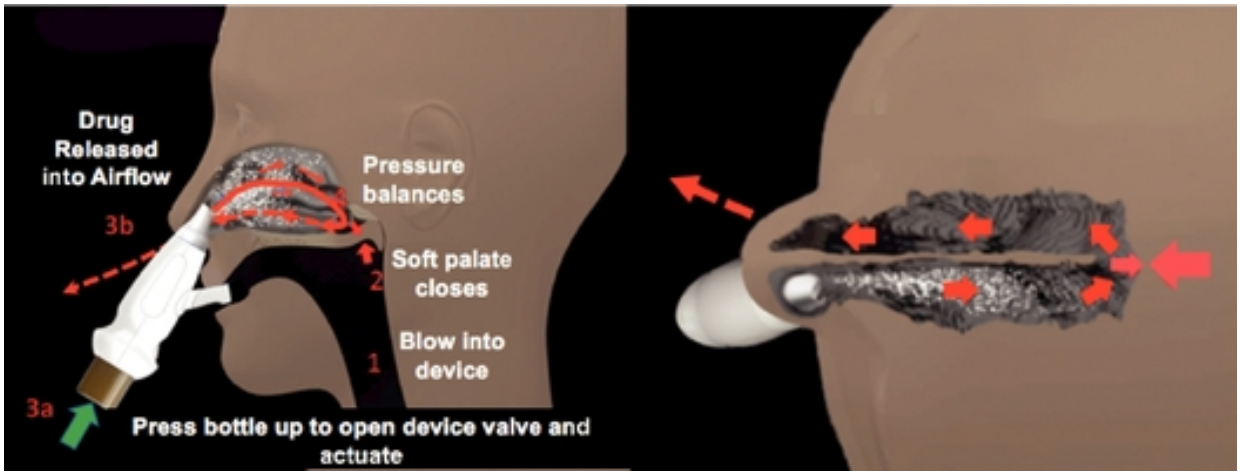
Powder EDS

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

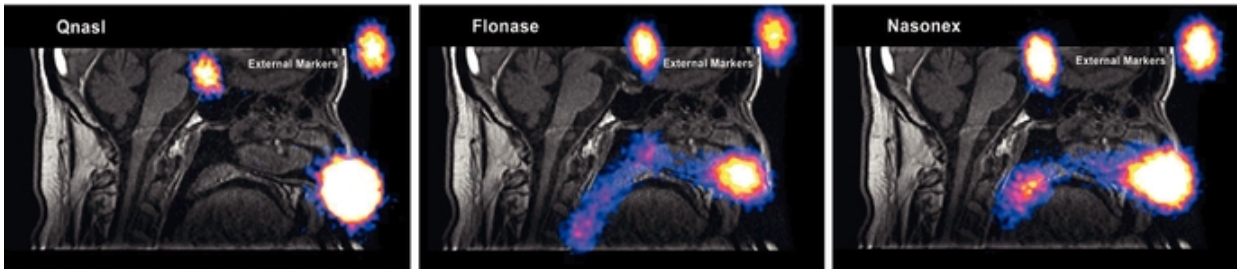
When exhaling into an EDS, the soft palate automatically elevates and creates an air-tight seal separating the nasal cavity from the throat and lungs. This natural action is the same as that which prevents air from escaping from the nose when trying to blow up a balloon or blow a trumpet. The exhaled 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 deliver 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

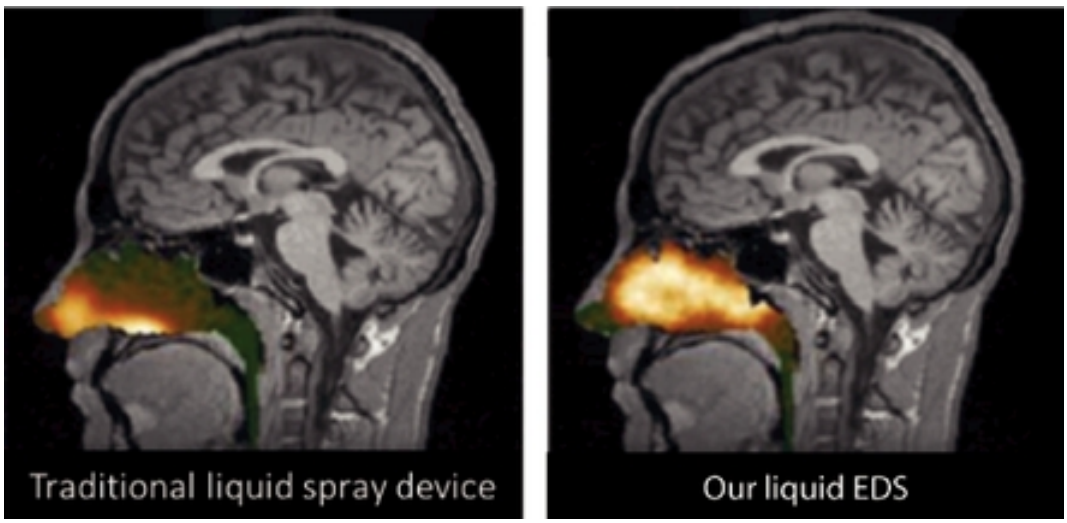
expansion of the nasal valve or the nasal passages and may obstruct the drug from reaching deep into the nose where most nasal polyps and inflamed and swollen sinus membranes exist.

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 healthy 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 (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.

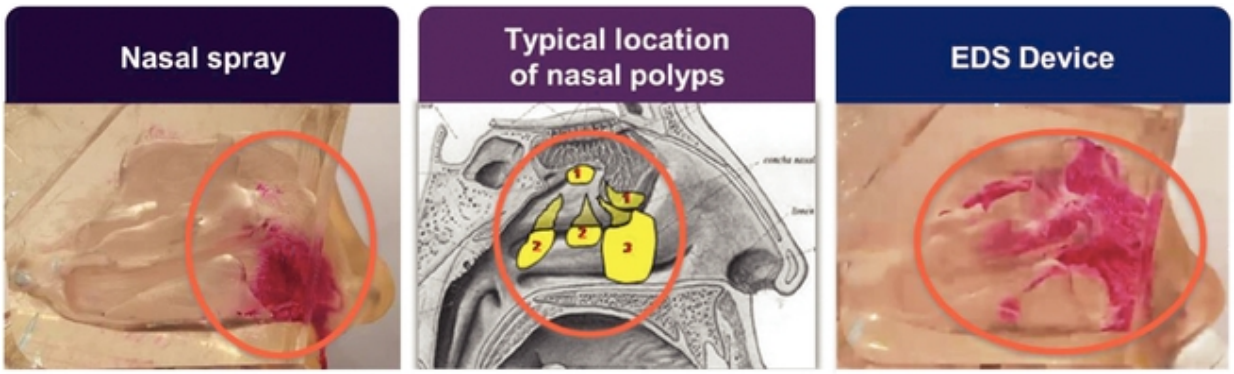
We conducted six deposition studies evaluating 53 healthy subjects that produced approximately 250 images. As depicted in the representative figures below, an Optinose EDS produced a differentiated pattern of drug delivery with significantly more drug deposited in the high and deep regions of the nasal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

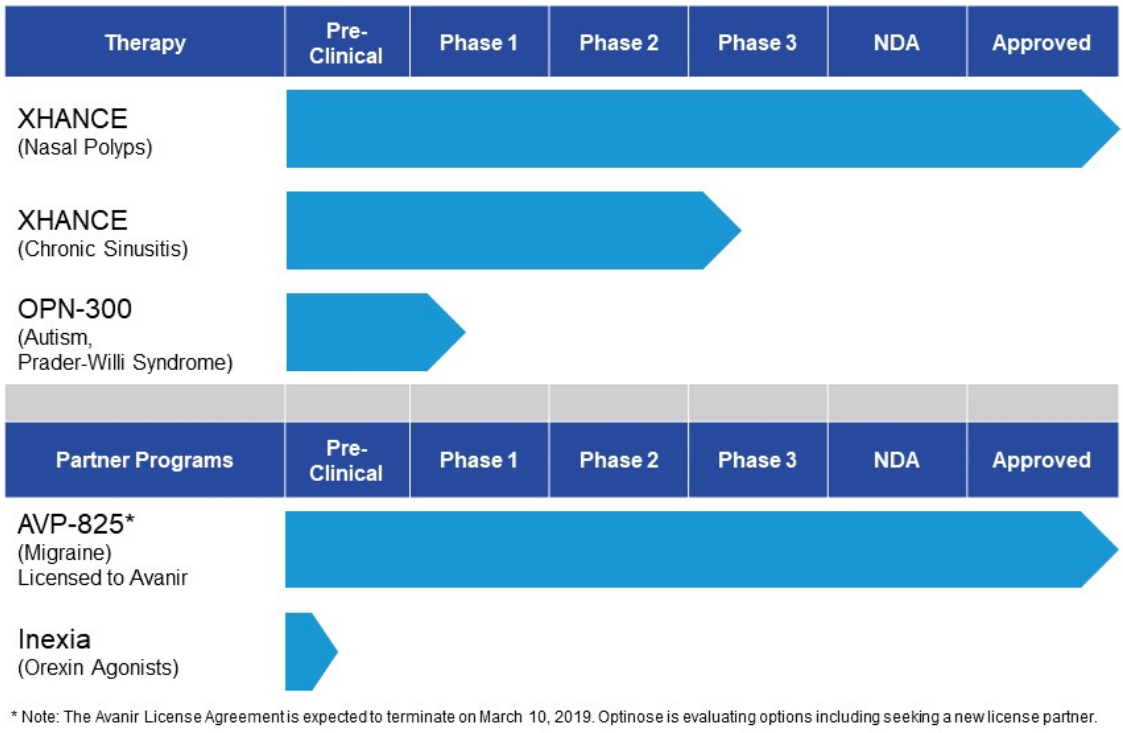
The pictures below illustrate how an Optinose EDS (with exhalation) places medication higher and deeper in the nasal passages than a conventional nasal spray (without sniffing) in nasal cast models. As depicted below, although conventional nasal spray systems can reach, and therefore treat, large nasal polyps, they are not

generally 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



* Note: The Avanir License Agreement is expected to terminate on March 10, 2019. Optinose is evaluating options including seeking a new license partner.

XHANCE for Chronic Sinusitis

We initiated a Phase 3b clinical trial program for XHANCE in the fourth quarter of 2018 to pursue 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 successful commercialization and continued development of XHANCE for 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 has been 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. In a second pilot clinical trial of OPN-300 in adult male patients with autism spectrum disorder, adult men with autism spectrum disorder receiving nasal oxytocin showed statistically significant differences in interpretation of facial expressions. We have completed planned internal development activities and in the future may pursue external partnerships for further development.

Other

We are evaluating the use of the Optinose EDS to deliver other drugs or drug combinations to treat diseases primarily managed by ENT and allergy specialists, and we opportunistically evaluate opportunities to develop product candidates using our EDS intellectual property for indications and markets outside of our ENT and allergy focus through business development and partnering activities.

Our Commercial Strategy

We are implementing our commercial strategy for XHANCE to focus on the following four 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:*** In 2018 we deployed an efficient, go-to-market commercialization model, including the build-out of our commercial team and organization. Our fully-dedicated specialty sales force of approximately 80 territory managers initiated promotion of XHANCE in March 2018 to a defined prescriber base of approximately 6,000 ENT and allergy specialists, as well as approximately 1,500 "specialty-like" primary care physicians. During the first half of 2019, we plan to internalize our contract sales team and deploy an additional 20 territory managers in “XHANCE naive” geographies to expand our reach among the ENT and allergy specialty universe. This is expected to grow the target audience for our sales team by approximately 25% to approximately 9,500 healthcare providers. Because we expect to continue to secure broader market access over time, we intend to eventually 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 additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers. We believe that 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.

- ***Targeted patient demand generation:*** In 2019, we intend to execute a branded, multi-channel direct to consumer (DTC) pilot in three cities targeting diagnosed and undiagnosed nasal polyp patients. Based upon extensive patient research, we believe a high level of frustration exists among nasal polyp patients and these patients are motivated to seek new treatments to relieve their suffering. If successful, we anticipate broadening the DTC pilot to a national campaign in 2020.
- ***Facilitate broader adoption:*** We are pursing a follow-on indication for XHANCE for the treatment of chronic sinusitis. If approved 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 broad 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 are efficiently commercializing XHANCE into the ENT and allergy specialty segments by utilizing the following strategies:

- ***Define a clear patient type for XHANCE.*** We are focusing on moderate-to-severely symptomatic nasal polyp 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 are, among other things, educating physicians, payors and patients on XHANCE's unique mechanism of action and differentiated efficacy profile.
- ***Develop a meaningful payor and patient-friendly value proposition.*** We are establishing 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 and 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. In addition, 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. Furthermore, we developed and implemented a patient affordability program that reduces the real and perceived economic barriers for patients to experience the potential benefits of XHANCE.

  In addition to our affordability program we offer patients the option of filling prescriptions through a network of preferred pharmacies that may be able to better serve the needs of patients through services including delivery of XHANCE by mail.
- ***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 XHANCE through specialty and retail pharmacies.
  - **Physicians:** In early March 2018, we trained and deployed a dedicated sales force of 80 territory managers to promote XHANCE to our target audience of ENTs, allergists and "specialty-like" primary care physicians. The focus of the sales team is to (i) highlight the unmet medical need and limitations of current treatments, (ii) define the target nasal polyp patient type for XHANCE, (iii) differentiate EDS and highlight the strong data supporting the efficacy of XHANCE and, (iv) ensure HCP awareness and appreciation of the XHANCE patient affordability program. In April 2019, we plan to increase our sales force by 20 territory managers and expand our reach within our target physician audience by approximately 25%.

- **Payors:** We continue to engage with payors 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. We also intend to contract for Medicare Part D and Medicaid lives.
- **Patients:** We have completed the build-out of a patient and physician support ecosystem in an effort to accelerate physician adoption and reduce the risk of patient abandonment during the fulfillment process. This ecosystem includes (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 supplemental distribution channel through preferred pharmacy network partners to assist patients with the complexities of the payor landscape, and (vi) 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 launch plan to drive awareness and appreciation of the clinical differentiation of XHANCE, designing and implementing our customer model to drive physician trial and adoption, and building market access for XHANCE to facilitate adoption and fulfillment through specialty and retail pharmacies. 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, journal advertising, and an 85 person nurse educator team calling on a universe of about 7,000 ENT and allergists and achieved 87% aided branded awareness of XHANCE among the ENT and allergy specialist universe prior to launch.
  - Finalized XHANCE core marketing strategies and launch tactic including a compliant, value optimizing and cost-effective promotion mix to appropriately engage our target audience
  - During the early launch phase of XHANCE, we introduced the XHANCE Xperience program to offer physicians and their patients an opportunity to gain initial experience with XHANCE. As part of this program, patients received up to two XHANCE prescriptions at no out-of-pocket cost to them ($0 co-pay). In order to receive the second prescription, patients were required to complete a brief survey regarding their use of XHANCE. The survey results were encouraging and also provided physicians an opportunity to receive individual feedback on early patient responses to treatment. As planned, we closed the Xperience program to new enrollments at the end of June 2018. From March 2018 through June 2018, over 11,000 patients were prescribed XHANCE through the XHANCE Xperience program by over 3,000 physicians.
  - Based upon a quantitative Awareness, Trial and Usage (ATU) market research study that we commissioned in January 2019, a majority of ENT and allergy specialists in our target audience, believed that XHANCE performed better on several efficacy measures than traditional intranasal steroids (e.g. Flonase) including improvement of four core symptoms of CRS with nasal polyps (congestion, rhinorrhea, facial pain and pressure and loss of sense of taste/smell), reduction in nasal polyp grade, polyp elimination, and improvement in quality of life.
- **Design and deploy our customer facing model to drive physician trial and adoption**
  - 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 Directors with an average of approximately 11 years of sales leadership experience
  - In partnership with our contract sales organization, approximately 80 territory managers were recruited, hired and trained. The territory managers have an average of 13 years of pharmaceutical sales experience and over 70% have experience in the respiratory therapeutic category. The

territory managers were deployed in early March 2018 in geographies where we expected to have greater than 65% coverage of commercial lives during launch.

- In April 2019, we plan to expand our sales force by 20 territory managers to call on an incremental 1,800 "XHANCE naive" physicians. We also intend to internalize the contract sales force in April 2019.

- **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 (HEOR) payor messages and payor partnership models
  - Completed pricing study to inform pricing decision and contracting strategy and launched with a Wholesaler Acquisition Cost (WAC) of $425 per unit of XHANCE. As of January 1, 2019, the WAC price for XHANCE was $468.12 per unit.
  - 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 (AMCP) Dossier format
  - Engaged with approximately 40 plans representing approximately 85% of commercial lives
  - Introduced co-pay assistance program and other patient affordability programs to appropriately support patient access to XHANCE
  - Based on currently available third-party data and our internal analyses as of December 31, 2018, we believe greater than 75% of commercially insured lives in the U.S. are plans that cover XHANCE in a tier 3 position

XHANCE Clinical Development

Overview

We 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 INS therapy 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 (polyp grade 0) 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 (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 nasal polyp 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 U.S., 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 (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.

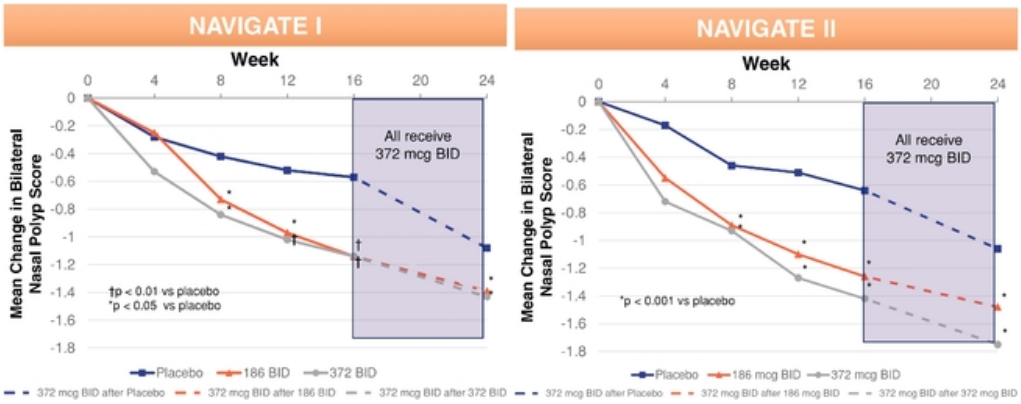
The following table summarizes the mean change in congestion scores in each of the pivotal clinical trials:

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

Treatment	N	Baseline Score (Standard Deviation)	Mean (Standard Error) Change from Baseline	Difference from Placebo EDS		
				Mean	95% confidence interval	p-value[1]
NAVIGATE I						
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)			
NAVIGATE II						
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)			

(1) The p-value (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 study-defined criteria. Surgery was not necessarily planned or pending for these patients. The proportion of patients meeting the study-defined surgical eligibility criteria 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 (polyp grade 0) 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 (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

		XHANCE	
Adverse Event	**Placebo EDS (N = 161) n (%)**	**186 mcg bid (N = 160) n (%)**	**372 mcg bid (N = 161) n (%)**
Epistaxis[1]	4 (2.5)	19 (11.9)	16 (9.9)
Nasopharyngitis	8 (5.0)	3 (1.9)	12 (7.5)
			12 (7.5)
Nasal septal ulceration[2]	3 (1.9)	11 (6.9)	
Nasal congestion	6 (3.7)	7 (4.4)	9 (5.6)
	6 (3.7)	7 (4.4)	
Acute sinusitis			8 (5.0)
Headache	5 (3.1)	8 (5.0)	6 (3.7)
Pharyngitis	2 (1.2)	2 (1.3)	5 (3.1)
	2 (1.2)		
Nasal mucosal ulceration[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.

1 Includes spontaneous adverse reaction reports.

2 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 U.S. 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 based on study-defined surgical eligibility criteria.

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 372 mcg (N = 898) n (%)
Patients with at least 1 Adverse Event	532 (59.2)
Epistaxis[1]	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)

1 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 (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 (C_{max}) and the total amount of absorption, known as the area under the curve from time 0 to infinity ($AUC_{0-\infty}$) 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 supported 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 13 issued device and method of use patents expiring through 2034, 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 U.S. and selected other countries.

Patents

As of February 28, 2019, we owned a total of 47 U.S. patents and 27 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2034. These U.S. patent applications, subject to issuance, would be projected to expire between 2020 and 2039, with potential patent term adjustments that would extend the patent term. In addition to our U.S. intellectual property, we also own 207 foreign issued patents, which will expire between 2020 and 2033 and 77 foreign patent applications, which will expire between 2020 and 2035, subject to issuance.

Our XHANCE U.S. patent portfolio consists of 13 issued device and method of use patents, three issued design patents and 10 pending patent applications. The 13 device and method of use patents expire between 2020 and 2034, the three design patents expire between 2029 and 2030 and the 10 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 13 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 (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 our EDS devices and related technologies.

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® and XHANCE® are registered trademarks of ours in the U.S.

License Agreements

AVP-825 License Agreement

In July 2013, we, through our wholly-owned subsidiary, OptiNose AS, entered into a license agreement (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 U.S., Canada and Mexico. 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 payment 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.

On December 10, 2018, we received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement is expected to terminate on March 10, 2019. Upon termination, we may elect to continue to commercialize Onzetra Xsail ourselves or through a new licensee, from which we may be required to pay Avanir a low double digit royalty until net sales reach a specified amount. We do not expect to receive any additional proceeds from the AVP-825 License Agreement.

Inexia

On January 31, 2019, we entered into a License Agreement (Inexia License Agreement), with Inexia Limited (Inexia). Under the terms of the Inexia License Agreement, we granted Inexia an exclusive, royalty-bearing, worldwide, non-transferable, sublicensable license to our EDS and other intellectual property for the use, sale, import and manufacture of products containing orexin receptor agonist and/or orexin receptor positive modulator molecule(s) as the sole active pharmaceutical ingredient(s) for the treatment, diagnosis or prevention of human diseases or conditions associated primarily with orexin receptor agonism and orexin receptor positive modulation. The license excludes the treatment of any disease or condition affecting the ear, nose or throat, or the treatment of any disease or condition associated primarily with another receptor, other than the Orexin 1 and Orexin 2 receptors. Inexia is solely responsible for all costs and activities related to its identification, development and commercialization of products under the Inexia License Agreement.

