

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

FORM 10-Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2021

1934 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF

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

Commission file number: 001-38241



**OPTINOSE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State of other jurisdiction of incorporation or organization)

**42-1771610**

(I.R.S. Employer Identification Number)

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

(Address of principal executive offices, including zip code)

**(267) 364-3500**

(Registrant's telephone number including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	OPTN	Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically 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

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

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

The number of shares of the registrant's common stock outstanding at October 31, 2021 was 53,449,567 shares.

---

---

	<a href="#">NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	1
	<a href="#">PART I — FINANCIAL INFORMATION</a>	
<a href="#">Item 1.</a>		4
	<a href="#">Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020</a>	4
	<a href="#">Consolidated Statements of Operations for the three and nine months ended September 30, 2021 and 2020</a>	5
	<a href="#">Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2021 and 2020</a>	6
	<a href="#">Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the nine months ended September 30, 2021 and 2020</a>	7
	<a href="#">Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020</a>	9
	<a href="#">Notes to Unaudited Interim Consolidated Financial Statements</a>	10
<a href="#">Item 2.</a>	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	21
<a href="#">Item 3.</a>	<a href="#">Qualitative and Quantitative Disclosure About Market Risk</a>	34
<a href="#">Item 4.</a>	<a href="#">Controls and Procedures</a>	34
	<a href="#">PART II — OTHER INFORMATION</a>	36
<a href="#">Item 1.</a>	<a href="#">Legal Proceedings</a>	36
<a href="#">Item 1A.</a>	<a href="#">Risk Factors</a>	36
<a href="#">Item 6.</a>	<a href="#">Exhibits</a>	39
	<a href="#">Signatures</a>	40

---

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

---

Trademark Notice

OPTINOSE® and XHANCE® are trademarks of ours in the United States. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

---

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q 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 impact of, our plans regarding and the uncertainties caused by, the COVID-19 pandemic, including without limitation, our expectation that the COVID-19 pandemic will negatively impact XHANCE prescription and product revenue growth rates for the remainder of 2021 and into 2022;
- the potential uses for and advantages of XHANCE®, our product candidates and Exhalation Delivery System (EDS) devices and technologies;
- our planned product development activities, studies and clinical trials in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis;
- the potential for XHANCE to be the first drug therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic sinusitis;
- the potential for XHANCE to be the standard of care for the treatment of chronic rhinosinusitis with and without nasal polyps;
- the potential for continued XHANCE prescription and net revenue growth and potential drivers of such growth;
- the potential for direct-to-consumer (DTC) advertising to be a future driver of XHANCE prescription growth;
- the potential benefits of our patient affordability programs and their potential effect on XHANCE demand and financial results;
- the potential for XHANCE prescriptions to be affected by the seasonality impact observed in the intranasal steroid (INS) market;
- the potential for XHANCE prescriptions and average net revenue per prescription to be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January;
- our expectation that consolidated XHANCE net product revenues for the full year of 2021 will be between \$71.0 and \$75.0 million;
- our expectation that average net product revenues per prescription for the full year of 2021 will exceed \$210 and the factors supporting such growth;
- our expectation that our total GAAP operating expenses in 2021 will be between \$132.0 million and \$137.0 million and that our non-cash stock-based compensation expense will be approximately \$10.0 million;
- our expectation that top-line results will be available from the first of our two ongoing Phase 3b chronic sinusitis clinical trials in the first quarter of 2022 and from the second clinical trial in the second quarter of 2022;
- our belief that, based on the results of blinded interim analyses and our assumptions and estimates relating to the trial, the initial targeted statistical power will be achieved with the approximately 330 patients currently enrolled in our first chronic sinusitis trial and the approximately 210 patients currently enrolled in our second chronic sinusitis trial;
- our belief that existing cash and cash equivalents will be sufficient to maintain the minimum cash balance required under the Note Purchase Agreement that we entered into with funds managed by Pharmakon Advisors, LP, the investment manager of the BioPharma Credit Funds (the Note Purchase Agreement) and to fund our operations for at least the next twelve months from the filing date of this Form 10-Q if, in the event of a default, the holders of the notes issued pursuant to the Note Purchase Agreement do not otherwise elect to accelerate repayment of all unpaid principal and accrued interest under the Note Purchase Agreement;

- our ability to continue as a going concern and maintain compliance with the financial covenants to achieve certain minimum trailing twelve-month consolidated XHANCE net product sales and royalties and other covenants under the Note Purchase Agreement and, if required, our ability to obtain a waiver or modification of such covenants;
- our expectation that the research and development costs associated with the conduct of our current chronic sinusitis clinical trials will significantly decrease;
- our ability to maintain sufficient inventory of XHANCE and for our manufacturers to timely supply XHANCE;
- our development, timing of data and funding plans for OPN-019 and the potential benefits of OPN-019; 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-Q entitled "Item 1. Financial Statements," and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations." In some cases, you can identify forward-looking statements by words such as "may," "will," "could," "would," "should," "expect," "confident," "intend," "plan," "anticipate," "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 in this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein under the caption "Risk Factors". Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (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-Q. 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-Q contains estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning markets for XHANCE, XHANCE market access, the INS market and prescription data. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances reflected in this information. As a result, you are cautioned not to give undue weight to such information.