Under the terms of the Inexia License Agreement, we received a $0.5 million upfront payment. For each product developed under the Inexia License Agreement, we are eligible to receive up to $8.0 million of development milestone payments and up to $37.0 million of sales milestone payments. In addition, we are eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the Inexia License Agreement. Other than the upfront payment, we do not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

As a result of the Inexia License Agreement, we have discontinued our preclinical OPN-021 program, which combined our EDS with orexin agonist molecules for the treatment of narcolepsy and symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease.

Manufacturing and Distribution

Manufacturing

We currently contract with third parties for the manufacture, testing and storage of our product candidates. In our experience, contract manufacturers (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:

- A supply agreement with Hovione Inter Ltd (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.

- A manufacture and supply agreement with Contract Pharmaceuticals Limited Canada (CPL) for the formulation and assembly of the finished drug product during the fill/pack operation. This agreement terminates in September 2022, 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.
- A manufacturing services agreement with Advance Mold & Manufacturing, Inc. (Flex) for the manufacture of the liquid delivery sub-assembly, which consists of injection molded parts and other purchased components. The initial term of the agreement expires on October 24, 2021 but will automatically renew for successive one-year terms unless either party provides at least ninety days prior written notice to the other that it does not intend to renew the agreement. We have certain rights to terminate the agreement, including upon advance notice to Flex, if Flex 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 if Flex fails to gain recommendation for approval by the FDA to manufacture the liquid delivery subassembly component to be manufactured pursuant to the agreement. Either party may terminate the Agreement for uncured material breaches or insolvency of the other party.

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

Distribution

We sell XHANCE to wholesale pharmaceutical distributors, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. We have also established relationship with preferred pharmacy network partners into which we sell XHANCE. We established this channel to offer patients the option of filling prescriptions through a network of preferred pharmacies that may be able to better serve the needs of patients through services including delivery of XHANCE by mail. 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 provides customer order fulfillment services and accounts receivable management.

Customers

Approximately 42% of our XHANCE net revenues during the fiscal year ended December 31, 2018 were to the three largest pharmaceutical wholesalers, Cardinal Health, McKesson Corporation, and AmerisourceBergen Drug Corporation. Additionally, approximately 57% of our XHANCE net revenues during the fiscal year ended December 31, 2018 were to preferred pharmacy network partners, the majority of which were to Foundation Care LLC. The remaining 1% of our XHANCE net sales were to regional pharmaceutical distributors.

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 competes primarily with INS, oral steroids and other medical management products, including locally compounded liquid budesonide in high-volume nasal rinses. XHANCE also competes 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. In addition, SINUVA™ is a commercially available corticosteroid-eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. In the SINUVA clinical studies, patients were advised to use nasal steroid sprays and sinus rinses for the duration of the study.

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. If these biologic monoclonal antibodies are successfully developed and approved for marketing, they could represent significant competition for XHANCE. In addition, there are new small molecules, including fevipiprant, being developed for the treatment of nasal polyps, that are also believed to inhibit specific pathways of inflammation present in nasal polyps.

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act (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 products and product candidates. Although the discussion below focuses on regulation in the U.S., 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 U.S., 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 U.S. 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 U.S., 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 (GLP) regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the U.S. cannot commence until an investigational new drug (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 (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 (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 U.S. 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 (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 (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 (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 (cGMP) requirements and adequate to assure consistent production of the product within required specifications.

Once the FDA accepts an NDA submission — 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 have since contracted with various clinical trial sites and begun patient enrollment. 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 there are new safety information developments.

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 product 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 (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 (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 (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 U.S. 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.

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 U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changed 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 (340B program), fraud and abuse, and enforcement. These changes impact existing government healthcare programs and have resulted 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 and product candidates for which we receive regulatory approval, and our 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.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (the Tax Act), which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the “donut hole,” by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business, financial condition and results of operations. It is possible 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 our products or product candidates for which we receive regulatory approval or to successfully commercialize our products and product candidates.

U.S. Tax Reform

On December 22, 2017, the U.S. 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 our products and any product candidates for which we may obtain regulatory approval. Sales of any of our products and product candidates, if approved, 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 (ASP), average manufacturer price (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 (CMS) surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost 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 requires 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 (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, which is administered by the Health Resource and Services Administration (HRSA) 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. HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. HRSA also is implementing a ceiling price reporting requirement related to the 340B program during the first quarter of 2019 under which we will be required to report

340B ceiling prices to HRSA on a quarterly basis. 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 an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate Program report ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

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 our products and any product candidates 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 harm our business.

In order to be eligible to have our products or any future products paid for with federal funds under the Medicaid and Medicare Part B programs, as applicable, and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under this program, we are 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 (DoD) Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price (FCP). The FCP is based on the non-federal average manufacturer price (Non-FAMP), which we calculate and report to the VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, under which we 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. Significant 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. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. 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 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 2027. 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 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 $2.8 billion in 2019, 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. 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.

Additional legislative changes, regulatory changes and judicial challenges related to the Affordable Care Act remain possible, 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 our products and any product candidates 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 is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These laws include, but are not limited to, the following:

- 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 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 any person from, among other things, 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 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 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, 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, prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also 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. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

- 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. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients. 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 manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

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, 2019, we had a total of 102 full-time employees and three part-time employees. The majority of our employees are located in the U.S., with the exception of three employees located in United Kingdom and two employees located in Norway. 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. The information contained on our website is not incorporated by reference into this Form 10-K.

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.

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 exhalation delivery system (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 from sales of XHANCE since its launch in 2018 and from our license agreement (the AVP-825 License Agreement) with Avanir Pharmaceuticals, Inc. (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 incurred net losses of $106.7 million and $48.9 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $317.9 million.

We expect to incur losses for the foreseeable future as we:

- continue 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;
- continue to focus our regulatory compliance efforts on requirements applicable to marketed drugs;
- continue clinical development activities for XHANCE, including the U.S. Food and Drug Administration (FDA) mandated pediatric studies, and a Phase 3b clinical trial in pursuit of 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 publicly traded commercial-stage 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. Our ability to generate revenue depends upon our ability to successfully commercialize XHANCE and any of our other product candidates or any other product candidates, if approved, that we may in-license or acquire in the future, as well as from our ability to successfully out-license any of our products or technology. 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 U.S.;
- the size of the markets in the territories for which we gain regulatory approval;
- the performance of our contract sales organization, and once onboarded our internal sales team, in marketing and promoting XHANCE;
- our ability to maintain and further 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;
- our ability to commercialize and/or find a partner to commercialize AVP-825; 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 enough product revenues to cover our operating expenses and prior losses, 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 continue 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, 2018 XHANCE revenue 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, 2018, we had cash and cash equivalents of $201.0 million. Although it is difficult to predict our future liquidity requirements, we believe that existing cash and cash equivalents at December 31, 2018 will be sufficient to meet our debt service obligations under our Notes, and to carry out our planned development and commercial activities into the fourth quarter of 2020. 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 insurance coverage and reimbursement for XHANCE;

- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the costs and timing of internalizing and expanding our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the supplemental 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;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- fluctuations in the three-month LIBOR-based floating interest rate of our Notes;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates; and
- the extent to which we in-license, acquire or otherwise partner in development of 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 U.S. 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 our EDS devices and technologies 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 may have the ability to obtain an additional $25.0 million through the issuance of additional senior secured notes pursuant to the Note Purchase Agreement, the availability of this $25.0 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 (the Collateral Agent) and the purchasers party thereto (the Purchasers) that provides for the issuance of up to $100.0 million of senior secured notes (the Notes). $75.0 million of the Notes were issued on December 29, 2017, of which $50.0 million were issued by OptiNose AS and $25.0 million were issued by OptiNose US, Inc. (the Issuers.) The remaining $25.0 million of Notes (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 $15.0 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 (the Maturity Date). The proceeds of the Notes were 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 11.8125% at December 31, 2018. 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 the additional $25.0 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 $15.0 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 carry forwards and other tax attributes may be limited.

As of December 31, 2018, we had U.S. federal net operating loss (NOL) carry forwards of approximately $86.6 million available to offset future U.S. taxable income and U.S. federal research and development (R&D) tax credits of $2.4 million. While some of our federal NOL carry forwards will carry forward indefinitely, some of our U.S. NOL and credit carry forwards will expire if not utilized with the first expiration occurring in 2030. We also have state NOL carry forwards of $57.0 million as of December 31, 2018. These state NOL carry forwards can only offset income in the same state in which they were generated and thus may not be utilized. The carry forward period varies among the states, with the first expiration in 2028, and some may expire unutilized. In addition, our Norwegian and UK subsidiaries have total foreign NOL carry forwards of $50.5 million as of December 31, 2018. These foreign NOL carry forwards do not expire but can only be used to offset profits generated in Norway or the United Kingdom, respectively, and may be limited in use based on the laws of those countries.

Our U.S. NOL and tax credit carry forwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of the 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 utilization of our federal tax attribute carry forwards 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 carry forwards to reduce U.S. taxable income or tax liability may be subject to limitation resulting 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 additional changes in our stock ownership which could be outside of our control. If an ownership change occurs and our ability to use our historical net operating loss and tax credit carry forwards is limited, it could adversely impact our future operating results by increasing our tax obligations.

The termination of the AVP-825 License Agreement may generate additional expenses for us.

On December 10, 2018, we received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement is expected to terminate on March 10, 2019 (the Termination Date). We do not expect to receive any additional proceeds from the AVP-825 License Agreement.

Upon termination of the AVP-825 License Agreement, we may elect to continue to commercialize Onzetra Xsail ourselves or through a new licensee. However, we may not be able to find a new licensee willing to enter into a license agreement on commercially reasonable terms, if at all. Further, we may incur additional expenses in connection with the process of identifying potential new licensees and in connection with the termination of the AVP-825 License Agreement.

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 U.S., 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 a limited 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, as well as commercializing XHANCE through the last nine months of 2018. 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. Further, while we have been commercializing XHANCE for the last nine months of 2018, we have limited history regarding sales, marketing, distribution and other 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, and once onboarded our internal sales team, 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 commercialize XHANCE at a profitable average net revenue per prescription;
- our ability to contract with wholesalers distributors and/or preferred pharmacy network partners (PPNPs) on acceptable terms;
- our ability to obtain regulatory approval for XHANCE for a follow-on indication for the treatment of chronic sinusitis;
- the effectiveness of our marketing campaigns;
- our ability to attract and retain qualified pharmaceutical industry personnel;
- 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 sell or intend to sell XHANCE; and
- our ability to successfully defend any challenges to our intellectual property relating to XHANCE.

It is difficult for us to predict future performance. As we gain additional commercial experience, a number of factors over which we have limited control may contribute to fluctuations in our financial results. Demand for our products may be impacted adversely by the annual resetting of patient healthcare insurance plan deductibles, both of which may cause patients to delay fulfilling an XHANCE prescription. Demand may also be impacted by the seasonal variation in patient visits with their doctor.

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 enough revenue from XHANCE to achieve profitability. 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;
- 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 depends 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 is 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 are currently commercializing XHANCE for the treatment of nasal polyps and intend to 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, while SINUVA™ is a commercially available corticosteroid-eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. 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. For dupilumab, the submission of an Supplemental Biologics License Application (sBLA) was recently publicly announced. In addition, there are new small molecules, including fevipiprant, being developed for the treatment of nasal polyps, that are also believed to inhibit specific pathways of inflammation present in nasal polyps. 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 consists 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, or we are unable to effectively onboard our third party sales force to employees, our business may be harmed.

We currently have limited sales, marketing or distribution capabilities. We have contracted to use an outsourced contract sales organization (CSO) to promote XHANCE to our defined specialty audience of ENT and allergy specialists and high-decile INS-prescribing primary care physicians. While we plan to transition to an internal sales force model in April 2019, our CSO may not dedicate sufficient resources to the commercialization of XHANCE prior to such transition 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. Additionally, we may not effectively or efficiently manage such transition and our sales force may fail to comply with applicable legal or regulatory requirements. This could subject us 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.

We may also seek to enter into a strategic collaboration with a third party to commercialize XHANCE. 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.

A significant portion of our sales are to a limited number of pharmaceutical wholesalers and PPNPs. Changes in terms required by these wholesalers, disruptions in these relationships or a default could harm our results of operations and financial condition.

Approximately 42% of our XHANCE net revenues during the fiscal year ended December 31, 2018 were to the three largest pharmaceutical wholesalers. Additionally, approximately 57% of our XHANCE net revenues during the fiscal year ended December 31, 2018 were to PPNPs, the majority of which relate to a particular PPNP, Foundation Care LLC. If any of these wholesalers or PPNPs ceases to purchase our product for any reason, then unless and until the remaining wholesalers or PPNPs increase their purchases of XHANCE or alternative distribution channels are established:

- our commercial operations could be significantly disrupted;
- the availability of XHANCE to patients could be disrupted; and
- we may not achieve the sales of XHANCE that we expect, which could decrease our revenues.

We do not require collateral from our wholesalers or PPNPs but rather maintain credit limits and as a result we have an exposure to credit risk in our accounts receivable. A default by a large wholesaler or PPNP could harm our results of operations and financial condition.

In addition to pharmaceutical wholesalers, we rely on PPNPs for distribution of XHANCE in the U.S., and the failure of those PPNPs to distribute XHANCE effectively would adversely affect sales of XHANCE.

Our reliance on PPNPs for the distribution of XHANCE in the U.S. involves certain risks, including, but not limited to, risks that these PPNPs will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products;
- reduce or discontinue their efforts to sell or support or otherwise not effectively sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- engage in unlawful or inappropriate business practices that result in legal or regulatory enforcement activity which could result in liability to our Company or damage our goodwill with patients; or

- be unable to satisfy financial obligations to us or others.

In the event that any of the PPNPs with whom we work do not fulfill their contractual obligations to us or refuse to or fail to adequately serve patients, or the agreements are terminated without adequate notice, shipments of XHANCE, and associated revenues, would be adversely affected.

If we cannot successfully implement our patient affordability programs or improve formulary access for XHANCE in the face of increasing pressure to reduce the price of medications, the adoption of XHANCE by physicians and patients may decline.

While we offer patient affordability programs through traditional retail pharmacies, part of our commercial strategy to increase adoption and access to XHANCE is to offer physicians the opportunity to have patients fill prescriptions through PPNPs that can apply appropriate patient affordability programs to help reduce eligible patients' out-of-pocket costs for prescriptions filled. Because of this assistance, eligible patients' out-of-pocket cost for XHANCE, when dispensed through PPNPs, may be lower than such costs when XHANCE is dispensed from traditional retail pharmacies. However, to the extent physicians do not direct prescriptions to the participating PPNPs, the adoption of XHANCE by physicians and patients may decline.

Our ability to increase utilization of our patient affordability programs will depend on physician and patient awareness and comfort with the programs, and we have limited ability to influence whether physicians use our patient affordability programs to prescribe XHANCE or whether patients will agree to receive XHANCE through PPNPs. In addition, the patient affordability programs are not available to federal health care programs (such as Medicare and Medicaid) beneficiaries. We have also contracted with certain Pharmacy Benefit Managers (PBMs) and other payors to secure formulary status and reimbursement for XHANCE, which generally require us to pay administrative fees and rebates to the PBMs and other payors for qualifying prescriptions. While we have business relationships with three of the largest PBMs, as well as other PBMs, we believe these agreements will secure formulary status for XHANCE but we cannot guarantee that we will be able to agree to terms with other PBMs and other payors, or that such terms will be commercially reasonable to us. Despite our agreements with PBMs, the extent of formulary status and reimbursement will ultimately depend to a large extent upon individual healthcare plan formulary decisions. If healthcare plans that contract with PBMs with which we have agreements do not adopt formulary changes recommended by the PBMs with respect to XHANCE, we may not realize the expected access and reimbursement benefits from these agreements. Consequently, the success of our PBM contracting strategy will depend not only on our ability to expand formulary adoption among healthcare plans, but also upon the relative mix of healthcare plans that have PBM-chosen formularies versus custom formularies. If we are unable to realize the expected benefits of our contractual arrangements with the PBMs the adoption of XHANCE by physicians and patients may decline. If we are unable to increase adoption of PPNPs for filling prescriptions of XHANCE by physicians or to secure formulary status and reimbursement through arrangements with PBMs and other payors, particularly with healthcare plans that use custom formularies, our ability to achieve net sales growth for XHANCE would be impaired.

The negative publicity regarding specialty pharmacies may result in physicians being less willing to participate in our patient affordability programs, which would limit our ability to increase patient access and adoption of XHANCE.

There has been negative publicity and inquiries from Congress and enforcement authorities regarding the use of specialty pharmacies and drug pricing. PPNPs with whom we contract may be considered specialty pharmacies. Our patient affordability programs are in place to assist in ensuring that when a physician determines XHANCE offers a potential clinical benefit to their patients and they prescribe it for an eligible patient, financial assistance may be available to reduce the patient's out-of-pocket costs. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes XHANCE and our relationship with each pharmacy is non-exclusive and arm's length. All of our sales are processed through pharmacies independent of us. Despite this, the negative publicity and interest from Congress and enforcement authorities regarding specialty pharmacies may result in physicians being less willing to participate in our patient affordability programs and thereby limit our ability to increase patient access and adoption of XHANCE.

We may be unable to form and maintain relationships with pharmacies that participate in our patient affordability programs, which could adversely affect the commercialization of XHANCE and our operating results.

We may also encounter difficulty in forming and maintaining relationships with pharmacies that participate in our patient affordability programs. We currently depend on a limited number of PPNPs to fulfill patient prescriptions. If

these PPNPs are unable to process and fulfill the volume of patient prescriptions directed to them, our ability to maintain or increase prescriptions for XHANCE will be impaired. The commercialization of XHANCE and our operating results could be affected should any of the PPNPs choose not to continue to fulfill XHANCE prescriptions or by any adverse market events at any of the PPNPs. For example, pharmacies that dispense XHANCE could lose contracts that they currently maintain with managed care organizations (MCOs), including PBMs. Pharmacies often enter into agreements with MCOs. They may be required to abide by certain terms and conditions to maintain access to MCO networks, including terms and conditions that could limit their ability to participate in patient affordability programs like ours. Failure to comply with the terms of their agreements with MCOs could result in a variety of penalties, including termination of their agreement, which could negatively impact the ability of those pharmacies to dispense XHANCE and collect reimbursement from MCOs for such medicines.

Our patient affordability programs are subject to certain federal and state laws, the violation of which could have an adverse impact on our business and subject us to significant penalties.

Our patient affordability programs may implicate certain federal and state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. We have a comprehensive compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of XHANCE. Despite our compliance efforts, to the extent the patient affordability programs are found to be inconsistent with applicable laws or the pharmacies that participate in our patient affordability programs do not comply with applicable laws, we may be required to restructure or discontinue such programs, terminate our relationship with certain pharmacies, or be subject to other significant penalties.

If the cost of maintaining our patient affordability programs increases relative to our sales revenue, we could be force to reduce or eliminate our financial assistance programs, which could have an adverse effect on our financial results.

If the cost of maintaining our patient affordability programs increases relative to our sales revenues, we could be forced to reduce the amount of patient financial assistance that we offer or otherwise scale back or eliminate such programs, which could in turn have a negative impact on physicians' willingness to prescribe and patients' willingness to fill prescriptions of XHANCE. While we believe that our arrangements with PBMs will result in broader inclusion of certain of our therapies on healthcare plan formularies, and lower our cost of providing patient affordability programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and/or other payors and their effectiveness will ultimately depend to a large extent upon individual healthcare plan formulary decisions that are beyond the control of the PBMs. If our arrangements with PBMs and other payors do not result in increased prescriptions and reductions in our costs to provide our patient affordability programs that are sufficient to offset the administrative fees and rebate payments to the PBMs and/or other payors, our financial results may continue to be harmed.

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 (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 (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 U.S. 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 have since contracted with various clinical trial sites and begun patient enrollment. 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 U.S. 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 (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 (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 and further development of XHANCE, as well as potential future development programs, 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 federal Anti-Kickback Statute, prohibits persons or entities from, among other things, 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 federal 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 federal federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) 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.

- numerous federal and state laws and regulations that address privacy and data security, 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 (FTC Act)), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating relevant compliance efforts.
- a majority of states whom have adopted laws and regulations analogous to federal laws, 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. Other states have adopted laws that, among other things, 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. In addition, some states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients.

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

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.

The occurrence of any event or penalty described above may inhibit our ability to commercialize and further develop 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 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 are 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 (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 (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 (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 significant civil monetary penalties. 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.

The Health Resource and Services Administration (HRSA) issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. HRSA also is implementing a ceiling price reporting requirement related to the 340B program during the first quarter of 2019 under which we will be required to report 340B ceiling prices to HRSA on a quarterly basis. 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 an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate Program report ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program to be eligible to have its products paid for with federal funds. As part of this program, we are 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 (FCP) to four federal agencies (VA, U.S. Department of Defense (DOD) Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price (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 often prescribe XHANCE for the treatment of chronic rhinosinusitis and other chronic nasal inflammatory diseases, even though the FDA has granted approval of XHANCE only for the treatment of nasal polyps and we promote the use 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 U.S., we may never obtain approval for or successfully commercialize it outside of the U.S., which would limit our ability to realize its full market potential.

In order to market XHANCE outside of the U.S., 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 U.S. 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 U.S. 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 (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;
- price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entity types eligible for discounts under the Public Health Service's 340B drug pricing program;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (the Tax Act), which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the “donut hole,” by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business, financial condition and results of operations. 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 it.

We also 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 revenues, attain profitability or successfully 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 adversely affect our XHANCE product revenues, inhibit the development of XHANCE for additional indications or inhibit the development 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, AVP-825, our exhalation device technology 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, under the terms of the license agreement we entered into with Inexia we expect to enter into a clinical supply agreement with Inexia whereby we will provide certain exhalation devices to Inexia, which may expose us to indemnification obligations that may exceed the coverage under our product liability insurance policy or otherwise expose us to third party product liability losses.

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 have initiated 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 cease to pursuit of this follow-on indication. Additionally, clinical trials for this indication may not demonstrate sufficient efficacy or safety to support FDA approval for a follow-on indication for XHANCE. 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 may 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.

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.

The failure to obtain regulatory approval for a particular product candidate, could substantially harm our business.

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, investigators failure to comply with applicable laws, 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 this or any other product candidate fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA may not approve the product candidate and we would not be able to commercialize it, which could substantially harm our business.

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 ongoing and future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, timely enroll 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 (IRB) approval;
- delays in recruiting suitable patients to participate in a clinical trial;
- delays as a result of interim analyses, if any, of clinical trials that indicate futility of the trial or necessitate an increase in the number of patients enrolled in 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 (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 U.S. 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 U.S.

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 U.S. 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 (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 or cease sales and ongoing development of XHANCE, or find alternatives that may be more expensive than originally anticipated.

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, decreases in sales to customers, 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 (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 (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 expect to grow the size of our organization, and we may experience difficulties in managing this growth.

Implementation of our development and commercialization strategies may 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, including but not limited to in connection with the onboarding of our contract sales organization to become our internal sales team, 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 of 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 prescription and over-the-counter 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, and SINUVA™ is a commercially available corticosteroid-eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. 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 (which contains the same active pharmaceutical ingredient as XHANCE), 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. For dupilumab, the submission of an Supplemental Biologics License Application (sBLA) was recently publicly announced. In addition, there are new small molecules, including fevipiprant, being developed for the treatment of nasal polyps, that are also believed to inhibit specific pathways of inflammation present in nasal polyps. 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.

We have 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.

If we fail to comply with data and privacy 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.

Our business is subject to complex and evolving U.S., state and international data and privacy protection laws. In the U.S., 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.

Additionally, the General Data Protection Regulation (GDPR), applicable in the European Union (EU) as of May 25, 2018, applies to all of our activities conducted from an establishment in the EU or related to products and services that we may offer to EU users. The GDPR created a range of new compliance obligations, which could cause us to change our business practices, and has significantly increased financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements).

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 or those of any business partners.

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, loss of funds or information from phishing or other fraudulent schemes, 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 or loss of Company funds and have a negative financial consequence on our business. 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 XHANCE and our product candidates could be delayed. Additionally, breach remediation costs may be significant

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

In 2018 we implemented a new global enterprise resource planning (ERP) system. This system replaces many of our existing operating and financial systems. Such an implementation was a major undertaking, both financially and from a management and personnel perspective. Any disruptions, delays or deficiencies in the maintenance of our 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 and regulatory activities 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 U.S., 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 U.S.;

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. In addition, tax returns we file are subject to examination by U.S. federal, state and foreign tax authorities.

We have operations in Norway and the UK and a substantial portion of our intellectual property, including certain rights to XHANCE, are owned by OptiNose AS, our Norwegian subsidiary. We file tax returns in various jurisdictions and those returns are subject to examination by the tax authorities. During an examination, a tax authority could challenge positions taken on a return. Such a challenge could result in the loss of tax attributes or in the payment of tax which could have an unfavorable impact on our financial condition.

We operate pursuant to written intercompany license, service and related agreements that establish prices for intellectual property and for services provided such as production, marketing, management, and technology development activities that are performed by one group company for another group company. The amounts paid under these intercompany agreements are commonly considered for tax purposes as transfer prices. If the affiliated companies are located in different countries, the tax laws and regulations of each country generally require that transfer prices be at arm's length as if between unrelated companies. Our transfer pricing arrangements consider requirements of the jurisdictions in which we operate but are not binding on the tax authorities. If any tax authority is successful in challenging our transfer prices, there could be an increase in taxable income in that jurisdiction which could increase our tax liabilities. Further, if the tax authority in the other country does not agree with the adjustment, both countries could tax the same income, resulting in double taxation.

Any income earned by our foreign subsidiaries, including a portion of the sales of XHANCE in the U.S., may be subject to additional tax liabilities. If our foreign operations generate cash that we want to repatriate to the U.S. or if cash generated by our U.S. operations is not sufficient to fund our U.S. operations, we may face additional tax liabilities in returning or otherwise providing such cash to support our U.S. operations or other strategic opportunities in the U.S. 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.

If foreign subsidiary income is subject to the Subpart F, investment in US property or global intangible low-taxed income provisions, or similar provisions of the U.S. Internal Revenue Code, collectively referred to in this paragraph as Subpart F, the income may be subject to U.S. corporate income tax even if there is no cash distribution of those earnings to the U.S. For example, Subpart F income includes certain "passive" income, certain income from intercompany transactions, foreign subsidiary income over a legislative threshold or income of a 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 foreign subsidiary income subject to the Subpart F provisions would be included in determining U.S. taxable income and potentially subject to federal corporate income tax at rates up to 21%.

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

On December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (Tax Act). The Tax Act introduced significant changes to the U.S. corporate tax laws. The Tax Act changes include, but are not limited to:

- a reduction in the corporate tax rate from a top rate of 35% to a flat rate of 21%;
- limits on the tax deductibility of interest expense;
- limits on the utilization of net operating losses generated after 2017 to 80% of current year taxable income;
- elimination of net operating loss carrybacks;
- accelerated deduction for certain investments instead of depreciation deductions;
- allowing indefinite carry forward of net operating loss carry forwards generated after 2017;
- modifying or repealing certain business deductions and credits; and
- limits on the deduction for certain compensation in excess of $1 million.

While guidance has been provided on some of these new provisions, the overall impact of the Tax Act on our Company is uncertain and our business and financial condition could be adversely affected depending on how the new provisions are interpreted.

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 (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 U.S. 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. We have implemented policies to discourage these practices by our employees, consultants, sales agents and distributors. However, our 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 U.S. 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 U.S. 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 February 28, 2019, we owned a total of 47 U.S. patents and 27 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2034. 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 U.S. or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. 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 U.S. 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 U.S., 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 (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 U.S. 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 U.S. may be less extensive than those in the U.S. 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 U.S. 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 U.S., or from selling or importing products made using our inventions into or within the U.S. 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 U.S. 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 U.S. 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 U.S., 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 (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 U.S. 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 U.S. 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 U.S. 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 U.S. 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® and XHANCE® are registered trademarks of ours in the U.S. 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 U.S. 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, 2019, there were 41,264,422 outstanding shares of our common stock. Holders of an aggregate of 15,674,055 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 will likely 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 78.6% of our outstanding common stock as of March 1, 2019. Entities associated with Avista Capital Partners II, L.P. (Avista), our largest stockholder, collectively hold as a group approximately 37.6% of our outstanding common stock as of March 1, 2019. 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;
- 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 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 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, or a majority of our board of directors.

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 U.S. 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 U.S. 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 Select Market. We will need to satisfy the continued listing requirements of The Nasdaq Stock Market, LLC (Nasdaq) for inclusion on The Nasdaq Global Select 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 (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 (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 are 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 (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 RESISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on The Nasdaq Global Select Market under the symbol “OPTN”. As of March 1, 2019, there were 41,264,422 shares of our common stock outstanding. There were approximately 25 stockholders of record at March 1, 2019. 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.

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

In May 2018 and July 2018, we issued an aggregate of 14,647 shares of common stock to pursuant to the exercise of certain warrants issued prior to our initial public offering. The shares of common stock issued upon exercise of the warrants were offered and sold without registration under the Securities Act pursuant to the exemption provided by Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder as transactions not involving a public offering.

The certificates representing the issued shares of common stock 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, 2018 that were not registered under the Securities Act of 1933, as amended (the Securities Act) and that have not otherwise been described in a Quarterly Report on Form 10-Q or a Periodic Report on Form 8-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

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 initial public offering (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. All of the securities registered pursuant to the offering were sold prior to termination of the offering. Jefferies

and Piper Jaffray acted as joint lead 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.

There has been no material change in the use of proceeds from the IPO as described in the final prospectus for the IPO filed with the SEC on October 12, 2017 (the Final Prospectus). During the period from the closing of our IPO to December 31, 2018, we used $115.4 million of the proceeds as follows:

- approximately $70.3 million to support the launch of XHANCE, including investments in marketing and sales, inventory and our commercial infrastructure;
- approximately $9.7 million to fund further development efforts for XHANCE; and
- approximately $35.4 million to fund other working capital and general corporate purposes, including costs of operating as a public company.

The balance of the funds totaling approximately $10.1 million are expected to be used in a manner consistent with the use of proceeds described in 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.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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 (ENT) and allergy specialists. Our first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids (INS), which 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.

On September 18, 2017, the U.S. Food and Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through retail channels in April 2018.

Since the FDA approval of XHANCE, we have focused on executing our integrated launch plan and have made progress in each of these key strategic areas:

- Customer Model. We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENTs, allergists and "specialty-like" primary care physicians and have deployed a hybrid sales model that combines an internal sales leadership team with a fully-dedicated contract sales

force to call on our target health care provider (HCP) customer universe. We prioritized approximately 80 territories within our sales force footprint to deploy in 2018 based upon pre-launch expectations regarding where we could achieve an estimated 65% commercial market access within each territory. The initial 80 territory managers were deployed in March 2018, actively engaging approximately 7,600 ENTs, allergists and "specialty like" primary care physician targets to promote XHANCE for the treatment of nasal polyps. During the first half of 2019, we plan to internalize our contract sales team and deploy an additional 20 territory managers in “XHANCE naive” geographies to expand our reach among our target physician audience. This is expected to grow the target audience for our sales team by approximately 25% to approximately 9,500 HCPs. We intend to eventually increase the size of our sales force to approximately 120 territory managers to expand our called on target audience to approximately 14,000 ENT, allergists and specialty-like primary care physicians. Additionally, we expect to target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers.

- XHANCE Patient Affordability Programs. In late August 2018, we implemented our current co-pay savings program. We believe this program, with an indefinite duration, provides an affordability solution for patients that physicians will support. The current program provides patient co-pay assistance including a first prescription at no out-of-pocket cost to patients ($0 co-pay) to commercially insured patients and low subsequent co-pays for refills. Our data suggests these programs are playing a role in building demand for XHANCE, particularly as they become more widely understood in the prescribing community.

- Market Access. In meeting with pharmacy benefit managers (PBMs) and health insurers/potential payors, we share what we believe is a compelling economic value proposition. Our analyses suggest 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 other healthcare resource utilization, most notably the rate of endoscopic surgery and, therefore, surgery-related costs. For an insurance plan, this could represent potential for overall cost reduction in 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 trials, 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, including dupilumab, for which the submission of an Supplemental Biologics License Application (sBLA) was recently publicly announced.

  Based on currently available third-party data and our internal analyses, we believe that greater than 75% of commercially insured lives are currently in a plan in which XHANCE is covered in a Tier 3 formulary position, and approximately 60% of commercially insured lives are in a plan that covers XHANCE in a “low hassle factor” position. However, payors may change coverage levels for XHANCE or controls such as step edits and prior authorization (PAs), positively or negatively, at any time. We use the term “hassle factor” to characterize the level of difficulty that physicians and patients must overcome to prescribe and fill XHANCE. We define a low “hassle factor” as Tier 3 unrestricted, Tier 3 single step edit, or Tier 3 with a simple PA requiring, for example, only the prior use of an over-the-counter or generic INS - although we acknowledge that any step edit or PA involves a level of burden for physicians and patients that could negatively impact XHANCE utilization. Our initial goal was for 75% of commercially insured lives to have access to XHANCE in a Tier 3 formulary position with a “low hassle factor" by the end of 2018. While at approximately 60% "low hassle factor" at December 31, 2018 we did not meet this goal, it remains an important concept for us as we seek to expand overall coverage for XHANCE.

  We have also contracted with the Centers for Medicare and Medicaid Services for coverage of certain government insured lives and continue to expand XHANCE market access for other government-insured populations. As noted above, we have in place a co-pay assistance program for patients covered by commercial insurers and plan to continue to analyze affordability issues and assess patient affordability programs to appropriately support patient access to XHANCE for government insured patients.

- Infrastructure. We continue to develop our internal capabilities in a manner commensurate with having become a fully integrated and publicly traded commercial-stage specialty pharmaceutical company. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have also 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.

- XHANCE Prescriptions. Based on third-party prescription data as well as data from preferred pharmacy network partners, the total estimated number of XHANCE prescriptions in the second quarter, third quarter and fourth quarter 2018 were 8,611, 9,427, and 14,106, respectively, which represents 50% growth for prescriptions when comparing fourth quarter to third quarter. The INS market increased approximately 11% from third quarter to fourth quarter of 2018 based on third-party prescription data. Estimated XHANCE prescriptions in December 2018 and January 2019 were 4,570 and 6,292, respectively, which represents 38% month-over-month growth. The INS market increased approximately 5% from December 2018 to January 2019 based on third-party prescription data. In addition, XHANCE prescriptions for the 4-week periods ended January 25 and February 22, 2019 were 5,156 and 7,186, respectively, which represents period-over-period growth of 39%. The INS market decreased approximately 1% from the 4-week period ended January 25 to the 4-week period ended February 22 based on third-party prescription data.

  XHANCE prescribing may be subject to a seasonal effect historically observed in the INS market in which market volume generally peaks in the second quarter and declines in the third quarter of each calendar year. Although the underlying disease that we are treating is chronic and causes symptoms year-round, we believe the variation in patient flow through the offices of relevant specialists, and seasonality in disease flare-ups, may have an impact on the number of patients that present themselves and who are therefore available for prescribing a new medication like XHANCE. We also believe the annual resetting of patient healthcare insurance plan deductibles may have a negative impact on demand for XHANCE. Based on our limited commercial history, we are unable to estimate the extent to which INS market seasonality and deductible resets may affect XHANCE.

XHANCE Development Update

In addition to XHANCE's existing indication for the treatment of nasal polyps, in order to broaden our U.S. market opportunity we initiated a clinical research program in pursuit of a follow-on indication for the treatment of chronic sinusitis in the U.S. The program will comprise two phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018. We expect to initiate the second trial in 2019.

Financial Operations Overview

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

Net product revenues

Sales of XHANCE generated $7.1 million in net product revenues for the year ended December 31, 2018. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates.

Based on available XHANCE prescription data purchased from third parties and data from our pharmacy network, our average net revenues per prescription for the fourth quarter of 2018 was approximately $214, which is favorable compared to our average net product revenues per prescription of approximately $202 and $148 in the third and second quarters of 2018, respectively. The 6% improvement in the average net revenue per prescription in the fourth quarter vs. the third quarter of 2018 is primarily attributable to lower rates of utilization of our patient affordability programs. We calculate average net product revenues per prescription by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. As a result, average net product revenues per prescription is subject to variability. That variability is impacted by factors that do not necessarily reflect a change in the price that is paid for an individual unit of XHANCE, including but not limited to ordering patterns and inventory levels for our wholesale customers and preferred pharmacy network partners, patient utilization rates of affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. There is also the potential for variability that results from changes in estimation methodology by the third parties that we rely upon to provide prescription data which may lead to revisions of historical estimates of prescription volumes and our calculated average revenue per prescription.

Based on data available to date, we expect first quarter 2019 net revenue per prescription to be between $155 - $175. This decrease from the fourth quarter 2018 is a consequence of the reset of many patient insurance deductibles in January. As a result of this annual reset, we expect greater copay support to be provided by us under our assistance programs which are designed to support continued volume growth. For the remainder of 2019, we believe average net revenue per prescription will improve and we expect that the full-year 2019 average net

revenue per prescription will be between $185 - $205. Factors supporting this expected growth include patients meeting their out-of-pocket expense thresholds, expected improvements in insurance coverage and an increase in the proportion of prescription refills.

Costs of product sales

Costs of product sales includes the cost of inventory sold, which includes direct and indirect manufacturing and supply chain costs.

Research and development expense

Prior to the FDA approval of XHANCE in September 2017, research and development expense consisted primarily of costs incurred in connection with the development and pursuit of regulatory approval for XHANCE for the treatment of nasal polyps. Post-FDA approval of XHANCE, research and development expense consists primarily of expenses incurred to prepare for, initiate and conduct our planned clinical trials, ongoing research efforts of new products and device improvements. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding clinical development performed by third parties, including pursuant to agreements with contract research organizations (CROs), as well as investigative sites and consultants that conduct or support our nonclinical studies and clinical trials;
- expenses associated with the continued development of our EDS devices;
- expenses related to the continued development of our product sample portfolio;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale 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 prior to regulatory approval of products for commercial sale;
- 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 that were previously 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 the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, including rate of subject enrollment, number of subject required, and trial duration, 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

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.

Early sales and marketing related expenses included expenses related to building brand awareness through advertising and the deployment of our nurse educator team, training and deploying our contract sales force and securing market access for XHANCE as well as salaries and related benefits for employees focused on such efforts. Current and expected commercial investments include our sales team and supporting promotional materials, digital promotion, peer to peer education, congresses / conventions, samples, and marketing activities such as direct to patient / direct to consumer initiatives.

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

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 (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 account for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2018. This standard applies to all contracts with customers with the exception of contracts that are within the scope of other standards, such as leases, insurance and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services.

We perform the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer.

Net Product Revenues

We sell XHANCE to preferred pharmacy network partners and wholesalers in the U.S. (collectively, Customers). These Customers subsequently resell our products to healthcare providers, patients and other retail pharmacies. In addition to agreements with Customers, we enter into arrangements with healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts for the purchase of our products.

We recognize revenue from product sales at the point the Customer obtains control of the product, which generally occurs upon delivery. The transaction price that is recognized as revenue for products includes an estimate of variable consideration, which is described below. Payment terms with Customers do not exceed one year and, therefore, we do not account for a financing component in our arrangements. Incremental costs of obtaining a contract with a Customer (for example, sales commissions) are expensed when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to Customers are recorded as selling, general and administrative expenses.

Transaction Price, including Estimates of Variable Consideration

Revenue from products is recognized at the estimated net sales price (transaction price), which includes estimates of variable consideration. We include estimated amounts in the transaction price to the extent it is determined probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Our estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available.

Components of Variable Consideration

Components of variable consideration include provider chargebacks and discounts, trade discounts and allowances, product returns, government rebates, third-party payor rebates, sales order management fees and other incentives, such as voluntary patient assistance and other allowances that are offered within contracts between us and our Customers, payors and other indirect customers relating to our sale of products. Those components, as described below, are based on the amounts earned or to be claimed on the related sales and are presented as reductions of accounts receivable (if the amount is payable to the Customer) or as a current liability (if the amount is payable to a party other than the Customer). We consider all relevant factors, such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

- *Variable Consideration - Accounts Receivable Reductions*
    - Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Reserves for chargebacks consist of credits we expect to issue for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold to qualified healthcare providers, as well as chargebacks that Customers have claimed but for which we have not yet issued a credit.
    - Trade Discounts and Allowances. We generally provide Customers with discounts that include incentive fees which are explicitly stated in our contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized. In addition, we reimburse our Customers (through discounts and allowances) for sales order management, data and distribution services.
- *Variable Consideration - Current Liabilities*
    - Product Returns. Consistent with industry practice, we have a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the goods to a patient. We estimate the amount of our products that may be returned and present this amount as a reduction of revenue in the period the related product revenue is recognized in addition to establishing a liability. We consider several factors in the estimation process, including expiration dates of product shipped to preferred pharmacy network partners and wholesalers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.
    - Government Rebates. We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. For Medicaid, accruals are

based on estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. To estimate the cost to us of this Medicare coverage gap responsibility, we estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of the reporting period.

- Payor Rebates. We contract with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. These rebates are based on contractual percentages applied to the amount of product prescribed to patients who are covered by the plan or the organization with which we contract. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

- Other Incentives. Other incentives that we offer include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors, and coupon programs for cash payors. The calculation of the accruals for this assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Licensing Revenues

Through December 31, 2017, our revenues were 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 included licensed rights to patented technology, non-refundable up-front payment, research services, and regulatory and sales milestones as well as royalty payments. Through December 31, 2018, under the terms of the AVP-825 License Agreement, we received aggregate cash payments of $70.0 million in connection with the initial signing and the achievement of certain development milestones.

On December 10, 2018, we received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement is expected to terminate on March 10, 2019. Upon termination we may elect to continue to commercialize Onzetra Xsail ourselves or through a new licensee. We do not expect to receive any additional proceeds from the AVP-825 License Agreement.

Prior to the receipt of notice of termination of the License Agreement, we analyzed the performance obligations under the AVP-825 License Agreement, the consideration received to date and the consideration we could have received in the future as part of our analysis related to ASU 2014-09. The consideration received to date, which included an upfront payment, research and development funding and development milestone payments was recognized in prior years and our performance obligations pursuant to the arrangement have been completed.

Research and development expenses

Prior to the FDA approval of XHANCE in September 2017, research and development expense consisted primarily of costs incurred in connection with the development and pursuit of regulatory approval for XHANCE for the treatment of nasal polyps. Post-FDA approval of XHANCE, research and development expense consists primarily of expenses incurred to prepare for, initiate and conduct our clinical trials, ongoing research efforts of new products and device improvements. 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 (ASC), Topic 718, *Compensation — Stock Compensation (*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 shares issued under our employee stock purchase plan. 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 option shares issued under the employee stock purchase plan 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 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 (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.

	Year Ended December 31,	
	2018	2017
Expected term (in years)	5.95	6.06
Expected volatility	74.42%	78.67%
Risk free interest rate	2.74%	2.06%
Expected dividend yield	0.00%	0.00%
Fair value of common stock	$ 12.85	$ 9.68

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

Recent Accounting Pronouncements

See Note 3 of our audited consolidated financial statements 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, 2018 and 2017

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

	Year Ended December 31,	
	2018	2017
Net product revenues	$ 7,065	$ —
Cost of product sales	1,588	—
Gross margin	5,477	—
Operating expenses:		
Research and development	10,099	16,832
Selling, general and administrative	95,618	31,698
Total operating expenses	105,717	48,530
Loss from operations	(100,240)	(48,530)
Other (income) expense:		
Interest (income) expense	6,776	607
Other (income) expense	(358)	(235)
Total other (income) expense	6,418	372
Net loss	$ (106,658)	$ (48,902)

Net product revenues

Net product revenues related to sales of XHANCE were $7.1 million for the year ended December 31, 2018. We did not record any net product revenues during the year ended December 31, 2017.

Cost of product sales

Cost of product sales related to XHANCE were $1.6 million for the year ended December 31, 2018. We did not record any cost of product sales during the year ended December 31, 2017.

Research and development expense

Research and development expenses were $10.1 million and $16.8 million for the years ended December 31, 2018 and 2017, respectively. The $6.7 million decrease in 2018 was attributable primarily to:

- a $6.5 million decrease in regulatory and medical affairs expenses, including payroll and administrative expenses, as a result of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of XHANCE in September 2017; and
- a $3.0 million decrease related to the substantial completion of 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. in 2018.