## PART I

## ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 84,226	\$ 144,156
Accounts receivable, net	24,088	23,394
Inventory	13,161	9,042
Prepaid expenses and other current assets	3,967	4,060
Total current assets	<u>125,442</u>	<u>180,652</u>
Property and equipment, net	1,515	2,028
Other assets	4,960	6,133
Total assets	<u>\$ 131,917</u>	<u>\$ 188,813</u>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 6,502	\$ 5,489
Accrued expenses and other current liabilities	47,125	46,683
Total current liabilities	<u>53,627</u>	<u>52,172</u>
Long-term debt, net	126,542	125,202
Other liabilities	3,217	4,651
Total liabilities	<u>183,386</u>	<u>182,025</u>
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 53,449,567 and 52,945,865 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	53	53
Additional paid-in capital	542,996	534,585
Accumulated deficit	(594,437)	(527,765)
Accumulated other comprehensive loss	(81)	(85)
Total stockholders' equity (deficit)	<u>(51,469)</u>	<u>6,788</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 131,917</u>	<u>\$ 188,813</u>

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Operations**  
**For the Three and Nine Months Ended September 30, 2021 and 2020**  
**(in thousands, except share and per share data)**  
**(Unaudited)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Revenues:</b>				
Net product revenues	\$ 21,826	\$ 15,436	\$ 51,143	\$ 32,770
Licensing revenues	—	—	1,000	—
Total revenues	21,826	15,436	52,143	32,770
<b>Costs and expenses:</b>				
Cost of product sales	2,411	2,221	6,576	5,276
Research and development	6,654	6,524	20,058	16,930
Selling, general and administrative	25,801	24,575	80,293	77,332
Total operating expenses	34,866	33,320	106,927	99,538
Loss from operations	(13,040)	(17,884)	(54,784)	(66,768)
<b>Other (income) expense:</b>				
Interest income	(9)	(31)	(42)	(396)
Interest expense	4,072	3,350	11,959	9,506
Foreign currency (gains) losses	14	11	38	44
Gain on sale of equipment	\$ —	\$ —	\$ (67)	\$ —
Net loss	\$ (17,117)	\$ (21,214)	\$ (66,672)	\$ (75,922)
Net loss per share of common stock, basic and diluted	\$ (0.32)	\$ (0.43)	\$ (1.25)	\$ (1.62)
Weighted average common shares outstanding, basic and diluted	53,334,669	48,907,514	53,151,730	46,914,561

See accompanying notes to unaudited interim consolidated financial statements



**OptiNose, Inc.**  
**Consolidated Statements of Comprehensive Loss**  
**For the Three and Nine Months Ended September 30, 2021 and 2020**  
**(in thousands)**  
**(Unaudited)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net loss	\$ (17,117)	\$ (21,214)	\$ (66,672)	\$ (75,922)
Other comprehensive loss:				
Foreign currency translation adjustment	2	13	4	(17)
Comprehensive loss	<u>\$ (17,115)</u>	<u>\$ (21,201)</u>	<u>\$ (66,668)</u>	<u>\$ (75,939)</u>

See accompanying notes to unaudited interim consolidated financial statements

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

Nine Months Ended September 30, 2021

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2020	52,945,865	\$ 53	\$ 534,585	\$ (527,765)	\$ (85)	\$ 6,788
Stock compensation expense	—	—	2,596	—	—	2,596
Vesting of restricted stock units	166,709	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	2	2
Net loss	—	—	—	(26,053)	—	(26,053)
Balance at March 31, 2021	<u>53,112,574</u>	<u>\$ 53</u>	<u>\$ 537,181</u>	<u>\$ (553,818)</u>	<u>\$ (83)</u>	<u>\$ (16,667)</u>
Stock compensation expense	—	—	2,729	—	—	2,729
Vesting of restricted stock units	37,034	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	135,525	—	367	—	—	367
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	(23,502)	—	(23,502)
Balance at June 30, 2021	<u>53,285,133</u>	<u>\$ 53</u>	<u>\$ 540,277</u>	<u>\$ (577,320)</u>	<u>\$ (83)</u>	<u>\$ (37,073)</u>
Stock compensation expense	—	—	2,680	—	—	2,680
Vesting of restricted stock units	140,555	—	—	—	—	—
Exercise of common stock options	23,879	—	39	—	—	39
Foreign currency translation adjustment	—	—	—	—	2	2
Net loss	—	—	—	(17,117)	—	(17,117)
Balance at September 30, 2021	<u>53,449,567</u>	<u>\$ 53</u>	<u>\$ 542,996</u>	<u>\$ (594,437)</u>	<u>\$ (81)</u>	<u>\$ (51,469)</u>