These decreases were offset by:

- a $3.0 million increase in clinical expenses related to the preparation for and initiation of our clinical trials of XHANCE for a follow-on indication for the treatment of chronic sinusitis and FDA-mandated pediatric studies.

Selling general and administrative expense

Selling, general and administrative expenses were $95.6 million and $31.7 million for the years ended December 31, 2018 and 2017, respectively. The $63.9 million increase was due primarily to:

- a $37.3 million increase in sales and marketing expenses related to our preparation for and support of the commercial launch of XHANCE in the U.S. for the treatment of nasal polyps, of which:
  - $22.2 million related to the deployment of our contract sales force and our nurse educator team;
  - $15.1 million related primarily to marketing expenses for XHANCE;
- a $12.4 million increase in payroll-related expenses due to increases in headcount;
- a $6.5 million increase in regulatory and medical affairs expenses, including payroll-related and administrative expenses, as a result of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of XHANCE in September 2017;
- a $1.6 million increase in facilities expense, professional fees and consultancy expenses to support our expanding infrastructure to prepare for and support the commercial launch of XHANCE and operate as a public company; and
- a $3.7 million increase in stock-based compensation expense.

Interest (income) expense, net

Interest expense, net, was $6.8 million and $0.6 million for the years ended December 31, 2018 and 2017, respectively. The increase in interest expense, net, for the year ended December 31, 2018 was related to $9.2 million in interest expense on our long-term debt which was issued in December 2017, offset by $2.5 million in interest income. Interest income increased $2.2 million during the year ended December 31, 2018, as compared to the year ended December 31, 2017 as a result of higher cash balances. Interest expense for the year ended December 31, 2017 was related to our convertible notes, which were converted to shares of preferred stock in March 2017.

Other (income) expense, net

Other income, net, was $0.4 million and $0.2 million for the years ended December 31, 2018 and 2017, respectively. The income in both periods was attributable primarily to 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 incurred net losses of $106.7 million and $48.9 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $317.9 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 and revenues from sales of XHANCE. As of December 31, 2018, we had $201.0 million in cash and cash equivalents.

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

	Year Ended December 31,	
	2018	2017
Net cash used in operating activities	$ (91,817)	$ (35,680)
Net cash used in investing activities	(1,690)	(2,406)
Net cash provided by financing activities	59,579	236,125
Effects of exchange rates on cash and cash equivalents	64	(11)
Net (decrease) increase in cash and cash equivalents	$ (33,864)	$ 198,028

Operating activities

Cash used in operating activities increased by $56.1 million, from $35.7 million for the year ended December 31, 2017 to $91.8 million for the year ended December 31, 2018. The increase in cash used in operating activities was attributable primarily to the increase in our net loss from $48.9 million for the year ended December 31, 2017 to $106.7 million for the year ended December 31, 2018. The increase in net loss is primarily related increased in expenses related to our preparation for and ongoing efforts to support the commercial launch of XHANCE.

Investing activities

Cash used in investing activities decreased $0.7 million from $2.4 million for the year ended December 31, 2017 to $1.7 million for the year ended December 31, 2018. The decrease was related primarily to a decrease in equipment purchases related to our preparation for the commercial launch of XHANCE.

Financing activities

Cash provided by financing activities was $59.6 million for the year ended December 31, 2018, driven primarily by net proceeds to us of $59.9 million as a result of of the Offering of 5,750,000 shares of our common stock at a price of $22.25 per share, which consisted of 2,875,000 shares of our common stock sold by us and 2,875,000 shares of our common stock sold by certain stockholders.

Cash provided by financing activities was $236.1 million for the year ended December 31, 2017, driven primarily by the receipt of $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.

Senior Secured Note Purchase Agreement

In December 2017, we entered into a Note Purchase Agreement with Athyrium Opportunities III Acquisition LP, as collateral agent (the Collateral Agent) and the purchasers party thereto (the Purchasers) that provides for the issuance of up to $100.0 million of senior secured notes (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. (the Issuers). The remaining $25.0 million of Notes (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 (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.

Projected 2019 operating expenses

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2018 will be between $135.0 - $142.0 million of which $10 - $12 million is

expected to be stock-based compensation. Total GAAP operating expenses excluding stock-based compensation are expected to be in the range from $125 - $130 million.

Future funding requirements

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

- internalize and expand our commercial infrastructure to support the sales and marketing for XHANCE;
- maintain and expand our sales force;
- continue advertising and other promotional activities to support the commercialization of XHANCE;
- continue to provide co-pay and other patient affordability programs;
- 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;
- continue to 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 additional product candidates; and
- maintain infrastructure necessary to operate as a publicly traded commercial-stage 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 insurance coverage and reimbursement for XHANCE;
- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the costs and timing of internalizing and expanding our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the supplemental 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;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- fluctuations in the three-month LIBOR-based floating interest rate of our Notes;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates; and
- the extent to which we in-license, acquire or otherwise partner in development of other products, product candidates or technologies.

Although it is difficult to predict our future liquidity requirements, we believe that existing cash and cash equivalents at December 31, 2018 will be sufficient to meet our debt service obligations under our Notes, and to carry out our

planned development and commercial activities into the fourth quarter of 2020. Additional capital, secured in the future through equity or debt financings, partnerships, collaborations, or other sources, may not be available on a timely basis, on favorable terms, or at all, and such capital, if raised, may not be sufficient to meet our debt service obligations, including repayment, or enable us to continue to implement our long-term business strategy. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. 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, 2018 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases[1]	$ 3,128	$ 1,630	$ 1,498	$ —	$ —
Long-term debt[2]	117,229	$ 8,958	17,965	90,306	—
Purchase obligations [3]	2,335	$ 2,335	—	—	—
Total	$ 122,692	$ 12,923	$ 19,463	$ 90,306	$ —

[1] Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England and leases of certain other equipment.

[2] 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. We are 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, 2018 of 11.8125%.

[3] 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 U.S. Subject to certain limited exceptions, we could not terminate this agreement until after the first anniversary of the deployment of the sales force (which occurred in March 2018). In December 2018, as a result of our decision to manage the sales force directly, we terminated the agreement effective April 1, 2019. We estimate the expenses related to the remaining non-cancellable services to be approximately $2.3 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 a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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, 2018.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management’s assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management’s processes and assessment, as described above, management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

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, 2018 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 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018.

Our Board has adopted a written Code Conduct applicable to all officers, directors and employees, which is available on our website (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 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018.

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	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)	S-1	9/18/17	2.1	
3.1	Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc.	8-K	10/18/17	3.1	
3.2	Amended and Restated Bylaws of OptiNose, Inc.	8-K	10/18/17	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	10/3/17	4.1	
4.2	Second Amended and Restated Registration Rights Agreement, dated March 24, 2017, by and among the Registrant and certain of its stockholders.	S-1	9/18/17	4.2	
4.3	Form of Warrant issued by the Registrant on June 7, 2010.	S-1	9/18/17	4.4	
4.4	Stockholders' Agreement, dated October 2, 2017, by and among OptiNose, Inc. and certain of its stockholders.	S-1/A	10/3/2017	4.6	
4.5	First Amendment to the Second Amended and Restated Registration Rights Agreement, dated October 2, 2017, by and among the Registrant and certain of its stockholders.	S-1/A	10/11/2017	4.7	
10.1	Form of Indemnification Agreement.+				x
10.2	Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Peter K. Miller.+	8-K	10/18/17	10.1	
10.3	Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Ramy A. Mahmoud.+	8-K	10/18/17	10.2	
10.4	Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Thomas E. Gibbs.+	8-K	10/18/17	10.3	
10.5	Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Keith A. Goldan.+	8-K	10/18/17	10.4	
10.6	Employment Agreement, dated October 12, 2017, between OptiNose US, Inc. and Michael F. Marino.+	8-K	10/18/17	10.5	
10.7	Amended and Restated 2010 Stock Incentive Plan.+	S-1/A	10/3/17	10.7	
10.8	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Success Pool Grants).+	S-1/A	10/3/17	10.8	
10.9	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Option Pool Grants).+	S-1/A	10/3/17	10.9	
10.10	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan.+	S-1/A	10/3/17	10.10	
10.11	License Agreement, dated as of July 1, 2013, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.†	S-1	9/18/17	10.11	
10.12	First Amendment of License Agreement, dated as of April 25, 2014, by and between OptiNose US, Inc. and Avanir Pharmaceuticals, Inc.†	S-1	9/18/17	10.12	
10.13	Amendment to License Agreement, dated as of August 6, 2015, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.†	S-1	9/18/17	10.13	
10.14	Supply Agreement, dated July 1, 2017, by and between Hovione Inter Ltd and OptiNose US, Inc., OptiNose UK, Ltd and OptiNose AS.†	S-1	9/18/17	10.14	
10.15	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.†	S-1	9/18/17	10.15	

10.16	Manufacturing Services Agreement, dated as of August 31, 2017, by and among OptiNose US, Inc., OptiNose UK Ltd. and OptiNose AS and Ximedica, LLC.†	S-1	9/18/17	10.16	
10.17	Form of Non-Qualified Stock Option Agreement Under the Amended and Restated 2010 Stock Incentive Plan+	S-1/A	10/3/17	10.17	
10.18	2017 Employee Stock Purchase Plan.+	S-1/A	10/3/17	10.18	
10.19	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	10-K	3/13/18	10.19	
10.20	Manufacturing Services Agreement, dated December 21, 2018, by and among OptiNose US, Inc., OptiNose UK Ltd. and Optinose AS and Advance Mold & Manufacturing, Inc. d/b/a Vision Technical Molding.††				x
21.1	List of Subsidiaries				x
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.				x
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.				x
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.				x
32.1	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.				x
32.2	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.				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

† 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.

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

\+ 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.

OPTINOSE, INC.

Date: March 6, 2019

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.

Signature	Title	Date
/s/ PETER K. MILLER Peter K. Miller	Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2019
/s/ KEITH A. GOLDAN Keith A. Goldan	Chief Financial Officer (Principal Finance Officer and Principal Accounting Officer)	March 6, 2019
/s/ JOSEPH C. SCODARI Joseph C. Scodari	Chairman of the Board of Directors	March 6, 2019
/s/ ROBERT P. O'NEIL Robert P. O'Neil	Director	March 6, 2019
/s/ SRIRAM VENKATARAMAN Sriram Venkataraman	Director	March 6, 2019
/s/ WILLIAM F. DOYLE William F. Doyle	Director	March 6, 2019
/s/ JOSHUA A. TAMAROFF Joshua A. Tamaroff	Director	March 6, 2019
/s/ WILHELMUS GROENHUYSEN Wilhelmus Groenhuysen	Director	March 6, 2019
/s/ SANDRA L. HELTON Sandra L. Helton	Director	March 6, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Audited Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-3
Consolidated Statements of Operations for the years ended December 31, 2018 and 2017	F-4
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017	F-5
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2018 and 2017	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017	F-7
Notes to Consolidated Financial Statements	F-8

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, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, 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, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, 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 6, 2019

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 200,990	$ 234,854
Accounts receivable, net	2,310	—
Grants and other receivables	242	46
Inventory	7,132	2,013
Prepaid expenses and other current assets	2,183	1,254
Total current assets	212,857	238,167
Property and equipment, net	3,884	2,564
Other assets	248	405
Total assets	$ 216,989	$ 241,136
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,116	$ 5,893
Accrued expenses	18,421	8,698
Deferred other income	160	186
Total current liabilities	25,697	14,777
Long-term debt, net	72,500	71,863
Other liabilities	181	—
Total liabilities	98,378	86,640
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 December 31, 2018 and 2017; 41,227,530 and 37,802,556 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	41	38
Additional paid-in capital	436,554	365,838
Accumulated deficit	(317,927)	(211,269)
Accumulated other comprehensive loss	(57)	(111)
Total stockholders' equity	118,611	154,496
Total liabilities and stockholders' equity	$ 216,989	$ 241,136

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,	
	2018	2017
Net product revenues	$ 7,065	$ —
Cost of product sales	1,588	—
Gross margin	5,477	—
Operating expenses:		
Research and development	10,099	16,832
Selling, general and administrative	95,618	31,698
Total operating expenses	105,717	48,530
Loss from operations	(100,240)	(48,530)
Other (income) expense:		
Grant and other income	(406)	(162)
Interest income	(2,453)	(303)
Interest expense	9,229	910
Foreign currency (gains) losses	48	(73)
Net loss	$ (106,658)	$ (48,902)
Deemed dividend	—	11,969
Accretion to redemption value	—	1,096
Net loss attributable to common stockholders	$ (106,658)	$ (61,967)
Net loss per share of common stock, basic and diluted	$ (2.68)	$ (5.63)
Weighted average common shares outstanding, basic and diluted	39,765,983	10,999,121

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,	
	2018	2017
Net loss	$ (106,658)	$ (48,902)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	54	(12)
Comprehensive loss	$ (106,604)	$ (48,914)

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' Equity (Deficit)					
			Common Stock		Additional Paid -in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2017	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
Stock compensation expense	—	—	—	—	8,645	—	—	8,645
Sale of common stock, net of issuance costs	—	—	2,875,000	3	59,914	—	—	59,917
Exercise of common stock options	—	—	482,190	—	1,418	—	—	1,418
Exercise of warrants	—	—	14,647	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	53,137	—	739	—	—	739
Foreign currency translation adjustment	—	—	—	—	—	—	54	54
Net loss	—	—	—	—	—	(106,658)	—	(106,658)
Balance at December 31, 2018			41,227,530	$ 41	$ 436,554	$ (317,927)	$ (57)	$ 118,611

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,	
	2018	2017
Operating activities:		
Net loss	$ (106,658)	$ (48,902)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	539	166
Stock-based compensation	8,543	5,096
Amortization of debt discount and issuance costs	404	198
Changes in operating assets and liabilities:		
Accounts receivable	(2,310)	—
Grants and other receivables	(196)	337
Prepaid expenses and other assets	(762)	2,358
Inventory	(4,698)	(2,013)
Accounts payable	3,171	392
Accrued expenses and other liabilities	10,150	6,688
Cash used in operating activities	(91,817)	(35,680)
Investing activities:		
Purchases of property and equipment	(1,690)	(2,406)
Cash used in investing activities	(1,690)	(2,406)
Financing activities:		
Proceeds from the sale of Series D preferred stock	—	36,712
Proceeds from the issuance of common stock	63,969	138,000
Proceeds from the issuance of common stock under employee stock purchase plan	739	—
Proceeds from long-term debt	—	75,000
Proceeds from the exercise of stock options	1,488	134
Payments of withholdings on shares withheld for income taxes	(70)	(288)
Cash paid for financing costs	(6,547)	(13,433)
Cash provided by financing activities	59,579	236,125
Effects of exchange rate changes on cash and cash equivalents	64	(11)
Net (decrease) increase in cash, cash equivalents and restricted cash	(33,864)	198,028
Cash, cash equivalents and restricted cash at beginning of period	234,875	36,847
Cash, cash equivalents and restricted cash at end of period	$ 201,011	$ 234,875
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 8,253	$ —
Supplemental disclosure of noncash financing activities:		
Deemed dividend	$ —	$ 11,969
Accretion to redemption value	$ —	$ 1,096
Fixed asset purchases within accounts payable and accrued expenses	$ 146	$ —
Fixed asset additions acquired through tenant allowance	$ 361	$ —
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 commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing its proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). XHANCE was approved by the United States (US) Food and Drug Administration (FDA) in September 2017 for the treatment of nasal polyps in patients 18 years of age or older, and XHANCE was launched commercially in the US in March 2018.

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 and launching XHANCE. As of December 31, 2018, the Company had cash and cash equivalents of $200,990.

On June 11, 2018, the Company and certain stockholders closed an underwritten public offering (the Offering) of 5,750,000 shares of Company common stock (Common Stock) at a price of $22.25 per share. The Offering consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. As a result of the Offering, the Company received $59,917 in net proceeds, after deducting discounts and commissions of $3,678 and offering expenses of approximately $373 payable by the Company.

The Company will likely require additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under the Company's outstanding senior secured notes (Senior Secured Notes), including repayment, and to carry out 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, development and commercialization of its products and 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.

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.

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

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.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and accounts receivable.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 has exposure to credit risk in accounts receivable from sales of product. XHANCE is sold to wholesale pharmaceutical distributors and preferred pharmacy network partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Four customers represent approximately 90% of the Company's accounts receivable at December 31, 2018 and four customers represent approximately 94% of the Company's net product sales for the year ended December 31, 2018.

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 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 $199,507 and $233,772 at December 31, 2018 and 2017, 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.

- 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.

(in thousands, except share and per share data)

- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At December 31, 2018 and 2017, the Company's financial instruments included cash and cash equivalents, accounts receivable, 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, 2018, 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, 2018 and 2017, there were no financial assets or liabilities measured at fair value on a recurring basis.

Accounts receivable

Accounts receivable primarily relates to amounts due from customers, which are typically due within 31 to 61 days. The Company analyzes accounts that are past due for collectability. Given the nature and historical collectability of the Company’s accounts receivable, an allowance for doubtful accounts was not deemed necessary at December 31, 2018.

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. Costs of inventories, which include amounts related to materials and manufacturing overhead, are determined on a first-in, first-out basis. An assessment of the recoverability of capitalized inventory is performed during each reporting period and any excess and obsolete inventories are written down to their estimated net realizable value in the period in which the impairment is first identified.

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 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 property and equipment are as follows:

Computer equipment	2-3 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 did not recognize any impairment or disposition of long-lived assets for the years ended December 31, 2018 and 2017.

Revenue recognition

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2018. This standard applies to all contracts with customers, with the exception of contracts that are within the scope of other standards, such as leases, insurance and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services.

The Company performs the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

Net Product Revenues

The Company sells XHANCE to preferred pharmacy network partners and wholesalers in the US (collectively, Customers). These Customers subsequently resell the Company's products to healthcare providers, patients and other retail pharmacies. In addition to agreements with Customers, the Company enters into arrangements with healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts for the purchase of the Company's products.

The Company recognizes revenue from product sales at the point the Customer obtains control of the product, which generally occurs upon delivery. The transaction price that is recognized as revenue for products includes an estimate of variable consideration which is described below. Payment terms with Customers do not exceed one year and, therefore, the Company does not account for a financing component in its arrangements. The Company expenses incremental costs of obtaining a contract with a Customer (for example, sales commissions) when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to Customers are recorded as selling, general and administrative expenses.

Transaction Price, including Estimates of Variable Consideration

Revenue from products is recognized at the estimated net sales price (transaction price), which includes estimates of variable consideration. The Company includes estimated amounts in the transaction price to the extent it is determined probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The Company's estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available.

Components of Variable Consideration

Components of variable consideration include provider chargebacks and discounts, trade discounts and allowances, product returns, government rebates, third-party payor rebates, sales order management fees and other incentives, such as voluntary patient assistance and other allowances that are offered within contracts between the Company and its Customers, payors and other indirect customers relating to the Company's sale of products. Those components, as described below, are based on the amounts earned, or to be claimed, on the related sales and are presented as reductions of accounts receivable (if the amount is payable to the Customer) or as a current liability (if the amount is payable to a party other than the Customer). The Company considers all relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

- *Variable Consideration - Accounts Receivable Reductions*

  - Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Reserves for chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, as well as chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

  - Trade Discounts and Allowances. The Company generally provides Customers with discounts that include incentive fees which are explicitly stated in the Company's contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized. In addition, the Company reimburses (through discounts and allowances) its Customers for sales order management, data and distribution services.

- *Variable Consideration - Current Liabilities*

  - Product Returns. Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the goods to a patient. The Company estimates the amount of its products that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company considers several factors in the estimation process, including expiration dates of product shipped to preferred pharmacy network partners and wholesalers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

  - Government Rebates. The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. For Medicaid, accruals are based on estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. To estimate the cost to the Company of this Medicare coverage gap responsibility, the Company estimates the number of patients in the prescription drug coverage gap for whom it will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of the reporting period.

  - Payor Rebates. The Company contracts with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. These rebates are based on contractual percentages applied to the amount of product prescribed to patients who are covered by the plan or the organization with which it contracts. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

  - Other Incentives. Other incentives that the Company offers include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors and coupon programs for cash payors. The calculation of the accruals for this assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product

that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Licensing Revenues

Through December 31, 2017, the Company's revenues had 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 included licensed rights to patented technology, non-refundable up-front payment, research services, and regulatory and sales milestones as well as royalty payments. Through December 31, 2018, 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.

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement is expected to terminate on March 10, 2019. We do not expect to receive any additional proceeds from the AVP-825 License Agreement.

Prior to the receipt of notice of termination of the License Agreement, the Company analyzed the performance obligations under the AVP-825 License Agreement, the consideration received to date and the consideration the Company could have received in the future as part of its analysis related to ASU 2014-09. The consideration received to date, which included an upfront payment, research and development funding and development milestone payments was recognized in prior years and the Company’s performance obligations pursuant to the arrangement have been completed.

Advertising expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $9,767 and $1,833 for the years ended December 31, 2018 and 2017, 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.

(in thousands, except share and per share data)

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 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, 2018 and 2017, 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

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, 2018 and 2017, the outstanding common stock options and common stock warrants have been excluded from the calculation of diluted net 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.

Diluted net 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,	
	2018	2017
Stock options	6,182,873	2,141,367
Common stock warrants	1,866,831	1,890,489
Employee stock purchase plan	31,892	—
Total	8,081,596	4,031,856

Recent accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU 2018-15 requires that certain implementation costs incurred in a cloud computing arrangement be deferred and recognized over the term of the arrangement. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and 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 August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 resulted in certain modifications to fair value measurement disclosures, primarily related to level 3 fair value measurements. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its disclosures.

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 adoption of ASU 2017-09 did not have a material impact on the Company's results of operations, financial position, cash flows and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230).* ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new standard is effective for fiscal years beginning after December 15, 2017. The Company adopted ASU 2016-18 in the first quarter of 2018, and the guidance has been retrospectively applied to all periods presented. The restricted cash balance included in prepaid expenses and other assets was $21 as of December 31, 2018 and 2017.

In February 2016, the FASB issued ASU 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, with early adoption permitted. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients.

The following are other key disclosures, as well as determinations made and actions taken by the Company, related to the adoption of ASC 842:

- Elected the optional modified retrospective transition method as of January 1, 2019; therefore prior period amounts will not be restated;
- Established and implemented key implementation controls to ensure the Company meets the new reporting and disclosure requirements;
- Elected the following transition practical expedients:
    - to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the adoption of ASC 842;
    - to not separate lease and non-lease components for our office lease portfolio;
- Made policy elections as of January 1, 2019:
    - to not apply the recognition and measurement requirements to leases with an initial term of one year or less;
    - to apply the portfolio approach for the development of the discount rate related to leases with similar characteristics;
    - to keep leases with an immaterial right-of-use asset at inception, off the balance sheet and recognize this expense on a straight-line basis in the consolidated statements of operations;

While we continue to assess all the effects of adoption, the Company believes the most significant effect relates to the recognition of right-of-use assets and corresponding liabilities on its consolidated balance sheet, primarily related to its existing facility operating leases, and providing new disclosures with regards to the Company's leasing activities.

(in thousands, except share and per share data)

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU-2014-09, which replaced 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.

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 was effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. An entity could 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 assessed the impact that ASU No. 2014-09 had on its financial statements and related disclosures. Through the January 1, 2018 adoption 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. The Company analyzed the performance obligations under the AVP-825 License Agreement as well as the consideration received to date as part of its analysis of the impact of ASU 2014-09 on this arrangement.

The Company adopted ASU 2014-09 on January 1, 2018 using the modified retrospective transition method. No transition adjustments were recognized as a result of the adoption. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

4. Inventory

Inventory consisted of the following:

	December 31,	
	2018	2017
Raw materials	$ 1,969	$ 1,385
Work-in-process	2,344	628
Finished goods	2,819	—
Total inventory	$ 7,132	$ 2,013

5. Property and Equipment

Property and equipment, net, consisted of:

	December 31,	
	2018	2017
Computer equipment and software	$ 833	$ 307
Furniture and fixtures	389	89
Machinery and equipment	2,723	2,495
Leasehold improvements	609	28
Construction in process	481	—
	5,035	2,919
Less: accumulated depreciation	(1,151)	(355)
	$ 3,884	$ 2,564

(in thousands, except share and per share data)

Depreciation expense was $535 and $164 for the years ended December 31, 2018 and 2017, respectively. In addition, depreciation expense of $322 and $10 is included within inventory and prepaid expenses and other assets, respectively, as of December 31, 2018, which represents depreciation expense related to equipment involved in the manufacturing process.

6. Accrued Expenses

Accrued expenses consisted of:

	December 31,	
	2018	2017
Contract sales organization expenses	$ 4,482	$ 1,432
Selling, general and administrative expenses	4,812	2,031
Research and development expenses	933	80
Bonus expense	3,635	4,163
Payroll and benefit expenses	564	448
Employee contributions withheld	359	185
Product revenue allowances	2,856	—
Interest expense	345	45
Other	435	314
	$ 18,421	$ 8,698

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, 2018, 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. The Company did not recognize any licensing revenue during the years ended December 31, 2018 and 2017.

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement is expected to terminate on March 10, 2019. Upon termination, the Company may elect to continue to commercialize Onzetra Xsail itself or through a new licensee. We do not expect to receive any additional proceeds from the AVP-825 License Agreement.

8. Convertible Notes

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.

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 during the year ended December 31, 2017 in conjunction with the Notes. Total coupon interest on the Notes and back end fees was $743 during the year ended December 31, 2017.

The front-end fees of $450 were recorded as debt discount at issuance and were amortized to interest expense over the 18 months loan conversion period. During the year ended December 31, 2017, the Company recorded a total of $75 of interest expense related to the front end fees. Additionally, back end fees of $450 were amortized to interest expense over the 18 months loan conversion period of which $90 was recorded as interest expense and as an increase in the carrying amount of the Notes during the year ended December 31, 2017. The Company also incurred $265 in debt issuance costs during the year ended December 31, 2015 which were amortized to interest expense over the 18 months loan conversion period.

As of December 31, 2018 and 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 11.8125% at December 31, 2018. 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, 2018, the Company was in compliance with the covenants.

The Company recorded interest expense of $9,229 and $48 during the years ended December 31, 2018 and 2017, respectively, in conjunction with the Senior Secured Notes. Interest expense included total coupon interest, back

(in thousands, except share and per share data)

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 $2,181 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.

As of December 31, 2018 and 2017, the long-term debt balance is comprised of the following:

	December 31,	
	2018	2017
Face amount	$ 75,000	$ 75,000
Front end fees	(872)	(999)
Debt issuance costs	(1,902)	(2,139)
Back end fees	274	1
	$ 72,500	$ 71,863

10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan, which covers all employees. Employees are eligible to participate in the plan 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. The Company incurred costs of $645 and $230 related to the Company match applicable to employee contributions for the years ended December 31, 2018 and 2017. 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 $81 and $56 related to the pension plans for the years ended December 31, 2018 and 2017, respectively.

11. Commitments and Contingencies

Leases

The Company leases office space under four operating leases and has leases for certain other equipment. Rent expense is recognized as incurred.

The following is a schedule of future minimum annual payments as of December 31, 2018 under operating lease agreements:

For the years ending December 31:	
2019	1,630
2020	1,107
2021	391
Total future minimum lease payments as of December 31, 2018	$ 3,128

Rent expense related to leases of office space was $831 and $689 for the years ended December 31, 2018 and 2017, 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 $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 an 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 could not terminate this agreement until after the first anniversary of the deployment of the sales force (which occurred in March 2018). In December 2018, as a result of the Company's decision to manage its sales force directly, the Company terminated the agreement effective April 1, 2019 and accrued an early termination fee of $691. The Company estimates the expenses related to the remaining non-cancellable services, all of which will be provided in 2019, to be approximately $2,335.

As of December 31, 2018, the Company had no other material 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

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.

On June 11, 2018, the Company and certain stockholders closed the Offering of 5,750,000 shares of Common Stock at a price of $22.25 per share. The Offering consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. As a result of the Offering, the Company received $59,917 in net proceeds, after deducting discounts and commissions of $3,678 and offering expenses of approximately $373 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, 2018.

Common stock warrants

As of December 31, 2018, the Company had 1,866,831 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).

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, 2018 and 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, 2018, 8,406,547 shares of the Company's common stock were authorized to be issued under the A&R Plan, and 1,635,295 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.

Stock options

The Company has issued service-based and performance-based stock options that 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. Performance-based options may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued stock options in excess of the fair market value of Common Stock on the issuance date that were only exercisable upon a change in control or upon or after an initial public offering. As of December 31, 2018, all of the performance conditions related to performance-based stock options issued by the Company have been achieved.

(in thousands, except share and per share data)

The following table summarizes the activity related to stock option grants to employees and nonemployees for the years ended December 31, 2018:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2017	6,251,589	$ 9.34	6.67
Granted	472,792	19.36	
Exercised	(491,654)	3.21	
Expired	—	—	
Forfeited	(49,854)	9.67	
Outstanding at December 31, 2018	6,182,873	$ 10.60	6.48
Exercisable at December 31, 2018	3,804,999	$ 8.15	5.09
Vested and expected to vest at December 31, 2018	6,182,873	$ 10.60	6.48

During the year ended December 31, 2018, stock options to purchase 472,792 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 $12.85. 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 stock options exercised during the years ended December 31, 2018 and 2017 was $9,255 and $435, respectively. The aggregate intrinsic value of stock options outstanding and stock options exercisable as of December 31, 2018 was $8,470 and $8,028, respectively. At December 31, 2018, the unrecognized compensation cost related to unvested stock options expected to vest was $20,405. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.7 years.

2017 Employee Stock Purchase Plan

The Company's 2017 Employee Stock Purchase Plan (the 2017 Plan) became effective on October 12, 2017. As of December 31, 2018, 522,420 shares of the Company's common stock were authorized to be issued pursuant to purchase rights granted to its employees or to employees of any of its participating affiliates under the 2017 Plan. 469,283 shares of the Company's common stock were reserved for future issuance under the 2017 Plan. 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 85% of the lesser of the average high and low sales price of the Company's common stock on (i) the first trading day of the relevant offering period and (ii) on the last trading day of the relevant offering period (or, if the relevant offering period has multiple purchase periods, the last trading day of the relevant purchase 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 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 accumulated through June 30, 2018.

(in thousands, except share and per share data)

Beginning on January 1, 2018, employees who elected to participate in the 2017 Plan commenced payroll withholdings that accumulate during the following six month offering periods each calendar year while the Purchase Plan is effective:

- January 1 through June 30, and
- July 1 through December 31.

At the end of each offering period, shares of the Company's common stock may be purchased at 85% of the lesser of the average of the high and low sales price of the Company's common stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period (or, if the relevant offering period has multiple purchase periods, the last trading day of the relevant purchase 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 $446 and $106 during the years ended December 31, 2018 and 2017, respectively, 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, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
Cost of product sales	$ 9	$ —
Research and development	$ 989	1,288
Selling, general and administrative	7,545	3,808
Total stock-based compensation expense	$ 8,543	$ 5,096

In addition, stock-based compensation expense of $99 and $2 is included within inventory and prepaid expenses and other assets, respectively, as of December 31, 2018, which represents the total stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples during the period.

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 Incentive Plan	2017 Employee Stock Purchase Plan
	December 31, 2018	December 31, 2018
Risk free interest rate	2.74%	1.53%
Expected term (in years)	5.95	0.64
Expected volatility	74.42%	80.40%
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

(in thousands, except share and per share data)

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.

14. Income taxes

The Tax Cuts and Jobs Act (TCJA) was enacted on December 22, 2017 with most changes effective January 1, 2018. Among other changes, the TCJA significantly lowered the US corporate income tax rate from 35% to 21% as of 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 (E&P). As the Company's foreign subsidiaries did not have 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 (SEC) issued Staff Accounting Bulletin No. 118 (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 recorded a preliminary estimate of the impact of the TCJA and the re-measurement of its deferred tax assets and liabilities in 2017. The Company finalized its analysis of the impact of the TCJA and recorded the adjustment, which was not material, in 2018.

Income taxes have been recorded on the following book income (loss) before income tax expense:

	Year Ended December 31,	
	2018	2017
Domestic operations	$ (146,247)	$ (30,463)
Foreign operations	39,589	(18,439)
Loss before provision for income taxes	$ (106,658)	$ (48,902)

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

A reconciliation of income tax expense (benefit) at the US federal statutory income tax rate and the income tax provision in the financial statements is as follows:

	Year Ended December 31,	
	2018	2017
Income tax expense at statutory rate	21.0 %	35.0 %
Permanent items	0.5	0.5
Foreign rate differential	(0.8)	(4.2)
Impact of foreign operations	(7.2)	—
State taxes, net of federal benefit	3.9	0.8
Tax rate changes	(0.6)	(15.4)
Foreign exchange and other	(0.6)	—
Change in valuation allowance	(16.2)	(16.7)
Effective income tax rate	0.0 %	0.0 %

Tax rate changes includes the impact of the reduction in the US tax rate in 2017 under the TCJA and a reduction in the Norway tax rate in both 2017 and 2018.

The principal components of the Company's deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2018	2017
Deferred tax assets:		
Accrued expenses and other	$ 1,674	$ 972
Prepaid licensing arrangement	11,562	—
Property and equipment	—	55
Interest expense	1,267	783
Stock compensation	3,493	1,701
Research and development credits	2,485	2,485
Net operating losses	32,548	29,636
Total deferred tax assets	53,029	35,632
Deferred tax liabilities:		
Fixed assets	(409)	—
Total deferred tax liabilities:	(409)	—
Less: Valuation allowance	(52,620)	(35,632)
Total net deferred tax assets (liabilities)	$ —	$ —

During 2018, our wholly-owned subsidiary in Norway licensed certain intellectual property rights related to XHANCE to our US subsidiary. While this transaction did not result in any gain or loss in the condensed consolidated statements of operations, the transaction generated taxable income in both Norway and the US. Norway tax loss carryforwards were utilized to offset the taxable income in Norway and the income reduced the current year US taxable loss. There were no cash taxes associated with the transaction.

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, 2018, the Company had foreign net operating loss (NOL) carry forwards of $50,513 primarily from its operations in Norway. As of December 31, 2018, the Company had federal and state NOLs of $86,574 and $57,017, respectively. These domestic NOL carry forwards may be subject to an annual limitation in the event of cumulative changes in the ownership interests 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, 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 NOL generated in 2018 has an indefinite carry forward period. The federal NOLs generated prior to 2018 will expire from 2030 through 2037. Some state NOLs will not expire while other state NOLs expire over various periods depending on the rules of the jurisdiction in which they were generated. The earliest state NOL expiration is in 2028.

ASC 740 requires the establishment of a valuation allowance to reduce deferred tax assets if, based on the weight of the available positive and negative evidence it is more likely than not that all or a portion of the deferred tax assets will not be realized. There is insufficient positive evidence to overcome the negative evidence attributable to the Company's cumulative operating losses. Consequently, the Company established a full valuation allowance against its net deferred tax assets at December 31, 2018 and 2017, respectively, because the Company's management was unable to conclude that it is more likely than not that these assets will be fully realized. The Company had a net increase in its valuation allowance of $16,988 during the year ended December 31, 2018.

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 credits 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, 2018, 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, 2018 and 2017, the Company reimbursed Avista Capital Holdings, LP and related parties $51 and $157, respectively in expenses, primarily related to legal fees incurred in conjunction with the Company's Offering of Common Stock in June 2018, the IPO in October 2017 and the issuance of Series D redeemable convertible preferred stock March 2017.

16. Subsequent events

On January 31, 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into a license agreement (the Inexia License Agreement) with Inexia Limited (Inexia).

Under the terms of the Inexia License Agreement, Inexia paid the Company a $500 upfront payment. For each product developed under the Inexia License Agreement, the Company is eligible to receive up to $8,000 of development milestone payments and up to $37,000 of sales milestone payments. In addition, the Company is eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the Inexia License Agreement. Other than the upfront payment, the Company does not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

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 to 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 brings 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.

INDEMNITEE	DATE
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
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
Robert P. O'Neil	June 7, 2018

Exhibit 10.20

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MANUFACTURING SERVICES AGREEMENT FOR SUBASSEMBLY

(does not apply to cap)

This Manufacturing Services Agreement (this "**Agreement**"), dated as of December 21, 2018 (the "**Effective Date**"), is by and among, on the one hand, OptiNose US, Inc., duly organized and existing under the laws of Delaware and having offices located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 (referred to herein as "**OptiNose US**"), OptiNose UK Ltd. duly organized and existing under the laws of England and having offices located at Hunts Rise, South Marston Park, Wiltshire, SN3 4TG, England (referred to herein as "OptiNose UK"), and OptiNose AS, duly organized and existing under the laws of Norway and having offices located at Gaustadalléen 21, 0349 Oslo, Norway (referred to herein as "**OptiNose Norway**", and collectively with OptiNose US and OptiNose UK, "**OptiNose**"), and, on the other hand, and Advance Mold & Manufacturing, Inc., d/b/a Vision Technical Molding, a Connecticut corporation having offices located at 71 Utopia Road, Manchester, CT 06042 ("**VTM**").

WHEREAS, VTM is a device development and manufacturing company skilled in the design, development, manufacture and assembly of medical devices and delivery systems and of their components;

WHEREAS, VTM and OptiNose previously entered into a Molded Parts Agreement dated October 24, 2017 (the "**Molded Parts Agreement**") whereby VTM molded various product components and product cap for OptiNose;

WHEREAS, concurrent with the execution of this Agreement, the parties shall enter into an amendment to the Molded Parts Agreement whereby the parties will remove VTM's future manufacture for OptiNose of various product components thereunder (other than the product cap noted therein); and

WHEREAS, OptiNose desires to retain VTM to assemble and supply DSAs (as defined herein) for use by OptiNose in the subsequent production of Finished Product (as defined herein) under FDA and other regulations for the benefit of patients.

In consideration of the mutual covenants and agreements hereinafter set forth, the parties agree as follows:

ARTICLE I

DEFINITIONS

[***].

"**Action**" shall have the meaning set forth in Section 12.03.

"**Affiliate**" means any Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, another Person. The term

"control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agreement**" shall have the meaning set forth in the preamble.

"**Approved Vendor List**" shall mean the list of vendors approved in writing by OptiNose and VTM to provide the Inventory or services specified in the Bill of Materials for a DSA.

"**Bill of Materials**" shall mean the Inventory and OptiNose Components that comprise the DSA, as set forth in the Specifications.

"Binding Period" shall have the meeting set forth in Section 2.07.

"Capacity" means the facility space, equipment, utilities, maintenance capabilities, infrastructure, human capital, and other capabilities in sufficient volume needed to manufacture DSAs, except for the OptiNose Equipment.

"**Confidential Information**" means any information that is treated as confidential by a Disclosing Party, whether tangible or intangible, including, without limitation, any and all specification information, techniques, discoveries, inventions, processes, know-how, patent applications and related information, inventor certificates, trade names, trade secrets, methods of production, technology, other proprietary information, other intellectual property, information pertaining to business operations and strategies, and information pertaining to pricing, and marketing of Finished Product or Inventory. Confidential Information shall not include information that: (a) is already known to the Receiving Party without restriction on use or disclosure prior to receipt of such information from the Disclosing Party; (b) is or becomes generally known by the public other than by breach of this Agreement by, or other wrongful act of, the Receiving Party; (c) is developed by the Receiving Party independently of, and without reference to, any Confidential Information of the Disclosing Party; or (d) is received by the Receiving Party from a third party who is not under any obligation to the Disclosing Party to maintain the confidentiality of such information.

"**Defaulting Party"** shall have the meaning set forth in Section 15.02.

"**Defective Product**" means any DSA that fails to conform to the Specifications, Quality Agreement or applicable Laws or that contains a Latent Defect or Patent Defect.

"**Deliverables**" means all documents, work product and other materials that are delivered to OptiNose hereunder or prepared by or on behalf of VTM in the course of performing the services under this Agreement.

"**Disclosing Party**" means a party that discloses Confidential Information under this Agreement.

"DSA" means a device subassembly manufactured under this Agreement.

"**Effective Date**" shall have the meaning set forth in the preamble of this Agreement.

[***].

"FDA" means the U.S. Food & Drug Administration.

"**Excess Inventory**" shall mean any DSA, partially completed DSA or Inventory (in each instance, to the extent procured by or on-order with VTM) that is not required for consumption to satisfy the next [***] of demand for DSAs under the then-current Forecast.

"**FD&C Act**" means the Federal Food, Drug, and Cosmetic Act, as amended, and includes the rules, regulations and guidances promulgated thereunder (including, without limitation, current Good Manufacturing Practices).

"Finished Product" means the full saleable product unit for XHANCE® (formerly known as OPN-375) including without limitation active ingredient, delivery system, container closure system, and market package.

"Forecast" shall have the meeting set forth in Section 2.07.

"**Force Majeure Event**" shall have the meaning set forth in Section 17.01.

"**Intellectual Property Rights**" means all (a) patents, patent disclosures and inventions (whether patentable or not), (b) trademarks, service marks, trade dress, trade names, logos, corporate names and domain names, together with all of the goodwill associated therewith, (c) copyrights and copyrightable works (including computer programs), mask works, and rights in data and databases, (d) trade secrets, know-how and other confidential information, and (e) all other intellectual property rights, in each case whether registered or unregistered and including all applications for, and renewals or extensions of, such rights, and all similar or equivalent rights or forms of protection in any part of the world.

"**Inventory**" shall mean any materials, parts, components and inputs needed for VTM to manufacture the DSAs in accordance with the Specifications, whether made by VTM or procured from a third-party. (other than OptiNose Components) that are procured by or on-order with VTM in accordance with the applicable Lead Time for use in the manufacture of DSAs pursuant to a Purchase Order or Forecast from OptiNose, which may include (unless the context requires otherwise) Special Inventory and Minimum Order Inventory.

"**Inventory Procurement Lead Time**" shall mean, with respect to any particular item of Inventory, the longer of (a) the lead time to obtain such Inventory as recorded on VTM's system of record or (b) the actual lead time.

"**Latent Defect**" means a defect where any DSA fails to conform to the Specifications, Quality Agreement or applicable Laws, which could not reasonably have been discovered upon receipt and physical inspection of the DSA by OptiNose or its designee.

"**Law**" means any statute (including without limitation the FD&C Act), law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or guidance, or rule of law of any federal, state, local or foreign government or political subdivision thereof, or any arbitrator, court or tribunal of competent jurisdiction that is applicable: (a) to the obligations of VTM in supplying OptiNose with the DSAs, and performing any related activities under other terms of this Agreement, or (b) to the obligations of OptiNose.

"**Lead Time**" shall mean the Inventory Procurement Lead Time plus the manufacturing cycle time required from the delivery of the Inventory at VTM's facility to the completion of the manufacture, assembly and test processes for the DSA.

"**Long Lead Time Inventory**" shall mean Inventory with Lead Times exceeding the period covered by the accepted Purchase Orders for the DSA.

"**Losses**" means all losses, damages, liabilities, deficiencies, actions, judgments, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys' fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers.

"**Minimum Order Inventory**" shall mean Inventory purchased in excess of requirements for Purchase Orders and Forecast because of minimum lot sizes required by the vendor.

"**NDA**" means a new drug application filed with the FDA.

"**Obsolete Inventory**" shall mean any partially completed DSA or Inventory that is any of the following: (a) removed from the Bill of Materials for a DSA by an engineering change; or (b) no longer on an active Bill of Materials for a DSA.

"**OptiNose**" shall have the meaning set forth in the preamble.

"OptiNose Components" shall mean the consigned inventory that has the meaning set forth in Section 2.02(a).

"OptiNose Equipment" means equipment (i) that can be used only for production of DSA's under this Agreement or (ii) that OptiNose desires to have dedicated solely to the production of DSA's under this Agreement.

"OptiNose Indemnitee" shall have the meeting set forth in Section 12.02.

"**OptiNose Information**" means any documents, data, know-how, trade secrets, methodologies, software and other information (Confidential Information or otherwise) provided to VTM by or on behalf of OptiNose or developed by VTM on behalf of OptiNose, including without limitation computer programs, reports and specifications.

"**OptiNose Supply Relationship Manager**" shall have the meaning set forth in Section 7.01(a)

"**Patent Defect**" means any instance where any DSA fails to conform to the Specifications, Quality Agreement or applicable Laws, where such failure is or was discoverable upon reasonable physical inspection upon receipt by OptiNose or its designee.

"**Person**" means an individual, corporation, partnership, joint venture, limited liability company, governmental authority, unincorporated organization, trust, association or other entity.