## Nine Months Ended September 30, 2020

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2019	45,906,162	\$ 46	\$ 489,565	\$ (427,980)	\$ (48)	\$ 61,583
Stock compensation expense	—	—	2,429	—	—	2,429
Foreign currency translation adjustment	—	—	—	—	(25)	(25)
Net loss	—	—	—	(28,856)	—	(28,856)
Balance at March 31, 2020	45,906,162	\$ 46	\$ 491,994	\$ (456,836)	\$ (73)	\$ 35,131
Stock compensation expense	—	—	2,748	—	—	2,748
Exercise of common stock options	15,806	—	71	—	—	71
Issuance of common stock under employee stock purchase plan	70,305	—	516	—	—	516
Foreign currency translation adjustment	—	—	—	—	(5)	(5)
Net loss	—	—	—	(25,852)	—	(25,852)
Balance at June 30, 2020	45,992,273	\$ 46	\$ 495,329	\$ (482,688)	\$ (78)	\$ 12,609
Stock compensation expense	—	—	2,615	—	—	2,615
Exercise of common stock options	43,636	—	5	—	—	5
Sale of common stock, net of issuance costs	6,000,000	6	33,399	—	—	33,405
Issuance of common stock with Pharmakon Amendment	44,643	—	250	—	—	250
Foreign currency translation adjustment	—	—	—	—	13	13
Net loss	—	—	—	(21,214)	—	(21,214)
Balance at September 30, 2020	52,080,552	\$ 52	\$ 531,598	\$ (503,902)	\$ (65)	\$ 27,683

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Cash Flows**  
**For the Nine Months Ended September 30, 2021 and 2020**  
**(in thousands)**  
**(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating activities:</b>		
Net loss	\$ (66,672)	\$ (75,922)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
Depreciation and amortization	478	1,036
Stock-based compensation	8,027	7,857
Amortization of debt discount and issuance costs	1,364	899
Gain on sale of property and equipment	(67)	—
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(695)	(3,881)
Prepaid expenses and other assets	1,416	2,804
Inventory	(4,049)	(5,773)
Accounts payable	1,188	2,821
Accrued expenses and other liabilities	(1,209)	3,109
Cash used in operating activities	<u>(60,219)</u>	<u>(67,050)</u>
<b>Investing activities:</b>		
Purchases of property and equipment	(143)	(460)
Proceeds from sale of property and equipment	105	—
Cash used in investing activities	<u>(38)</u>	<u>(460)</u>
<b>Financing activities:</b>		
Proceeds from long-term debt	—	34,447
Repayment of long-term debt	—	(4,447)
Cash paid for financing costs	(95)	(690)
Proceeds from issuance of common stock under employee stock purchase plan	367	516
Proceeds from sale of common stock	—	33,600
Proceeds from the exercise of stock options	39	76
Cash provided by financing activities	<u>311</u>	<u>63,502</u>
Effects of exchange rate changes on cash and cash equivalents	2	(11)
Net decrease in cash, cash equivalents and restricted cash	(59,944)	(4,019)
Cash, cash equivalents and restricted cash at beginning of period	144,179	147,165
Cash, cash equivalents and restricted cash at end of period	<u>\$ 84,235</u>	<u>\$ 143,146</u>
<b>Supplemental disclosure of noncash activities:</b>		
Fixed asset purchases within accounts payable and accrued expenses	\$ 8	\$ 55
Recognition of right-of-use assets	\$ 157	\$ 6,174
Recognition of lease liabilities	\$ 157	\$ 6,174

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Notes to Unaudited Interim 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, and Oslo, Norway. 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<sup>®</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing its proprietary Exhalation Delivery System (EDS) device that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also referred to 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. XHANCE was made widely available through commercial channels in April 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, commercializing XHANCE in the US. As of September 30, 2021, the Company had cash and cash equivalents of \$84,226. For the nine months ended September 30, 2021, the Company had a net loss of \$66,672 and negative cash from operations of \$60,219. As of September 30, 2021, the Company had an accumulated deficit of \$594,437.

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.

The Company's continuation as a going concern is dependent on its ability to continue to maintain compliance with its covenants under that certain Note Purchase Agreement, dated as of September 12, 2019, as amended pursuant to that certain letter agreement dated as of August 13, 2020 and as further amended by that certain first amendment to the Note Purchase Agreement dated as of March 2, 2021 (the Note Purchase Agreement) that the Company entered into with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit Funds (BioPharma), including the minimum trailing twelve-month consolidated XHANCE net sales and royalties the Company is required to achieve each quarter and its ability to generate sufficient cash flows from operations to meet its obligations and/or obtain additional financing from its stockholders or other sources, as may be required. The Note Purchase Agreement includes events of default, in certain cases subject to customary periods to cure, following which Pharmakon may accelerate all amounts outstanding under the senior secured notes issued pursuant to the Note Purchase Agreement (Pharmakon Senior Secured Notes). The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

As of the filing of this quarterly report on Form 10-Q, the Company expects consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 to be between \$71,000 and \$75,000. If the Company is unable to achieve \$80,000 of consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 and the Company is unable to obtain a waiver or modification to this financial covenant, the Company will be in breach of a financial covenant under the Note Purchase Agreement, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the Pharmakon Senior Secured Notes elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes, the Company may need to delay or curtail its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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

The Company will likely require additional capital in the future, secured through equity or debt financings, partnerships, collaborations, or other sources, in order to meet its debt service obligations under the Pharmakon Senior Secured Notes, including repayment, and to carry out the Company's planned development and commercial activities. Financial capital, secured through equity 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 the Company's debt service obligations, including repayment, or enable the Company to continue to implement its long-term business strategy. If additional capital is not secured, the Company may need to delay or curtail its operations until such funding is received. The terms of the Note Purchase Agreement, including applicable covenants, are described in Note 8.