"**Production Materials**" shall mean materials that are consumed in the production processes to manufacture DSAs including without limitation, [***]; Production Materials do not include any such production materials that have been specified by OptiNose.

"Purchase Order" shall have the meaning set forth in Section 2.09(a).

"Quality Agreement" means that Quality Agreement between OptiNose and VTM to be entered between the parties related to production of the DSAs.

"Quantitative Defect" means any instance in which VTM has delivered a quantity that is [***] less than, or [***] greater than, the quantity stated in any invoice or bill of lading.

"**Receiving Party**" means a party that receives or acquires Confidential Information directly or indirectly under this Agreement.

"**Special Inventory**" shall mean any mutually agreed Inventory acquired by VTM to support flexibility, demand requirements, safety stock or pricing discounts.

"Specifications" shall mean the procedures, standards, quality control and other data and requirements for each DSA, which shall include, without limitation: Bills of Materials, designs, schematics, assembly drawings, process documentation, specifications according to the Device Master Record for the DSA, current revision number, and an Approved Vendor List.

"**Standard Cost**" shall mean, as applicable, (a) the quoted cost of Inventory represented on the Bill of Materials current at the time such Inventory is acquired; or (b) the value of any services required to be performed hereunder on work-in-progress at the time such services are performed.

"**Term**" shall have the meaning set forth in Section 14.01.

"**VTM**" shall have the meaning set forth in the preamble.

"**VTM Supply Relationship Manager**" shall have the meaning set forth in Section 6.01(a).

"**VTM Equipment**" means any and all equipment, systems, or facilities owned or leased, by or on behalf of VTM and made available for either direct or indirect performance by VTM under this Agreement.

"**VTM Personnel**" means all employees, contractors, and consultants, engaged by VTM to perform under this Agreement.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

"**VTM Tools**" means all documents, data, know-how, methodologies, software and other information provided by or used by VTM in connection with performance by VTM under this Agreement, in any case developed or acquired by VTM independently of this Agreement and of other services performed by VTM for OptiNose prior to or after the date hereof.

ARTICLE II

MANUFACTURE AND SUPPLY OF DSAS

Section 2.01 Manufacture and Supply. During the Term and subject to the terms and conditions set forth herein, VTM shall procure Inventory and manufacture and assemble DSAs in compliance with the Specifications, Quality Agreement, applicable Laws and the other terms of this Agreement and deliver them to OptiNose or its designee. Delivery of the DSAs shall be EXW ("**Ex-Works**") VTM's manufacturing facility 71 Utopia Road, Manchester, CT 06042 (INCOTERMS 2000); [***] shall arrange for the DSAs to be picked up by a carrier identified and paid by [***] or its designee. During the Term, VTM shall use [***] to ensure that it has the Capacity to meet all of OptiNose's requirements for DSAs in a timely manner based on the applicable Forecast under this Agreement; provided that if new or additional OptiNose Equipment is required, VTM will inform OptiNose with sufficient lead time for such OptiNose Equipment to be acquired by OptiNose [***] and qualified for use under this Agreement taking into account normal equipment malfunctions and breakdowns not preventable through normal maintenance; Capacity metrics will be agreed upon and equipment will be initiated if projected utilization for the following year exceeds [***], or if OptiNose deems to initiate a project for business continuity.

Section 2.02 Inputs for Supply of DSA's.

(a) OptiNose is responsible for negotiation of agreements and payment to third parties for the items listed on Exhibit B (the "**Third Party Components**") and was responsible for the agreements and payment for the Pre-Existing Inventory (as defined in Exhibit A) listed on Exhibit B (collectively with the Third Party Components, the "**OptiNose Components**"), in each instance for use in the manufacture of DSAs.

(b) OptiNose will manage the relationship with suppliers of the OptiNose Components identified in Exhibit B, placing orders for Third Party Components, arranging delivery to VTM of the OptiNose Components at OptiNose's cost, and ensuring that such suppliers perform in accordance with requirements of OptiNose. VTM shall manage suppliers of the OptiNose Components within VTM's quality systems as appropriate to ensure compliance with the quality agreements referenced in this Section 2.02(b). OptiNose may initiate the addition or replacement of suppliers for each OptiNose Component upon [***] written notice to VTM and will work with VTM to execute such addition or replacement according to relevant OptiNose and VTM procedures at OptiNose's expense.

(c) If the suppliers of the OptiNose Components cause the assembly line at VTM to halt production due to lack of OptiNose Components, and if VTM has provided OptiNose at least [***] advance written notice of VTM's projected or actual shortage of such OptiNose Components, then subject to the following sentence, VTM may invoice OptiNose for the reasonable costs incurred by VTM for such idle VTM operator time, which shall not exceed $[***]per week for [***] shift, or $[***] per week if running [***] shifts, in the aggregate, for which VTM shall provide OptiNose with a detailed breakdown of such costs and which shall solely include the compensation of the operators (and not any other overhead, facility costs, or profit of VTM), such amount to be the sole amount payable by OptiNose with respect to such idle time. If OptiNose provides VTM with at [***] prior written notice of any such lack of OptiNose Components then VTM shall use its [***] efforts to reassign its staff and otherwise mitigate its costs, which shall be deducted from any amounts due by OptiNose to VTM for such lack of OptiNose Components.

(d) If any time after [***] VTM's production of DSA requires less operators than anticipated or no operators at all, and then an increase in demand requires operators to be retrained to manufacture and assemble the DSAs, (1) OptiNose shall pay for such retraining at a rate [***], and (2) OptiNose must provide at least [***] prior written notice before VTM shall be required to effectuate such an increase.

(e) At OptiNose's request, VTM shall warehouse up to [***] pallets of the OptiNose Components listed on Exhibit B. The parties will mutually agree to any additional warehousing and associated cost. Notwithstanding the foregoing, VTM shall at OptiNose's request warehouse [***] any and all OptiNose Components that VTM previously manufactured for OptiNose pursuant to the Molded Parts Agreement.

(f) [***] is responsible for the negotiation, payment, purchase, and delivery to VTM of all Inventory, but not the OptiNose Components. Appropriate agreements and documentation of quality related requirements will also be the responsibility of [***].

Section 2.03 Specifications. The Specifications may be amended in accordance with the terms of this Agreement, the Quality Agreement, or as required by the FDA or other similar regulatory authority, and by the written agreement of the parties. VTM shall not make changes to the Specifications without OptiNose's prior written approval as provided for in the Quality Agreement.

Section 2.04 Validation and Other Services. Before manufacturing DSAs under this Agreement, VTM will have completed validation necessary and appropriate for such manufacture in accordance with the Specifications, applicable protocols- and the other requirements of this Agreement and the Quality Agreement.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Section 2.05 Engineering Changes. Either party may request that VTM incorporate engineering changes into the DSAs or Specifications by providing a written description of the proposed engineering change sufficient to permit the parties to evaluate the feasibility and cost of the proposed change. VTM shall proceed with engineering changes when the parties have agreed in writing upon the changes to the Specifications, delivery schedule and adjustments to the Pricing, [***]. In all instances VTM shall use [***] to incorporate engineering changes requested by OptiNose.

Section 2.06 Pricing.

(a) [***], the initial pricing for all DSAs and any associated services for such calendar year shall be the respective column as set forth on Exhibit A based on the [***] Forecast in such calendar year. At the end of each calendar year, if the actual volume of DSA production would have resulted in a lower applicable price per unit had the pricing been based on such respective column (i.e. if the pricing was initially based at the beginning of such calendar year on the [***] column but [***] DSA were actually assembled during such calendar year, then the pricing will be based solely on the [***] column in Exhibit A), then VTM shall apply the appropriate credit due OptiNose against future production until the full credit has been issued (if the amount of the credit is over [***], the credit will be applied [***]), while in the event the actual volume of DSA production would have resulted in a higher applicable price per unit had the pricing been based on such respective column (i.e. if the pricing was initially based at the beginning of such calendar year on the [***] column but [***] DSA were actually assembled during such calendar year, then the pricing will be based solely on the [***] column in Exhibit A), then VTM shall invoice OptiNose for the appropriate amount. Notwithstanding the foregoing, for the calendar year 2019 the charge shall be based on the column [***] set forth in Exhibit A less any credit due to OptiNose per Exhibit A, and [***]. [***].

(b) VTM will use [***] to engage in continuous improvement processes with respect to the manufacture of the DSAs and any such resulting cost reductions shall be applied to lower the pricing set forth in Exhibit A hereto. [***]. Additionally, the price may be adjusted prospectively for any costs directly related to any changes in the Specifications and/or levels of service requested by OptiNose and agreed to by VTM, in writing. VTM shall provide sufficient documentation to support any price adjustment in accordance with this Section [***].

(c) Commencing on [***] and [***] thereafter, during the Term of this Agreement, the unit price of each DSA shall be increased or decreased, which adjustment shall become effective on January 1 and July 1, respectively, of the applicable calendar year, by the [***] provided, that, with respect to price increases of [***], (A) VTM shall have used [***] to negate, defer or reduce proposed [***] cost increases, and (B) the parties shall have discussed in good faith such increases and VTM shall have provided OptiNose with reasonable documentation to explain and support such increase or

decrease. [***]. This pricing review may be triggered immediately if the price of [***] increases or decreases by more [***] at any time between the scheduled review periods, in which case such change will not be considered for any price change to be implemented under the preceding sentence in this Section 2.06(c).

Section 2.07 Forecasts. Commencing on January 1, 2019, OptiNose shall provide VTM with a non-binding, rolling [***] forecast of its DSA requirements by month to VTM ("**Forecast**"). The portion of the Forecast for the first [***] period shall be binding (a "**Binding Period**") and the remaining [***] shall be for planning purposes and not binding (a "**Non-Binding Period**"). OptiNose shall place Purchase Orders for the Binding Period of the Forecast in accordance with Section 2.09 of this Agreement. The Forecast shall be updated [***] by OptiNose no later than the [***] day of each calendar month with the Binding Period updated with each Forecast to include the new [***] of the going forward [***] rolling forecast. VTM shall participate in periodic sales and operations planning meetings with OptiNose and other suppliers as OptiNose [***] deems appropriate. VTM shall provide OptiNose monthly inventory reports of DSAs, OptiNose Components and all other Inventory inventoried by VTM solely for the manufacture of DSAs.

Section 2.08 Use of Forecasts. VTM will reference the latest available Forecasts when ordering Inventory (excluding the OptiNose Components which shall be ordered by OptiNose) necessary or appropriate to fulfill the forecasted DSA requirements, taking into account necessary lead times, volume-based pricing, the applicable Inventory' expiration periods, the Binding Period, and any Purchase Orders for DSAs outside the Binding Period. VTM may purchase such Inventory (including minimum quantities required by suppliers) on the basis of OptiNose's most recent Forecasts for the applicable Binding Period and, further, the Forecast for the longer period in the case of such Inventory having a longer lead time than [***]. Notwithstanding anything contained in this Agreement to the contrary and other than as set forth in Section 3.09(d), in no case shall VTM maintain more than a [***] supply of Inventory (other than OptiNose Components) based on the then [***] rolling forecast without OptiNose's prior written consent. Beginning on July 1, 2020 and on an annual basis thereafter, if less than [***] DSAs are assembled over the prior [***] period (and such shortage is due to OptiNose ordering less than this amount and not due to any production delays attributable to VTM or otherwise), OptiNose will pay a fee equal to the number of DSAs below [***] not assembled over the relevant [***] period multiplied by [***] of the assembly fee set forth in Exhibit A (for example, if only [***] DSAs were assembled during the relevant [***] period then the amount due is $[***] ([***] multiplied by $[***] ([***] of $[***]))].

Section 2.09 Purchase Orders.

(a) The terms and conditions contained in this Agreement shall prevail over any terms and conditions of any Purchase Order, acknowledgment form or other form instrument exchanged by the

parties. OptiNose shall submit purchase orders specifying: (a) the number of units of DSAs to be manufactured, (b) the price (determined in accordance with Exhibit A hereto) and (c) the expected delivery date ("**Purchase Orders**"). Unless otherwise agreed, a Purchase Order shall not request a shipment date sooner than [***] days from the date of the Purchase Order unless agreed to separately by both parties. VTM shall confirm acceptance of Purchase Orders and projected dates of shipment within [***] days of receiving a Purchase Order. Failure of VTM to confirm any Purchase Order within the [***] day period shall be deemed to be acceptance of such Purchase Order, price and delivery.

(b) For any Binding Period, OptiNose shall submit Purchase Orders that aggregately meet at least [***] of the Forecast for such Binding Period, and VTM shall fulfill such Purchase Orders. If the Purchase Orders for a month in the Binding Period in aggregate exceed the Forecast for such month by an amount between [***], VTM shall supply such excess under this Agreement, provided, however, that, in any consecutive [***] in a Binding Period, VTM shall not be required to supply DSAs in aggregate in excess of [***]. If such Purchase Orders in aggregate exceed the Forecast for such month in the Binding Period by more than [***], VTM shall use [***] to fill such orders, but shall not be in breach of this Agreement if VTM does not accept such portion of the order in excess of such [***], as applicable. VTM shall promptly advise OptiNose to what extent VTM can fulfill such excess amount above [***], as applicable, which amount shall be considered part of the accepted Purchase Order hereunder.

Section 2.10 Release of DSAs. Upon completion of manufacture and associated testing documentation [***] and before shipping each batch, VTM shall send batch documentation, prepared pursuant to the Quality Agreement, to OptiNose's designee for review and approval. If OptiNose or its designee advises VTM of any issues or concerns regarding such batch documentation in accordance with this Agreement, VTM shall promptly rectify any such issue or concern and reissue updated batch documentation for review and approval within the time periods set forth in the Quality Agreement. Upon OptiNose's (or OptiNose's designee) receipt of complete batch documentation for such shipment, OptiNose's designee shall, within the time period set forth in the Quality Agreement, review and respond as to whether the batch is approved for shipment. [***].

Section 2.11 Non- or late Deliveries. In the event that VTM is unable to make delivery by a ready to ship date specified in the applicable Purchase Order, VTM shall immediately notify OptiNose (and any designee of OptiNose) of such delay and provide the date of availability for the shipment. If VTM fails to deliver the DSAs in the quantities ordered in any Purchase Order within [***] of the date specified in such Purchase Order, then in addition to, and without waiver or limitation of any of its other rights hereunder, at law or in equity, in all instances VTM shall use [***] to timely deliver DSAs even if there were prior delays in the OptiNose Components due to [***]. If shipment of Product is more than [***] late from the most recent agreed upon shipping date pursuant to the

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

accepted Purchase Order, then promptly following OPN's written request for expedited shipping, VTM shall be responsible for the cost of such expedited shipping over and above standard shipping costs for that shipment, but only if the reason for such expedited shipping is attributable to a cause within VTM's reasonable control. In the event that there is an actual or anticipated delay in shipping beyond [***] or other project delay due to events within VTM's control, OPN may request an immediate escalation of the issue to VTM's senior management at the subsidiary level (e.g., Vice-President, Precision Plastics), and failing resolution of the issue in [***], to Flex's senior management at the corporate level (e.g., President, Medical Segment). Failing resolution at such point, the matter shall be further escalated pursuant to Exhibit D attached hereto after each [***] period.

Section 2.12 Manager Meetings. The parties shall meet periodically [***] at meetings to be organized by the OptiNose Supply Relationship Manager and the VTM Supply Relationship Manager to discuss, agree upon, and oversee implementation of initiatives to plan Capacity and OptiNose Equipment requirements, improve the DSA manufacturing process to improve quality and to reduce cost and price for the benefit of both parties. Participants in such meetings will be agreed to by the parties. For each such agreed initiative, the parties shall agree on the capital and expense to implement the initiative, the party to provide funds for such capital and expense, the expected cost savings to result, and an equitable sharing of the cost and other benefits from the initiative after recoupment of the funds provided for the initiative (which sharing shall take into account a reasonable return on investment for the party providing the funds to implement such initiative). Additionally, promptly following the execution of this Agreement, the parties shall use [***] to agree upon reporting metrics, which shall include but are not limited to [***].

ARTICLE III

EQUIPMENT, INVENTORY AND WORK IN PROGRESS

Section 3.01 OptiNose Equipment

(a) VTM acknowledges that the OptiNose Equipment [***], is owned by OptiNose and that OptiNose may place identifying tags on the OptiNose Equipment confirming and providing notice of OptiNose's ownership. VTM shall not permit [***] and shall only use the OptiNose Equipment for the manufacture of the DSAs hereunder or other activities for OptiNose. VTM hereby disclaims any interest, to the extent it has any, in the OptiNose Equipment and agrees to execute and deliver any agreements or other documents evidencing OptiNose's ownership of such OptiNose Equipment. In the event that any OptiNose Equipment is to be shipped from VTM to OptiNose or any third party, [***] shall be responsible for all reasonable packing and shipping costs related thereto.

(b) VTM shall, [***], maintain the OptiNose Equipment in good working order (including maintenance and repair in the ordinary course and calibration, if needed) such that the OptiNose

Equipment enables VTM to produce DSAs according to the Specifications and otherwise in accordance with this Agreement. OptiNose shall be responsible for [***].

(c) At OptiNose's written request, VTM shall make available at VTM's facility such OptiNose Equipment as OptiNose may designate, [***], and VTM shall provide [***] at [***] in transitioning such OptiNose Equipment to OptiNose [***].

Section 3.02 Inventory and Work In Progress. The parties acknowledge that the OptiNose Components are significant inputs to the DSAs by value and that the OptiNose Components will be the property of OptiNose at all times that such OptiNose Components are in VTM's possession. [***], VTM shall not [***].

Section 3.03 Bailment Agreements. VTM agrees to enter a bailment agreement with OptiNose in the form reasonably acceptable to both parties for the OptiNose Equipment, and the OptiNose Components.

Section 3.04 Inventory. Authorization. OptiNose's accepted Purchase Orders and each Forecast shall constitute authorization for VTM to procure, without OptiNose's prior approval, but subject to the [***] limitation set forth in Section 2.08: (a) Inventory to manufacture the DSAs covered by such Purchase Orders and Forecast based on the applicable Lead Times, including Long Lead Time Inventory; (b) Minimum Order Inventory reasonably required to support OptiNose's Purchase Orders and Forecast; and (c) any Special Inventory which is separately authorized in writing by OptiNose.

Section 3.05 Supply Chain Management. Purchases from Approved Vendor List. VTM shall maintain an Approved Vendor List. VTM shall purchase Inventory required to manufacture the DSA only from vendors listed on such Approved Vendor List.

Section 3.06 Vendor Warranties for Inventory. To the extent VTM actually receives from a vendor of Inventory or services the benefit arising from said vendor's warranty obligations related to its Inventory or services, including OptiNose Components, VTM shall transfer such benefit to OptiNose (without any actual liability for such vendor's warranty obligations) related to the following warranties with regard to the Inventory or services: (i) conformance of the Inventory or services with the vendor's specifications; (ii) that the Inventory or services shall be free from defects in design, materials, or workmanship; (iii) that the Inventory or services shall comply with environmental regulations and all other applicable Laws; and (iv) that the Inventory or services shall not infringe the intellectual property rights of third parties. Nothing contained in this Section 3.06 is intended to limit the warranties provided by VTM under Section 4.02 of this Agreement or any other obligation of VTM under this Agreement.

Section 3.07 OptiNose Responsibility for Inventory. Subject to the other terms of this Section 3, OptiNose is financially responsible under the conditions provided in this Agreement for all Inventory purchased by VTM under this Section 3 that can only be used for manufacturing the DSAs. VTM agrees to maintain sufficient level of Inventory to manufacture the DSAs in accordance with the Forecast and Purchase Orders and the terms of this Agreement; provided, that in the event such Inventory is not used in connection with the manufacture of DSA then VTM shall use [***] to return or utilize such Inventory and if they are unable to do so OptiNose shall reimburse VTM for such Inventory, as the case may be.

Section 3.08 Quantity Increases and Shipment Schedule Changes.

(a) For any accepted Purchase Order, OptiNose may request an increase in the quantity of DSAs ordered. All DSA quantity increases in excess of the amount set forth in such Purchase Order ("**Excess Request**") shall require VTM's approval, which is subject to Inventory, OptiNose Component and capacity availability. VTM shall use [***] to meet any DSA quantity increases in an Excess Request.

(b) For any accepted Purchase Order, OptiNose may request a reschedule of the expected delivery date set forth in the applicable Purchase Order not to exceed [***] days. All DSA reschedules in excess of [***] days require VTM's approval, which, in its reasonable discretion, may or may not be granted. If VTM agrees to accept a reschedule of any length of time, and if there are extra costs to meet such reschedule, then OptiNose shall be liable for such extra costs, provided, that VTM provides OptiNose advance notice of such costs and OptiNose elects to proceed with such reschedule.

(c) Any delays in the normal production or interruption in the workflow process caused by OptiNose's changes to the Specifications shall be considered a reschedule of any affected Purchase Orders for purposes of this Section 3.08 for the period of such delay.

(d) Cancellations. OptiNose may not cancel all or any portion of DSA quantity of an accepted Purchase Order without VTM's prior written approval, which, in its [***], may or may not be granted; provided, however, that any reduction of the DSAs ordered in an accepted Purchase Order which reduction is equal to or less than [***] shall not require VTM's approval and shall not be subject to the other terms and conditions of this Section 3.08; and, provided, further, that VTM will not withhold its approval of any cancellation in the event VTM is able to utilize the production capability that would have been utilized to produce product or otherwise provide services for another customer.

Section 3.09 Excess and Obsolete Inventory.