### **3. Basis of Presentation and Summary of Significant Accounting Policies**

The accompanying unaudited interim 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).

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2021 and its results of operations for the three and nine months ended September 30, 2021 and 2020 and cash flows for the nine months ended September 30, 2021 and 2020. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2020 contained in the Company's annual report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 3, 2021.

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

The preparation of the unaudited interim 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 unaudited interim 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 unaudited interim 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 unaudited interim consolidated financial statements in the period they are determined to be necessary.

#### ***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.

#### ***Customer and supplier concentration***

XHANCE is sold to wholesale pharmaceutical distributors and Preferred Pharmacy Network (PPN) partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Five customers represented approximately 39% of the Company's accounts receivable at September 30, 2021 and five customers represented

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

approximately 33% and 32% of the Company's net product sales for the three and nine months ended September 30, 2021, respectively.

The Company currently purchases XHANCE and its components from several third-party suppliers and manufacturing partners, certain of which are available through a single source. The Company has initiated the process of qualifying alternate third-party suppliers for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA.

***Fair value of financial instruments***

At September 30, 2021 and December 31, 2020, 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 approximate their respective fair values because of the short-term nature of these instruments. In addition, the Company believes that at September 30, 2021, the carrying value of long-term debt approximated fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At September 30, 2021 and December 31, 2020, there were no financial assets or liabilities measured at fair value on a recurring basis.

***Restricted cash***

As of September 30, 2021 and December 31, 2020, the restricted cash balance included in prepaid expenses and other assets was \$9 and \$23, respectively.

***Net product revenues***

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606), which the Company adopted on January 1, 2018. The Company recognizes revenue from XHANCE sales at the point customers obtain 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. 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. The components of the Company's variable consideration include the following:

***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.

***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.

***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 Company estimates the amount of its product 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 customers, 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. Reserves related to these discount obligations 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. The Company's

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

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.

**Patient Assistance.** Other programs that the Company offers include voluntary co-pay patient assistance programs intended to provide financial assistance to eligible patients with prescription drug co-payments required by payors and coupon programs for cash payors. The calculation of the current liability 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**

The Company has license agreements with Inexia Limited (Inexia) and Currax Pharmaceuticals LLC (Currax). These license agreements provide for exclusive licensed rights to certain intellectual property, a non-refundable up-front payment, potential milestone payment(s) and potential royalty payment(s). The Company analyzed the performance obligations under the license agreements, the consideration received to date and the consideration the Company could receive in the future as part of its analysis related to ASC 606. The Company recognized \$1,000 as licensing revenue from Currax during the nine months ended September 30, 2021 and is not eligible to receive any further payments under the Currax license agreement other than reimbursement for certain expenses.

**Net income (loss) per common share**

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to Company common stock (Common Stock) holders by the weighted average common shares outstanding during the period. For the three and nine months ended September 30, 2021 and 2020, the outstanding Common Stock options, Common Stock warrants and shares to be issued under the Company's 2017 Employee Stock Purchase Plan 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:

	September 30,	
	2021	2020
Stock options	7,928,817	8,157,752
Restricted stock units	2,013,934	1,499,456
Common stock warrants	810,357	2,677,188
Employee stock purchase plan	123,754	62,699
Total	10,876,862	12,397,095

**Income taxes**

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2021 and 2020, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 30, 2021 and December 31, 2020, the Company concluded that a full valuation allowance would be 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.



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

**Recent accounting pronouncements**

In July 2021, the FASB issued ASU No. 2021-05, *Leases (Topic 842): Lessors—Certain leases with variable payments*. ASU No. 2021-05 is intended to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing transactions. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU No. 2021-04 requires that issuers clarify and reduce diversity in accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption 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 December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminated certain exceptions and changed guidance on other matters. The exceptions relate to the allocation of income taxes in separate company financial statements, tax accounting for equity method investments and accounting for income taxes when the interim period year-to-date loss exceeds the anticipated full year loss. Changes relate to the accounting for franchise taxes that are income-based and non-income-based, determining if a step up in tax basis is part of a business combination or if it is a separate transaction, when enacted tax law changes should be included in the annual effective tax rate computation, and the allocation of taxes in separate company financial statements to a legal entity that is not subject to income tax. The Company has adopted ASU 2019-12 in the first quarter of 2021, and there was no significant impact.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-03, in conjunction with ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 for companies deemed to be smaller reporting companies as of November 15, 2019, with early adoption permitted. The Company has adopted ASU 2016-13 and there was no significant impact.