OptiNose shall be responsible for the following:

a. Excess Inventory. When applicable, VTM shall report the Excess Inventory to OptiNose on a monthly basis. VTM shall advise whether such Excess Inventory was due to a decrease within the first [***] period of a Forecast in DSA production hereunder or due to VTM's purchase of Inventory

beyond the amount reasonably necessary for the next [***] of demand for DSAs under the then-current Forecast. Such Excess Inventory reports shall be deemed agreed to by OptiNose, unless OptiNose provides a written objection within [***] days of the end of the calendar month in which such report is received by OptiNose. Upon notice from VTM to OptiNose of any Excess Inventory pursuant to a report, VTM shall attempt to cancel or amend any pending orders for such inventory to the extent such inventory is not reasonably likely to be necessary for any Forecasts hereunder or otherwise for VTM to comply with its obligations hereunder.

b. Purchase of Excess Inventory. OptiNose shall pay VTM for Excess Inventory, as identified by VTM in each monthly report, and not objected to by OptiNose or returned/cancelled by VTM, in each instance pursuant to the process set forth above in Section 3.09(a), at a price equal to (as applicable) the price from the price list set forth in Exhibit A for any finished DSAs, the proportionate amount of such price for any partially completed DSAs, or the listed price for individual components, in each instance such price to be the price in existence at the time such Excess Inventory was acquired, used or completed; provided that if any such completed DSAs, partially completed DSAs or other Excess Inventory are subsequently utilized by VTM for the manufacture and supply of DSAs under this Agreement, VTM shall provide OptiNose a credit for the amount previously paid by OptiNose for such completed DSA, partially completed DSA or other Excess Inventory pursuant to this Section 3.09(b); [***]. In connection with any payments made by OptiNose to VTM pursuant to this Section 3.09(b), at VTM's discretion and OptiNose's request (1) VTM shall safely store such Excess Inventory at the rate to be mutually agreed to by the parties, and/or (2) OptiNose can, [***], have some or all of such Excess Inventory stored by a third party for VTM's potential future use.

c. Obsolete Inventory. When applicable, VTM shall report the Obsolete Inventory to OptiNose on a monthly basis. OptiNose's failure to object to VTM's Obsolete Inventory report (or failure to deny its responsibility for such inventory) within [***] days of the end of the calendar month in which such report is received by OptiNose shall constitute its acceptance of VTM's Obsolete Inventory report. After a validation period, which shall not exceed [***] from the date of such report, OptiNose shall purchase the Obsolete Inventory (and pay in accordance with Section 2 of this Agreement) at a price equal to (as applicable) the price from the price list set forth in Exhibit A for any finished DSAs, the proportionate amount of such price for any partially completed DSAs, or the listed price for individual components.

d. Notwithstanding the foregoing in Sections 3.09(a), (b) and (c) above, for those OptiNose Components set forth on Exhibit C, the [***] period noted in Sections 3.09(a) and (b) shall instead be [***] with respect to the items set forth in Exhibit C for which VTM shall also be required to maintain at least [***] but not more than [***] of available inventory at all times.

e. Prior to invoicing OptiNose for the amounts due pursuant to Section this 3.09, VTM shall use [***] for a period not to exceed [***] to return for refund unused Inventory from Excess Inventory and Obsolete Inventory and to otherwise mitigate the amounts payable by OptiNose. OptiNose shall submit payment for the amounts identified and invoiced pursuant to this Section 3.09 in accordance with the terms for payment set forth above in Section 2. At OptiNose's discretion, VTM shall ship the Excess Inventory and Obsolete Inventory to OptiNose promptly following said payment by OptiNose, or destroy such Excess Inventory and Obsolete Inventory, at [***]. [***].

f. For changes (including cancellation and reschedules) that are not consistent with Sections 3.08 or 3.09, [***] shall be responsible for any vendor cancellation charges incurred.

ARTICLE IV

DEFECTIVE PRODUCT

Section 4.01 Notification of Defective Product. OptiNose or its designee shall notify VTM within:

- [***] days after receiving a shipment of DSAs if it determines that such shipment contains a Quantitative Defect,
- [***] days after receiving a shipment of DSAs if it determines that such shipment contains a Patent Defect, and
- [***] days after OptiNose becomes aware of a Latent Defect.

OptiNose or its designee shall provide VTM a sample of what it alleges contains a Latent or Patent Defect, subject to compliance with the foregoing notice requirements and the provisions of Section 4.02, below.

Section 4.02 Resolution of Defective Product.

(a) Patent Defect and Latent Defect. VTM warrants and covenants that: (i) for a period of [***] from invoice date, such DSAs shall be free from defects in workmanship; (ii) be manufactured and delivered in accordance with the terms of this Agreement, the Specifications, and the Quality Agreement, (iii) it shall perform its obligations under this Agreement using personnel of required skill, experience and qualifications and in a professional and workmanlike manner in accordance with generally recognized industry standards, (iv) it is in compliance with, and shall perform under this Agreement in compliance with, all applicable Laws, and (v) OptiNose will receive good and valid title to all DSAs, free and clear of all encumbrances and liens of any kind (collectively, the "Warranty").

(b) Notwithstanding anything else in this Agreement, this Warranty does not apply to, and VTM makes no representations or warranties whatsoever with respect to any of: (i) defects resulting from adherence to the Specifications, or any written instructions provided by or on behalf of OptiNose; (ii) the design of the DSAs; (iii) DSAs that have been abused, damaged, altered or misused or

mishandled by any person or entity after title passes to OptiNose; or (iv) defects resulting from tooling, designs or written instructions produced or supplied by OptiNose.

(c) Upon any failure of a DSA to comply with this Warranty, VTM shall, [***]; provided that OptiNose's inspection or approval shall not excuse Supplier's responsibility with respect to Latent Defects. [***] shall bear all of the risk, and shipping costs, associated with DSAs that have been returned to VTM for which there is no defect found under the Warranty.

(d) OptiNose or its designee must obtain a Returned Material Authorization (RMA) Number from VTM prior to returning any DSA. The RMA must be indicated on the return package as notice to VTM's Shipping Department to accept shipment. Any package not so marked will be returned at [***] expense. [***] is responsible for risk of loss and all costs associated with the return to VTM of the DSAs; provided that [***] shall reimburse [***] for such costs if it is determined that the DSA is non-conforming. For purposes of this Agreement, a DSA shall be deemed to be "non-conforming" if it does not meet the Specifications or the other requirements of this Warranty. If OptiNose and VTM are unable to agree as to whether a DSA is conforming, then after [***] to resolve the disagreement, and subject to, and without waiver or limitation of OptiNose's and/or VTM's rights and remedies hereunder, at law and/or in equity, either party may submit a sample of such DSA to a mutually agreed upon independent third party testing laboratory which is an expert in the industry and which will expertly apply the agreed upon testing protocol in order to determine whether the DSA is conforming or non-conforming. The independent laboratory's results shall be final and binding for purposes of determining whether payment is owed (but not for purposes of any pending or potential product liability litigation which shall be governed by Article XII). If the parties or the independent laboratory determine that the DSA was non-conforming, then in addition to, and without waiver or limitation of OptiNose's rights and remedies hereunder, at law and/or in equity, OptiNose shall [***]. If the parties or the independent laboratory determine the DSA was conforming, OptiNose shall [***]. Unless otherwise agreed to by the parties in writing, the costs associated with testing and review of a DSA pursuant to this Section shall be borne by [***].

(e) The above warranties are given in lieu of any other representation or warranty, express or implied, and including but not limited to the implied warranty of merchantability or fitness for a particular purpose.

(f) Quantitative Defect. If OptiNose believes that a shipment of DSAs hereunder has a Quantitative Defect, OptiNose shall notify VTM within the applicable period. If VTM agrees with such Quantitative Defect, VTM will promptly, and in no event more than [***] days, ship sufficient DSAs at OptiNose's direction to remedy such Quantitative Defect. If VTM does not agree with OptiNose's determination that such shipment has a Quantitative Defect, then after [***] to resolve the disagreement, and subject to, and without waiver or limitation of OptiNose's and/or VTM's rights and

remedies hereunder, at law and/or in equity, VTM may require a mutually agreed upon independent third party to determine whether the shipment had a Quantitative Defect. The independent party's results shall be final and binding for purposes of determining whether VTM is obligated to ship additional DSAs, and the costs of such independent third party shall be borne by [***]. If such results indicate that the shipment had a Quantitative Defect, OptiNose shall be entitled to [***].

ARTICLE V

RECORDS AND REGULATORY MATTERS

Section 5.01 Recordkeeping. VTM shall maintain true and accurate books, records, inventory of Inventory and finished DSAs, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Law. Such information shall be maintained for the period specified in the Quality Agreement or longer if required under Law. VTM shall provide or make such information available to OptiNose upon request and shall notify and provide OptiNose with advance notice and opportunity to obtain such information at the end of the retention period.

Section 5.02 Regulatory Compliance. VTM will be responsible to maintain all permits and licenses required by any Law with respect to the facility and its equipment for the manufacture and delivery of DSAs and will manufacture and deliver the DSAs in accordance with the requirements of this Agreement, including the Quality Agreement, the Specifications and applicable Laws. In addition, during the Term, at OptiNose's request VTM will provide [***] assistance [***] with all regulatory matters relating to the manufacturing of the DSAs and services under this Agreement. Each Party intends and commits to cooperate to satisfy all Law within the scope of its respective responsibilities under this Agreement.

Section 5.03 Regulatory Correspondence. VTM shall notify OptiNose in accordance with the Quality Agreement of any notice, correspondence, and the result of any inspection(s) by or with the FDA or any Regulatory Authority (including without limitation any 483, warning letter, or similar correspondence) concerning an actual or potential regulatory deficiency, noncompliance or problem that directly or indirectly relates to the manufacturing of the DSAs or any of the services provided by VTM under this Agreement. VTM shall notify OptiNose in accordance with the Quality Agreement of any other notice or correspondence, and the result of any inspection(s), with the FDA or any Regulatory Authority that is reasonably likely to impact or directly relates to the manufacture of DSAs or other performance under this Agreement. In all of the foregoing notifications, VTM shall provide OptiNose with copies of any such notices, correspondences, or results of inspection in accordance with the Quality Agreement subject to any other customer confidentiality requirements of VTM; provided VTM shall attempt to reasonably redact any such other customer confidential information in order to provide OptiNose with such information. Furthermore, VTM shall send a draft

to OptiNose of all correspondence VTM intends to send to any Regulatory Authority with any substantial relation to DSAs. For all correspondence with a Regulatory Authority related directly to DSAs that is in response to any 483, warning letter, regulatory deficiency or other problem relating to the manufacture of DSAs, VTM shall consult with, and reasonably consider the input of, OptiNose on the draft correspondence before such correspondence is sent to the Regulatory Authorities. Regarding all interactions with Regulatory Authorities, both parties shall make [***] to act expeditiously in cooperating with each other and responding to Regulatory Authorities.

Section 5.04 Governmental Inspections and Requests. VTM shall as soon as [***] in accordance with the Quality Agreement inform OptiNose in writing of any inspection, notice or request for inspection, and other regulatory action, by any regulatory agency relating to the manufacture of DSAs and/or, in the case of a facility to the extent related to VTM's manufacturing, packaging, testing and storage of DSAs at such facility, so that OptiNose has as much advance notice as possible to enable it to, as applicable and relevant, participate in preparation and/or strategy regarding and/or attend the inspection. VTM shall permit the OptiNose's representatives to be present during any such inspection related to DSAs ([***]), including being present at any inspection of the facility to the extent such inspection is related to VTM's manufacturing, packaging, testing or storage of the DSAs. As provided in Section 5.03, VTM will provide OptiNose with the results of all regulatory inspection or audits related to the DSAs after VTM's receipt of such results in accordance with the Quality Agreement.

Section 5.05 Recall. In the event VTM believes a recall, field alert, product withdrawal or field correction may be necessary with respect to any DSA provided under this Agreement, VTM shall as soon as practicable notify OptiNose in writing. VTM will not act to initiate a recall, field alert, product withdrawal or field correction with respect to the DSAs. In the event OptiNose believes a recall, field alert, product withdrawal or field correction may be necessary with respect to any DSA provided under this Agreement, OptiNose shall immediately notify VTM in writing and VTM shall provide [***] cooperation and assistance to OptiNose. The cost of any recall, field alert, product withdrawal or field correction, and any assistance in connection therewith, shall be borne by [***]. For avoidance of doubt and subject to applicable Laws, OptiNose shall have the ultimate and final authority to initiate a field alert or recall of the Finished Product.

Section 5.06 Inspections and Audits by OptiNose. [***], representatives of OptiNose shall have access upon [***] prior notice to VTM's facility where it manufactures DSAs for the purpose of: (a) conducting inspections of such facility and VTM's maintenance and usage of the equipment utilized in the manufacture of the DSAs, (b) performing quality control and quality assurance (including without limitation cGMP) audits (c) witnessing the manufacture, storage or transportation of the DSAs or the Inventory, (d) verifying the storage of the OptiNose Components, and (d) requiring cycle counts by VTM (and adjustments to inventory as necessary). OptiNose shall have access to the

results of any tests performed by VTM relating to DSAs and Inventory and the processes or the Inventory that VTM's purchases directly from a third party used in their manufacture. Such inspections shall not relieve VTM of any of its obligations under this Agreement or create new obligations on the part of OptiNose. This right of inspection can be exercised [***] (and as often as necessary for cause), subject to a written notice to VTM given in accordance with the time periods specified in the Quality Agreement, or at any time for cause. VTM shall permit such inspection during normal business hours at reasonable and mutually acceptable times [***]. At all times, OptiNose's representatives shall be accompanied by VTM personnel and follow all site reasonable health and safety policies of VTM. Each inspection, audit and witnessing shall be subject, at all times, to VTM's confidentiality and non-disclosure obligations to its other third party customers.

ARTICLE VI

ADDITIONAL VTM OBLIGATIONS

Section 6.01 VTM shall:

(a) appoint a VTM employee to serve as a primary contact with respect to this Agreement and who will have the expertise and authority to act on behalf of VTM in connection with matters pertaining to this Agreement (the **"VTM Supply Relationship Manager**");

(b) [***] maintain the same VTM Supply Relationship Manager throughout the Term, however VTM has the right to replace the VTM Supply Relationship Manager [***];

(c) before the date on which the services under this Agreement are to start, obtain, and at all times during the Term maintain, all necessary licenses and consents and comply with all Laws;

(d) prior to any VTM Personnel performing any services hereunder: (i) ensure that such VTM Personnel are suitably trained, skilled, experienced and qualified to perform such services; and (ii) ensure that such VTM Personnel have the legal right to work in the United States; and

(e) maintain complete and accurate records relating to the provision of services under this Agreement, including records of the time spent and Inventory and OptiNose Components used by VTM in providing such services in such form as [***] shall [***]. During the Term and for a period of [***] thereafter, upon OptiNose's written request, VTM shall allow OptiNose or OptiNose's representative to inspect and make copies of such manufacturing and quality records in connection with the provision of the services under this Agreement; provided that any such inspection shall take place during regular business hours no more than [***] (which limit shall not include any inspections for cause) and OptiNose provides VTM with [***] advance written notice.

Section 6.02 VTM is responsible for all VTM Personnel and for the payment of their compensation, including, if applicable, withholding of income taxes, and the payment and

withholding of social security and other payroll taxes, unemployment insurance, workers' compensation insurance payments and disability benefits.

Section 6.03 VTM acknowledges that time is of the essence with respect to VTM's obligations hereunder and that prompt and timely performance of all such obligations is strictly required.

Section 6.04 The obligations of VTM under this Agreement shall be performed fully within the facility located at 71 and 20 Utopia Road, Manchester, CT 06042 United States, unless approved in writing in advance by OptiNose.

Section 6.05 Upon VTM's receipt of OptiNose Components, VTM shall promptly inspect such OptiNose Components in accordance with the applicable inspection criteria provided by OptiNose and ensure that such OptiNose Components provided by each such supplier meets the applicable specifications for such OptiNose Components. VTM shall do such inspection within [***] days of its receipt of such OptiNose Components. Should the OptiNose Components fail any such inspection or should VTM identify any issues with the OptiNose Components, VTM shall provide OptiNose and the applicable supplier of such OptiNose Components notice of such failure and/or issue within [***] day.

ARTICLE VII

ADDITIONAL OPTINOSE'S OBLIGATIONS

Section 7.01 OptiNose shall:

(a) appoint an OptiNose employee to serve as the primary contact with respect to this Agreement and who will have the expertise and authority to act on behalf of OptiNose with respect to matters pertaining to this Agreement (the "**OptiNose Supply Relationship Manager**");

(b) respond [***] to any VTM request to provide direction, information, approvals, authorizations or decisions that are reasonably necessary for VTM to perform in accordance with this Agreement;

(c) provide such information as VTM may reasonably request and OptiNose considers [***] necessary in order to perform under this Agreement;

(d) obtain and maintain all necessary licenses and consents and comply with all Law to the extent necessary for OptiNose's performance under the Agreement; and

(e) obtain and maintain throughout the term of this Agreement insurance on the OptiNose Equipment in [***] amounts and coverage.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE VIII

FEES AND EXPENSES; PAYMENT TERMS

Section 8.01 VTM shall issue invoices to OptiNose upon delivery to OptiNose in accordance with Section 2.01 of DSAs with pricing pursuant to Exhibit A for such DSAs produced, and OptiNose shall pay all properly invoiced amounts due to VTM within [***] days after the date of the invoice except for any amounts disputed by OptiNose in good faith (subject to OptiNose's match process for Purchase Order, invoice and receipt). VTM shall provide, for OptiNose's review and prior written approval, statements of work with budgetary allowances for any services not required to be provided by VTM at its costs by the quality agreement or this Agreement. VTM will provide invoices to those services if incurred. All payments hereunder shall be in US dollars and made by check or wire transfer. The provisions of this Agreement shall govern over any terms and conditions listed on any invoice or Purchase Order. A service fee of [***]% per month will be added to all accounts more than [***] days past due, and [***] is responsible for all collection and attorneys' fees and costs required to collect unpaid amounts.

Section 8.02 [***] shall be responsible for all sales, use and excise taxes, and any other similar taxes, duties and charges of any kind imposed by any federal, state or local governmental entity on any amounts payable to VTM. [***]. In no event shall [***] pay or be responsible for any taxes imposed on, or with respect to, [***] income, revenues, gross receipts, personnel or real or personal property or other assets.

ARTICLE IX

INTELLECTUAL PROPERTY RIGHTS; OWNERSHIP

Section 9.01 Except as set forth in Section 9.03, OptiNose is, and shall be, the sole and exclusive owner of all right, title and interest in and to any Intellectual Property Rights generated in connection with VTM's performance under this Agreement, and to any of the Deliverables, including all Intellectual Property Rights therein. VTM agrees, and will cause its VTM Personnel to agree, that with respect to any Intellectual Property Rights or Deliverables that may qualify as "work made for hire" as defined in 17 U.S.C. §101, such Intellectual Property Rights and Deliverables are hereby deemed a "work made for hire" for OptiNose. To the extent that any of the Intellectual Property Rights or Deliverables hereunder do not immediately vest in OptiNose or do not constitute a "work made for hire", VTM hereby irrevocably assigns on behalf of itself and all VTM Personnel, and, [***], shall cause the VTM Personnel to irrevocably assign to OptiNose, in each case without additional consideration, all right, title and interest throughout the world in and to such Intellectual Property Rights and Deliverables, including all Intellectual Property Rights therein. VTM hereby waives on behalf of itself and all VTM Personnel, and, [***], shall cause the VTM Personnel to irrevocably waive, to the extent permitted by applicable Law, any and all claims VTM and/or such VTM Personnel

may now or hereafter have in any jurisdiction to so-called “moral rights” or rights of droit moral with respect to such Intellectual Property Rights and Deliverables.

Section 9.02 Upon the request of OptiNose, VTM shall, and shall cause the VTM Personnel to, promptly take such further actions, including execution and delivery of all appropriate instruments of conveyance, as may be necessary to assist OptiNose to prosecute, register, perfect or record its rights in or to any Deliverables.

Section 9.03 VTM and its licensors are, and shall remain, the sole and exclusive owners of all right, title and interest in and to the VTM Tools, including all Intellectual Property Rights therein. VTM represents and warrants that the DSAs delivered hereunder shall not incorporate any VTM Tools, and that OptiNose can use and/or sell the DSAs without the requirement of any approval and/or license from VTM

Section 9.04 OptiNose and its licensors are, and shall remain, the sole and exclusive owner of all right, title and interest in and to the OptiNose Information, including all Intellectual Property Rights therein. VTM shall have no right or license to use any OptiNose Information, except solely during the Term of the Agreement to the extent necessary to perform under this Agreement. All other rights in and to the OptiNose Information are expressly reserved by OptiNose.

ARTICLE X
CONFIDENTIAL INFORMATION

Section 10.01 The Receiving Party agrees:

(a) not to disclose or otherwise make available Confidential Information of the Disclosing Party to any third party without the prior written consent of the Disclosing Party; *provided, however*, that the Receiving Party may disclose the Confidential Information of the Disclosing Party to its Affiliates, and their officers, employees, consultants and legal advisors who have a “need to know”, who have been apprised of this restriction and who are themselves bound by nondisclosure obligations at least as restrictive as those set forth in this Article X, provided, that, the Receiving Party shall be responsible for any disclosure or use of Confidential Information by such persons or entities that is contrary to the terms of this Agreement;

(b) to use the Confidential Information of the Disclosing Party only for the purposes of performing its obligations under the Agreement or, in the case of OptiNose, to make use of the services under this Agreement and Deliverables; and

(c) to promptly notify the Disclosing Party in the event it becomes aware of any loss or disclosure of any of the Confidential Information of the Disclosing Party.

Section 10.02 If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall provide: (i) prompt written notice of such

requirement so that the Disclosing Party may seek, at its sole cost and expense, a protective order or other remedy; and (ii) [***] assistance, [***], in opposing such disclosure or seeking a protective order or other limitations on disclosure. If, after providing such notice and assistance as required herein, the Receiving Party remains required by Law to disclose any Confidential Information, the Receiving Party shall disclose no more than that portion of the Confidential Information which, on the advice of the Receiving Party's legal counsel, the Receiving Party is legally required to disclose and, upon the Disclosing Party's request, shall use commercially reasonable efforts to obtain assurances from the applicable court or agency that such Confidential Information will be afforded confidential treatment.

ARTICLE XI

REPRESENTATIONS AND WARRANTIES

Section 11.01 Each party further represents and warrants to the other party that:

(a) it is duly organized, validly existing and in good standing as a corporation or other entity as represented herein under the laws and regulations of its jurisdiction of incorporation, organization or chartering;

(b) it has the full right, power and authority to enter into this Agreement, to grant the rights and licenses granted hereunder and to perform its obligations hereunder;

(c) the execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary corporate action of the party;

(d) when executed and delivered by such party, this Agreement will constitute the legal, valid and binding obligation of such party, enforceable against such party in accordance with its terms; and

(e) it will comply at all times with the provisions of applicable Laws of the United States (and, as applicable, analogous such laws in any other territories where regulatory approval is sought) regarding debarment and will upon request certify in writing to the other parties that none of its employees nor any person providing services in connection with this Agreement have been debarred under the provisions of such laws.