**4. Inventory**

Inventory consisted of the following:

	September 30, 2021	December 31, 2020
Raw materials	\$ 3,330	\$ 2,669
Work-in-process	4,456	2,676
Finished goods	5,375	3,697
Total inventory	<u>\$ 13,161</u>	<u>\$ 9,042</u>

Inventories are stated at the lower of cost or net realizable value, as determined on a first-in, first-out, basis.

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

**5. Property and Equipment**

Property and equipment, net, consisted of the following:

	September 30, 2021	December 31, 2020
Computer equipment and software	\$ 1,157	\$ 1,128
Furniture and fixtures	366	366
Machinery and equipment	3,266	3,440
Leasehold improvements	609	609
Construction in process	216	271
	<u>5,614</u>	<u>5,814</u>
Less: accumulated depreciation	(4,099)	(3,786)
	<u>\$ 1,515</u>	<u>\$ 2,028</u>

Depreciation expense was \$153 and \$473 for the three months ended September 30, 2021 and 2020, respectively. Depreciation expense was \$476 and \$1,035 for the nine months ended September 30, 2021 and 2020, respectively. In addition, depreciation expense of \$551 and \$13 was charged to inventory and prepaid expenses and other assets, respectively, as of September 30, 2021, which represents depreciation expense related to equipment involved in the manufacturing process.

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of:

	September 30, 2021	December 31, 2020
Accrued expenses:		
Selling, general and administrative expenses	\$ 6,997	\$ 7,385
Research and development expenses	6,208	5,202
Payroll expenses	7,119	9,063
Product revenue allowances	21,833	20,917
Other	2,859	2,008
Total accrued expenses	<u>45,016</u>	<u>44,575</u>
Other current liabilities:		
Lease liability	2,109	2,108
Total other current liabilities	<u>2,109</u>	<u>2,108</u>
Total accrued expenses and other current liabilities	<u>\$ 47,125</u>	<u>\$ 46,683</u>

**7. Licensing Revenue**Currax License Agreement

On September 25, 2019, OptiNose AS entered into a license agreement (the Currax License Agreement) with Currax pursuant to which the Company granted Currax a license to certain intellectual property for the commercialization of Onzetra Xsail® in the US, Canada and Mexico.

Under the terms of the Currax License Agreement, Currax paid the Company an upfront payment of \$3,730, which was recognized as license revenue during the year ended December 31, 2019. On December 29, 2020, the Company received an additional \$750 upon the expiration of the escrow that was established for a limited period to cover potential indemnification obligations. In addition, in January 2021 the Company received a \$1,000 milestone payment in connection with the achievement of a specified regulatory milestone. The Company does not expect to receive any further payments from Currax under the terms of the Currax License Agreement other than reimbursement for certain expenses.

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

## **8. Long-term Debt**

On September 12, 2019 (the Closing Date), the Company entered into the Note Purchase Agreement with funds managed by Pharmakon, the investment manager of BioPharma. The Note Purchase Agreement provided the Company with \$130,000 in debt financing, of which \$80,000 was issued on the Closing Date, \$30,000 was issued on February 13, 2020 (the First Delayed Draw Notes) after achieving the \$9,000 consolidated XHANCE net sales and royalties threshold for the quarter ended December 31, 2019 and \$20,000 was issued on December 1, 2020 after achieving the \$14,500 consolidated XHANCE net sales and royalties threshold for the quarter ended September 30, 2020.

On August 13, 2020, the Company entered into a letter agreement (the Pharmakon Letter Agreement) to the Note Purchase Agreement. The Pharmakon Letter Agreement provided the Company with the option to issue additional Pharmakon Senior Secured Notes, subject to the Company achieving specified consolidated XHANCE net sales and royalties for the quarter ended June 30, 2021 and certain other conditions. As consideration for the Pharmakon Letter Agreement, the Company issued 44,643 shares of Common Stock to Pharmakon. The aggregate fair value of \$250 was recorded as debt issuance costs and is being amortized to interest expense over the five-year term of the Pharmakon Senior Secured Notes. The Company was no longer eligible for the additional Pharmakon Senior Secured Notes as the requisite conditions were not satisfied as of June 30, 2021.

On March 2, 2021, the Company entered into the first amendment (the First Amendment) to the Note Purchase Agreement. The amendment revised certain minimum trailing twelve-month consolidated XHANCE net sales and royalties the Company is required to achieve. As consideration for the amendment, the Company will pay an amendment fee of \$1,300 upon the earlier of the prepayment of the Pharmakon Senior Secured Notes and the Maturity Date (defined below). The amendment fee was recorded as debt issuance costs and is being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). The Company is required to make quarterly interest payments until the Maturity Date. The Company is also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that the Company may, at its election, postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain minimum trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved.

In conjunction with the Pharmakon Senior Secured Notes, the Company paid an upfront fee of \$1,125 on the Closing Date and issued warrants to purchase an aggregate of 810,357 shares of Common Stock at an exercise price equal to \$6.72 per share, which expire on September 12, 2022. The upfront fees were recorded as debt discount at issuance and are being amortized to interest expense over the five-year term of the Pharmakon Senior Secured Notes. The Company also incurred \$6,514 in debt issuance costs, including \$2,404 related to the fair value of the warrants which are also being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

The Company is required to repay the Pharmakon Senior Secured Notes in full upon the occurrence of a change of control (as defined in the Note Purchase Agreement). In addition, the Company may make voluntary prepayments in whole or in part. All mandatory and voluntary prepayments are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the third anniversary of the Closing Date, an amount equal to 2% of the principal prepaid, (ii) if prepayment occurs on or after the third anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, an amount equal to 1% of the principal prepaid, and (iii) if prepayment occurs on or after the fourth anniversary of the Closing Date, no prepayment premium is required. The Company is also required to pay a "make-whole" amount in respect of any principal prepayments (whether mandatory or voluntary) made prior to the 30-month anniversary of the issuance of the applicable Pharmakon Senior Secured Note, in an amount equal to the interest that would have accrued through the 30-month anniversary in respect of such note but for such principal prepayment.

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

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of the Company's assets and the Note Purchase Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its 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, 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 the Company to maintain at all times certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis, and at least \$30,000 of cash and cash equivalents. As of September 30, 2021, the Company was in compliance with the covenants. The Note Purchase Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the Pharmakon Senior Secured Notes.

The Company recorded interest expense of \$4,072 and \$3,350 during the three months ended September 30, 2021 and 2020, respectively, and \$11,959 and \$9,506 during the nine months ended September 30, 2021 and 2020, respectively. Interest expense included total coupon interest and the amortization of debt issuance costs.

The long-term debt balance is comprised of the following:

	September 30, 2021	December 31, 2020
Face amount	\$ 130,000	\$ 130,000
Front end fees	(701)	(855)
Debt issuance costs	(4,057)	(3,943)
Back end fees	1,300	—
Long-term debt, net	<u>\$ 126,542</u>	<u>\$ 125,202</u>

#### 9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of September 30, 2021, \$151 was recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

For foreign employees, the Company maintains defined contribution pension plans which meet the statutory requirements of those jurisdictions. The Company incurred costs related to the pension plans of \$1 and \$5 for the three months ended September 30, 2021 and 2020, respectively, and \$5 and \$15 for the nine months ended September 30, 2021 and 2020, respectively.

#### 10. Stockholders' Equity

As of September 30, 2021, the Company had the following warrants outstanding to purchase shares of Common Stock:

Number of Shares	Exercise Price Per Share	Expiration Date
810,357	\$ 6.72	September 12, 2022

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

**11. Stock-based Compensation**

The Company recorded stock-based compensation expense related to stock options and shares issued under the Company's 2017 Employee Stock Purchase Plan (2017 Plan) in the following expense categories of its accompanying consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of product sales	\$ 20	\$ 25	\$ 38	\$ 113
Research and development	298	334	865	922
General and administrative	2,366	2,267	7,124	6,822
	<u>\$ 2,684</u>	<u>\$ 2,626</u>	<u>\$ 8,027</u>	<u>\$ 7,857</u>

In addition, stock-based compensation expense of \$87 and \$1 was charged to inventory and prepaid expenses and other assets, respectively, during the nine months ended September 30, 2021, 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.

**Stock Options**

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 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 Company's board of directors or committee thereof. 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 September 30, 2021, all of the performance conditions related to performance-based stock options issued by the Company had been achieved.

The following table summarizes the activity related to stock option grants to employees and non-employees for the nine months ended September 30, 2021:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2020	6,852,733	\$ 10.34	6.84
Granted	1,615,696	3.48	
Exercised	(23,879)	1.63	
Expired	(307,892)	12.30	
Forfeited	(207,841)	6.46	
Outstanding at September 30, 2021	<u>7,928,817</u>	\$ 8.97	6.72
Exercisable at September 30, 2021	<u>5,029,197</u>	\$ 11.19	5.54
Vested and expected to vest at September 30, 2021	<u>7,928,817</u>	\$ 8.97	6.72

During the nine months ended September 30, 2021, stock options to purchase 1,615,696 shares of Common Stock were granted to employees and generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$2.26. During the nine months ended September 30, 2020, stock options to purchase 1,303,210 shares of Common Stock were granted to employees that generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$3.44.

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

Included in the table above are 200,000 of options granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

The grant date fair value of each stock option grant was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Nine Months Ended September 30,	
	2021	2020
Risk free interest rate	1.00 %	0.71 %
Expected term (in years)	6.08	6.03
Expected volatility	74.18 %	68.77 %
Annual dividend yield	0.00 %	0.00 %
Fair value of common stock	\$ 3.48	\$ 5.64

At September 30, 2021, the unrecognized compensation cost related to unvested stock options expected to vest was \$8,570. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.31 years.

#### **Restricted Stock Units**

The Company has issued service-based and performance-based restricted stock units (RSUs). Vesting generally occurs over a period not greater than four years. Vesting of the performance-based RSUs is subject to the achievement of certain milestones in connection with the Company's development programs.