Section 11.02 VTM further represents and warrants to OptiNose that:

(a) it shall perform the services under this Agreement using personnel of required skill, experience and qualifications and in a professional and workmanlike manner in accordance with generally recognized industry standards for similar services and shall devote adequate resources to meet its obligations under this Agreement;

(b) it is in compliance with, and shall perform under this Agreement in compliance with, all applicable Laws;

(c) Upon delivery of DSAs to OptiNose in accordance with Section 2.1, OptiNose will receive good and valid title to all Deliverables, free and clear of all encumbrances and liens of any kind;

(d) the DSAs provided under this Agreement shall be manufactured and delivered in strict compliance with the terms of this Agreement, including (i) the Specifications; (ii) all Laws relating to the manufacture of the DSAs, including without limitation the FD&C Act and cGMPs; and (iii) the Quality Agreement; and

(e) as of the date hereof, there are no pending or, to VTM's knowledge, threatened claims, litigation or other proceedings pending against VTM by any third party, in each case, excluding any infringement or claim, litigation or other proceedings to the extent arising out of (x) any OptiNose Information or any instruction, information, designs, specifications or other materials provided by OptiNose to VTM, (y) use of the Deliverables in combination with any materials or equipment not supplied or specified by VTM, if the infringement would have been avoided by the use of the Deliverables not so combined, and (z) any modifications or changes made to the Deliverables by or on behalf of any Person other than VTM.

Section 11.03 EXCEPT FOR THE EXPRESS WARRANTIES IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EITHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE UNDER THIS AGREEMENT, INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE XII
INDEMNIFICATION

Section 12.01 OptiNose acknowledges that VTM has no control over, and is not responsible for, the manner in which the DSAs will be used or otherwise dealt with by OptiNose. OptiNose shall defend, indemnify and hold VTM and VTM's Affiliates and their officers, directors, employees, agents, successors and permitted assigns (each, a "**VTM Indemnitee**") harmless from and against any and all third party suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) ("**Losses**") and agree to assume all responsibility for any and all actions, claims, or demands arising out of or in any way connected with, and any and all amounts which VTM and/or OptiNose becomes obligated to pay, caused by or resulting directly or indirectly from the use or operation of the DSAs, including any intellectual property claims, except to the extent VTM is required to indemnity OptiNose for such Loss pursuant to Section 12.02.

Section 12.02 VTM agrees to defend, indemnify and hold harmless OptiNose and OptiNose's Affiliates and their officers, directors, employees, agents, successors and permitted assigns (each, an "**OptiNose Indemnitee**") from and against, any and all Losses as follows: (a) any

actual or alleged injury or damage to any person (including death) or property caused, or alleged to be caused, by a DSA sold by VTM to OptiNose hereunder, but solely to the extent such injury or damage has been caused by the breach by VTM of its Warranty set forth in Article IV, including but not limited to the failure of the DSA to conform to the Specifications; and (b) any actual or alleged infringement or misappropriation of the intellectual property rights (including any industrial design rights, database rights or any other form of intangible or business property rights) of any third party, but solely to the extent that such infringement or misappropriation is caused by a process, VTM Tools, or Production Materials that VTM elects to use to manufacture, assemble or test the DSAs; however, VTM shall not have any obligation to indemnify OptiNose if such claim would not have arisen but for VTM's manufacture, assembly or test of the DSA in accordance with the Specifications.

Section 12.03 The party seeking indemnification hereunder shall promptly notify the indemnifying party in writing of any third party claim, suit, action or proceeding ("**Action**") and cooperate with the indemnifying party [***]. The indemnifying party shall immediately take control of the defense and investigation of such Action and shall employ counsel of its choice to handle and defend the same, [***]. The indemnifying party shall not settle any Action in a manner that adversely affects the rights of the indemnified party without the indemnified party's prior written consent. The indemnified party's failure to perform any obligations under this Section 12.3 shall not relieve the indemnifying party of its obligations under this Section 12.3 except to the extent that the indemnifying party can demonstrate that it has been materially prejudiced as a result of such failure. The indemnified party may participate in and observe the proceedings [***].

ARTICLE XIII
LIMITATION OF LIABILITY

Section 13.01 EXCEPT AS OTHERWISE PROVIDED IN SECTION 13.02, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER OR TO ANY THIRD PARTY FOR ANY LOSS OF USE, REVENUE OR PROFIT OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. FURTHERMORE, EXCEPT WITH RESPECT TO THE EQUITABLE EXCEPTIONS, IN NO EVENT WILL VTM BE LIABLE FOR THE VALUE OF THE INTERNAL TIME OF OPTINOSE'S EMPLOYEES TO REMEDY A BREACH.

Section 13.02 The exclusions and limitations in Section 13.01 shall not apply to the following (the "**Equitable Exceptions**"):

(a) damages or other liabilities arising out of or relating to a party's failure to comply with its obligations under Article IX (Intellectual Property Rights; Ownership);

(b) damages or other liabilities arising out of or relating to a party's failure to comply with its obligations under Article X (Confidentiality);

(c) a party's indemnification obligations under Article XII (Indemnification); and

(d) damages or other liabilities arising out of or relating to a party's gross negligence, willful misconduct or intentional acts.

EXCEPT WITH RESPECT TO THE EQUITABLE EXCEPTIONS ABOVE AND NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, VTM'S TOTAL LIABILITY TO OPTINOSE HEREUNDER SHALL BE SUBJECT TO AN AGGREGATE CAP IN ACCORDANCE WITH THE FOLLOWING: [***].

Section 13.03 No Double Recovery. Notwithstanding OptiNose's rights under the Molded Parts Agreement, in the event of a dispute of a claim under either this Agreement or the Molded Parts Agreement, OptiNose is only entitled to recover under this Agreement with respect to the DSAs, and the Molded Parts Agreement with respect to the cap covered thereunder. Further, notwithstanding the preceding sentence, if there are any disputes or claims regarding Pre-Existing Inventory that OptiNose purchased from VTM prior to the date of this Agreement and such Pre-Existing Inventory would not be covered under this Agreement for any claims or disputes related thereto, then the parties agree and acknowledge that OptiNose maintains any and all rights set forth in the Molded Parts Agreements regarding such Pre-Existing Inventory.

ARTICLE XIV
TERM

Section 14.01 This Agreement shall commence as of the Effective Date and shall expire at 11:59PM on October 24, 2021, unless sooner terminated pursuant to Article XV. After the expiration of the initial term hereunder, this Agreement shall be automatically renewed for separate but successive one-year terms unless either party provides written notice to the other party that it does not intend to renew this Agreement ninety (90) days or more prior to the end of any term.

ARTICLE XV
TERMINATION; EFFECT OF TERMINATION

Section 15.01 OptiNose, in its sole discretion, may terminate this Agreement:

(a) [***];

(b) by providing VTM written notice if VTM fails an inspection or suffers a hold, 483, warning letter, or other disciplinary action by the FDA or any other government authority and VTM fails to cure such inspection shortcoming, or remove or resolve such hold or disciplinary action in such a manner that the VTM facility passes re-inspection by the FDA or government authority and/or is free of the hold or disciplinary action, in good standing with FDA or such other government authority,

and is lawfully able to and does resume timely and conforming manufacture and delivery of OptiNose's DSAs requirements in accordance with this Agreement within thirty days of such original inspection, or imposition of the hold or disciplinary action; or

(c) by providing VTM written notice if VTM fails to gain recommendation for approval by FDA to manufacture DSAs in accordance with this Agreement (with such recommendation being either unqualified or with any qualifications resolved to FDA's acknowledged satisfaction) in a manner that does not delay such approval by the FDA.

Section 15.02 Either party may terminate this Agreement, effective upon written notice to the other party (the "**Defaulting Party**"), if the Defaulting Party:

(a) materially breaches this Agreement, and such breach is incapable of cure, or with respect to a material breach capable of cure, the Defaulting Party does not cure such breach within [***] days after receipt of written notice of such breach.

(b) (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within seven business days or is not dismissed or vacated within forty-five days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

Section 15.03 Upon expiration or termination of this Agreement for any reason:

(a) OptiNose shall have the right at any time after a notice of termination has been given or an event has occurred which, with the passage of time, will cause this Agreement to terminate to require VTM, as soon as reasonably practicable and in no more than [***] days from the effective date of termination, to make available for removal by OptiNose or its designee [***]: (i) all DSAs, all Inventory, all partially completed DSAs, all Deliverables and all OptiNose Information ([***]), and (ii) all OptiNose Equipment. Upon payment, as applicable, all of the foregoing items for removal shall be made available at the facility, [***], claims and encumbrances, and VTM shall provide [***] cooperation and assistance to OptiNose upon OptiNose's written request [***] in transitioning the manufacture of DSAs and related services under this Agreement to an alternate supplier. [***].

(b) Each party shall (i) return to the other party all documents and tangible materials (and any copies) containing, reflecting, incorporating or based on the other party's Confidential Information, (ii) if the other party requests, use [***] efforts to permanently erase all of the other party's Confidential Information from its computer systems, and (iii) certify in writing to the other party that it has complied with the requirements of this clause; *provided, however*, that OptiNose may retain copies of any Confidential Information of VTM incorporated in the Deliverables or to the extent necessary to allow

it to make full use of the DSAs and any Deliverables; and *provided further, however,* that VTM shall retain such documents and tangible materials as are required to be maintained by VTM under Law.

(c) In no event shall OptiNose be liable for [***].

Section 15.04 The rights and obligations of the parties set forth in this Section 15.04 and Article I, Sections 5.01, 5.03, 5.04, 5.05, 5.06 and 6.01(e), Article IX, Article X, Article XI, Article XII, Article XIII, Section 15.03, Article XVI and Article XVIII, and any right or obligation of the parties in this Agreement which, by its nature, should survive termination or expiration of this Agreement, will survive any such termination or expiration of this Agreement. For purposes of clarity, in no event shall any termination or expiration of this Agreement excuse either party from any breach or violation of this Agreement or other obligation that occurred prior to such termination or expiration and, in each such case, full legal and equitable remedies shall remain available to address such issues.

ARTICLE XVI
INSURANCE

Section 16.01 At all times during the Term and for a period of at least [***] thereafter, VTM shall procure and maintain, at its sole cost and expense, at least the following types and amounts of insurance coverage:

(a) Commercial General Liability/ Completed Operation Liability with limits no less than $[***] per occurrence, including bodily injury and property damage and products, which policy will include contractual liability coverage insuring the activities of VTM under this Agreement;

(b) Worker's Compensation with employer's liability limits no less [***];

(c) Errors and Omissions and/or Professional Liability with limits no less than $[***] per occurrence; and

(d) Umbrella Liability with limits no less than $[***] per occurrence and $[***] in the aggregate providing excess coverage of the primary Commercial General Liability, including Products/Completed Operations Liability.

Section 16.02 All insurance policies required pursuant to this Article XVI shall:

(a) be issued by an insurance company or insurance companies having an A.M. Best Rating of [***] or better;

(b) provide that such insurance be primary insurance and any similar insurance in the name of and/or for the benefit of OptiNose shall be excess and non-contributory; provided, however, this provision shall not apply to the insurance required by Section 16.01(b); and

(c) name OptiNose and OptiNose's Affiliates, including, in each case, all successors and permitted assigns, as Additional Insureds; provided, however, this provision shall not apply to the insurance required by Section 16.01(b).

Section 16.03 Upon the written request of OptiNose, VTM shall provide OptiNose with copies of the certificates of insurance for all insurance coverage required by this Article XVI, and shall not do anything to invalidate such insurance. This Article XVI shall not be construed in any manner as waiving, restricting or limiting the liability of either party for any obligations imposed under this Agreement (including but not limited to, any provisions requiring a party hereto to indemnify, defend and hold the other harmless under this Agreement).

ARTICLE XVII

FORCE MAJEURE

Section 17.01 No party shall be liable or responsible to the other party, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement, when and to the extent such failure or delay is caused by or results from acts beyond the affected party's reasonable control, including, without limitation:

(a) acts of God;

(b) flood, fire or explosion;

(c) war, invasion, riot or other civil unrest;

(d) actions, embargoes or blockades in effect on or after the date of this Agreement;

(e) national or regional emergency;

(f) strikes, labor stoppages or slowdowns or other industrial disturbances; or

(g) compliance with any law or governmental order, rule, regulation or direction, or any action taken by a governmental or public authority, including but not limited to imposing an embargo, export or import restriction, quota or other restriction or prohibition, or failing to grant a necessary license or consent;

(each of the foregoing, a "**Force Majeure Event**"). A party whose performance is affected by a Force Majeure Event shall give notice to the other party, stating the period of time the occurrence is expected to continue and shall use [***] to end the failure or delay and minimize the effects of such Force Majeure Event.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Section 17.02 During the Force Majeure Event, the non-affected party may similarly suspend its performance obligations until such time as the affected party resumes performance.

Section 17.03 The non-affected party may terminate this Agreement if such failure or delay continues for a period of [***] days or more and, [***].

ARTICLE XVIII
MISCELLANEOUS

Section 18.01 Each party shall, upon the reasonable request, promptly execute such documents and perform such acts as may be necessary to give full effect to the terms of this Agreement.

Section 18.02 The relationship between the parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever.

Section 18.03 Neither party shall issue or release any announcement, statement, press release or other publicity or marketing materials relating to this Agreement, or otherwise use the other party's trademarks, service marks, trade names, logos, symbols or brand names, in each case, without the prior written consent of the other party, except to the extent necessary pursuant to any applicable securities exchange rule.

Section 18.04 All notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); or (c) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the addresses indicated below (or at such other address for a party as shall be specified in a notice given in accordance with this Section 18.04.)

If to VTM:

VTM, LLC
Attn: Chief Executive Officer
71 Utopia Road
Manchester, CT 06042

Flex Health Solutions
6201 America Center Drive
San Jose, CA
Attn: Medical, General Counsel

If to OptiNose:

OptiNose US, Inc.
Attn: Chief Executive Officer
1020 Stony Hill Road, Suite 300
Yardley, PA 19067

To OptiNose UK:
OptiNose UK, Ltd.
Hunts Rise
South Marston Park, Wiltshire
SN3 4TG, England
Attention: Chief Executive Officer

To OptiNose Norway:
OptiNose AS
Gaustadalléen 210349
Oslo, Norway
Attention: Chief Executive Officer

In each instance, with cc to:

OptiNose US, Inc.
Attn: Chief Legal Officer
1020 Stony Hill Road, Suite 300
Yardley, PA 19067

Section 18.05 For purposes of this Agreement, (a) the words “include,” “includes” and “including” shall be deemed to be followed by the words “without limitation”; (b) the word “or” is not exclusive; and (c) the words “herein,” “hereof,” “hereby,” “hereto” and “hereunder” refer to this Agreement as a whole. Unless the context otherwise requires, references herein: (x) to Sections and Exhibits refer to the Sections of, and Exhibits attached to, this Agreement; and (y) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any

presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. The Schedules, Exhibits and Statements of Work referred to herein shall be construed with, and as an integral part of, this Agreement to the same extent as if they were set forth verbatim herein.

Section 18.06 This Agreement, together with all Exhibits and any other documents incorporated herein by reference, constitutes the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. For purposes of clarity, this Agreement shall not supersede the development agreements and other related project work between the parties not otherwise covered by this Agreement.

Section 18.07 Neither party may assign, transfer or delegate any or all of its rights or obligations under this Agreement (including without limitation to any subcontractors), without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed; *provided, that*, upon prior written notice to the other party, either party may assign the Agreement to an Affiliate of such party or to a successor of all or substantially all of the assets of such party through merger, reorganization, consolidation or acquisition; provided further, that, notwithstanding the foregoing, VTM may not make such an assignment without OptiNose's prior written consent, not to be unreasonably withheld. No assignment shall relieve the assigning party of any of its obligations hereunder. Any attempted assignment, transfer or other conveyance in violation of the foregoing shall be null and void. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.

Section 18.08 This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Agreement.

Section 18.09 The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

Section 18.10 This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each party hereto. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power or privilege arising from this Agreement shall operate or be construed 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.

Section 18.11 If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 18.12 This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, exclusive of conflict or choice-of-law rules, except to the extent there may be any conflict between the laws of the State of New York and the Incoterms of the International Chamber of Commerce, 2010 edition, in which case the Incoterms shall be controlling. The parties specifically agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods, as may be amended from time to time, shall not apply to this Agreement. The parties hereby consent to the personal and exclusive jurisdiction and venue of the New York state courts and the federal courts located in New York, New York.

Section 18.13 Any controversy, claim, or dispute arising out of or relating to this order and not resolved by agreement of the parties shall be resolved in Arbitration in New York, New York. The decision and award of the arbitrator(s) shall be final and binding and may be entered in any court having jurisdiction thereof. The parties will pay their respective attorneys' fees and equally share all other costs and expenses of the arbitration proceedings.

Section 18.14 Notwithstanding the foregoing, except with respect to enforcing claims for injunctive or equitable relief, any dispute, claim or controversy arising out of or relating in any way to this Agreement, any other aspect of the relationship between VTM and OptiNose or their respective affiliates and subsidiaries, the interpretation, application, enforcement, breach, termination or validity thereof (including, without limitation, any claim of inducement of this Agreement by fraud and a determination of the scope or applicability of this agreement to arbitrate), or its subject matter (collectively, "Disputes") shall be determined by binding arbitration before one arbitrator. The arbitration shall be administered by JAMS conducted in accordance with the expedited procedures set forth in the JAMS Comprehensive Arbitration Rules and Procedures as those Rules exist on the Effective Date of this Agreement, including Rules 16.1 and 16.2 of those Rules. Notwithstanding anything to the contrary in this Agreement, the Federal Arbitration Act shall govern the arbitrability of all Disputes. The arbitration shall be held in New York, New York and it shall be conducted in the English language. The parties shall maintain the confidential nature of the arbitration proceeding and any award, including the hearing, except as may be necessary to prepare for or conduct the arbitration hearing on the merits, or except as may be necessary in connection with a court application for a

preliminary remedy, a judicial challenge to an award or its enforcement, or unless otherwise required by law or judicial decision. The arbitrator shall have authority to award compensatory damages only and shall not award any punitive, exemplary, or multiple damages and the parties waive any right to recover any such damages. Judgment on any award in arbitration may be entered in any court of competent jurisdiction. Notwithstanding the above, each party shall have recourse to any court of competent jurisdiction to enforce claims for injunctive and other equitable relief.

Section 18.15 IN THE EVENT OF ANY DISPUTE BETWEEN THE PARTIES, WHETHER IT RESULTS IN PROCEEDINGS IN ANY COURT IN ANY JURISDICTION OR IN ARBITRATION, THE PARTIES HEREBY KNOWINGLY AND VOLUNTARILY, AND HAVING HAD AN OPPORTUNITY TO CONSULT WITH COUNSEL, WAIVE ALL RIGHTS TO TRIAL BY JURY, AND AGREE THAT ANY AND ALL MATTERS SHALL BE DECIDED BY A JUDGE OR ARBITRATOR WITHOUT A JURY TO THE FULLEST EXTENT PERMISSIBLE UNDER APPLICABLE LAW. To the extent applicable, in the event of any lawsuit between the parties arising out of or related to this Agreement, the parties agree to prepare and to timely file in the applicable court a mutual consent to waive any statutory or other requirements for a trial by jury.

Section 18.16 Each party acknowledges that a breach by a party of Article IX (Intellectual Property Rights; Ownership) or Article X (Confidentiality) may cause the non-breaching party irreparable damages, for which an award of damages would not be adequate compensation and agrees that, in the event of such breach or threatened breach, the non-breaching party will be entitled to seek equitable relief, including a restraining order, injunctive relief, specific performance and any other relief that may be available from any court, in addition to any other remedy to which the non-breaching party may be entitled at law or in equity. Such remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

Section 18.17 In the event that any action, suit, or other legal or administrative proceeding is instituted or commenced by either party hereto against the other party arising out of or related to this Agreement, the prevailing party shall be entitled to recover its reasonable attorneys' fees and court costs from the non-prevailing party.

Section 18.18 This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

Section 18.19 [***].

[Signature Page Follows]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

ADVANCE MOLD & MANUFACTURING, INC.

By: /s/ Fabio Scagliarini
Name: Fabio Scagliarini
Its: General Manager

OPTINOSE US, INC.

By: /s/ Peter Miller
Name: Peter Miller
Its: Chief Executive Officer

OPTINOSE UK LTD.

By: /s/ Ricci Whitlow
Name: Ricci Whitlow
Its: VP, Tech Ops

OPTINOSE AS

By: /s/ Peter Miller
Name: Peter Miller
Its: Chief Executive Officer

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A

PRICING

[***]

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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

OPTINOSE COMPONENTS

[***]

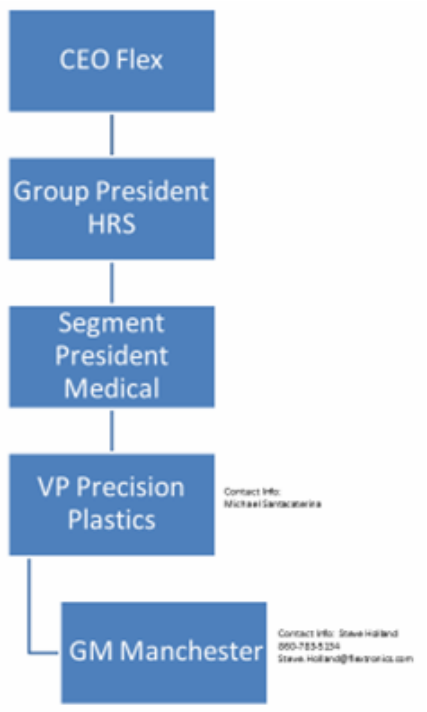
[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C
OPTINOSE COMPONENTS WITH ADDITIONAL STORAGE TIME

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT D
ESCALATION MATRIX



[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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 following Registration Statements:

(1) 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 OptiNose, Inc.
(2) Registration Statement (Form S-8 No. 333-223617) pertaining to the Amended and Restated 2010 Stock Incentive Plan and the 2017 Employee Stock Purchase Plan of OptiNose, Inc.
(3) Registration Statement (Form S-3 No. 333-228122) of OptiNose, Inc.

of our report dated March 6, 2019, with respect to the consolidated financial statements of OptiNose, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 6, 2019

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. 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 6, 2019

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. 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 6, 2019

/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 PURSUANTTO 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, 2018 (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 6, 2019

/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, 2018 (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 6, 2019

/s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)