The following table summarizes the activity related to RSUs granted to employees for the nine months ended September 30, 2021:

	Shares
Balance at December 31, 2020	1,491,589
Granted	957,990
Vested and settled	(344,298)
Expired/forfeited/canceled	(91,347)
Balance at September 30, 2021	<u>2,013,934</u>
Expected to vest at September 30, 2021	<u>2,013,934</u>

In March 2021, the Company granted 957,990 RSUs at a grant date fair value of \$3.51, all of which were service-based RSUs. No performance-based RSUs were granted in 2021. As of September 30, 2021, the milestones associated with previously granted performance based-RSUs were not probable of achievement, and accordingly, no stock based compensation expense has been recognized for these awards. At September 30, 2021, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was \$5,432, to be recognized over an estimated weighted-average amortization period of 2.81 years. The unrecognized compensation cost related to unvested performance-based RSUs was \$3,095, which will be recognized commencing in the period in which the performance condition is deemed probable of achievement over the remaining service period.

Included in the table above are 60,000 RSUs granted outside the A&R Plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

#### **2017 Employee Stock Purchase Plan**

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. The Company recognized stock-based compensation expense of \$65 and \$102 during the three months ended September 30, 2021 and 2020, respectively, and \$264 and \$389 during the nine months ended September 30, 2021 and 2020, respectively, related to the 2017 Plan.

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

The Company calculated the fair value of each option grant and the shares issued under the 2017 Plan on the respective dates of grant using the following weighted average assumptions:

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Risk free interest rate	0.07 %	0.96 %
Expected term (in years)	0.5	0.5
Expected volatility	65.43 %	84.55 %
Annual dividend yield	0.00 %	0.00 %

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I, Item 1 of this Form 10-Q and our audited consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission (SEC) on March 3, 2021. In addition to historical information, some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by such forward-looking statements. Please refer to the "Note Regarding Forward-Looking Statements" section of this Form 10-Q for additional information.*

### 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 micrograms (mcg), is a therapeutic utilizing our proprietary Exhalation Delivery System (EDS) device that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also referred to as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is 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 conventional INS.

In September 2017, the United States 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 commercial channels in April 2018.

### Business Updates in Response to the COVID-19 Pandemic

The COVID-19 pandemic has caused business and economic disruption, and the duration and impact of that disruption is uncertain at this time.

- In mid-March 2020, we transitioned to a full-time, virtual work environment in which all employees, including sales representatives (whom we refer to as territory managers), were encouraged to work from their place of residence. Our decision was based on actions taken by federal, state and local governments to contain the spread of severe acute respiratory coronavirus 2 (SARS-CoV-2) and the related Coronavirus Disease 2019 (COVID-19), as well as the impact of "social distancing" efforts and various mitigation actions implemented by healthcare practices across the United States. Shortly after our transition to a full-time, virtual work environment, our territory managers began virtual details of XHANCE to target audience physicians.
- We have been monitoring, and will continue to monitor, federal, state, and local government requirements and guidances. In certain instances, the various mitigation efforts have been updated to facilitate a return to a working environment with fewer restrictions. Where permitted by governmental requirements and the policies of physician offices, our territory managers began to return to in-person detailing of physicians in May and June 2020. Given the localized nature of the restrictions that are in place and the potential for restrictions to return, we have equipped our territory managers to operate in an environment that will include a mix of virtual and in-person physician detailing with dependencies on geography and time.
- Federal, state and local government requirements and guidances have impacted virtually all of the physicians' offices in which our territory managers detail XHANCE. These impacts include reduced patient visits, temporary halt of territory managers' visits, restrictions imposed on territory managers' visits and temporary closings of physicians' offices.
- Late in the first quarter of 2020 we began to observe an adverse impact of the COVID-19 pandemic on XHANCE prescription growth and, as a result XHANCE net revenue. Based on third-party prescription data as well as data from Preferred Pharmacy Network (PPN) partners, XHANCE prescriptions increased 11% from first quarter 2020 to second quarter 2020, increased 11% from second quarter 2020 to third quarter 2020, increased 7% from third quarter 2020 to fourth quarter 2020, decreased 2% from fourth quarter 2020



to first quarter 2021, increased 14% from first quarter 2021 to second quarter 2021, and increased 4% from second quarter 2021 to third quarter 2021. Although XHANCE prescriptions and XHANCE net revenue have grown during this COVID-19 period, the rate of growth was below our pre-pandemic expectations. Additionally, the duration and magnitude of the impact of the COVID-19 pandemic on XHANCE prescriptions and XHANCE net revenue remains uncertain and it has, and is likely continue to affect our ability to remain in compliance with our financial covenants under that certain Note Purchase Agreement dated as of September 12, 2019, as amended pursuant to that certain letter agreement dated as of August 13, 2020 and as further amended by that certain First Amendment to Note Purchase Agreement dated as of March 2, 2021 (the Note Purchase Agreement) that we entered into with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit Funds (BioPharma).

- Due to the impacts of the COVID-19 pandemic, one of our contract manufacturers implemented a reduced work schedule and additional precautions which resulted in delays in the manufacture of XHANCE in second quarter 2020 but did not result in an interruption to commercial or clinical supply. We believe we are maintaining appropriate levels of finished product inventories in the event of future supply disruption; however, the duration and magnitude of a future negative impact from the COVID-19 pandemic could constrain our supply of XHANCE.
- Previous guidance related to the expected timing of results from our two ongoing chronic sinusitis clinical trials indicated that top-line results from both trials would be available in the second half of 2021. Pauses in patient enrollment due to factors related to the COVID-19 pandemic have had, and may continue to have, varying effects in different geographies and over time have led to a change in our projected timeline for initial data availability and may lead to additional changes in the future. We completed enrollment in the first of our ongoing chronic sinusitis clinical trials in July 2021 and expect top-line results in the first quarter of 2022. We completed enrollment of subjects in our second clinical trial for chronic sinusitis in October of 2021 and expect top-line results in the second quarter of 2022. For those subjects currently participating in these studies, procedures to facilitate ongoing treatment and capture of data during periods of in-person care restrictions have been put in place.

The full impact of the COVID-19 pandemic, including the potential for and emergence of different strains of the virus, on our business is still unknown. The COVID-19 pandemic is likely to continue to have adverse impacts on XHANCE prescription growth and XHANCE net revenues growth for the remainder of 2021 and into 2022 as result of fewer patients visiting physician offices and restrictions and limitations imposed by physicians' offices on territory manager visits, continued high unemployment adversely affecting demand and payor mix, and on the availability and cost of capital for us to fund our business operations and service our debt. We will continue to assess the evolving impact of the COVID-19 pandemic and will make adjustments to our operations as necessary.

#### **XHANCE Business Update**

We track and report metrics that we believe are an important part of assessing our progress in key strategic areas including:

- XHANCE Prescriptions and Market Share. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE prescriptions in the third quarter of 2021 was 86,300, which represents 25% growth for prescriptions when compared to estimated third quarter 2020 prescriptions of 69,000. The INS prescription market increased 4% from third quarter 2020 to third quarter 2021 based on third-party prescription data. In addition, the total estimated number of XHANCE prescriptions was 73,900 in the fourth quarter of 2020, 72,600 in the first quarter of 2021 and 82,900 in the second quarter of 2021.

A seasonal effect has historically been observed in the INS prescription market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. As the result of the COVID-19 pandemic, the market volume peak and subsequent declines did not follow the normal trends in 2020. Based on third-party prescription data, INS market prescriptions increased 7% from the fourth quarter of 2019 to the first quarter of 2020, decreased 16% from the first quarter of 2020 to the second quarter of 2020, decreased 6% from the second quarter of 2020 to the third quarter of 2020, increased 3% from the third quarter of 2020 to the fourth quarter of 2020, decreased 4% from fourth quarter 2020 to the first quarter of 2021, increased 14% from the first quarter of 2021 to the second quarter of 2021, and decreased 4% from the second quarter of 2021 to the third quarter of 2021.

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 physician specialists, and seasonality in disease flare-ups, has an impact on the number of patients that present themselves and who are therefore available to receive a new prescription for XHANCE. Demand has historically been, and we expect will continue to be, impacted by the INS market seasonality and the seasonal variation in patient visits with their doctor, resulting in reduced XHANCE prescription demand in the third quarter.

Additionally, we believe that first quarter prescription demand and average net revenue per prescription for XHANCE is adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January.

We track the market share of XHANCE within our current target audience. For this purpose, we calculate market share as the proportion of XHANCE prescriptions to the number of prescriptions written for other INS within our current target audience of approximately 18,000 physicians. Our target physician audience includes all ENT and allergy specialist physicians who, based on third-party data, write intranasal steroid spray prescriptions. In addition, our current target audience includes specialty-like primary care physicians called on by our territory managers or kaléo sales representatives. Prior to the fourth quarter 2020 initiation of XHANCE co-promotion by kaléo, our target audience included approximately 10,000 physicians called on by Optinose sales territory managers. We have mutually agreed to terminate our co-promotion agreement with kaléo as of December 31, 2021.

We believe market share, in addition to XHANCE prescription volume, provides important information regarding XHANCE utilization because market share normalizes XHANCE prescriptions for market effects including the INS market seasonality, seasonal variation in patient visits with their doctor, annual deductible resets and annual changes in individual patient's healthcare insurance coverage referenced above. Based on third-party prescription data as well as data from PPN partners, we estimate XHANCE had a market share in our current target audience of 18,000 physicians of 4.9% in the third quarter of 2020, 5.1% in the fourth quarter of 2020, 5.4% in the first quarter of 2021, 5.4% in the second quarter of 2021 and 6.0% in the third quarter of 2021. Note that most of the INS prescriptions written within our target physician audience are for chronic sinusitis, allergic rhinitis and other conditions outside of our nasal polyp indication. Our target physician audience is subject to revision each quarter to account for changes such as revised sales target prioritization, and physician retirements. Changes to the target physician audience can contribute to some of the quarter-over-quarter change in market share.

- XHANCE New Prescriptions and Refill Prescriptions. The underlying disease that we are treating is chronic and, as a result, many patients may fill multiple prescriptions per year. We monitor new prescriptions as they create the potential for future refill prescriptions. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE new prescriptions in the third quarter of 2021 was 27,900, which represents 22% growth for new prescriptions when compared to estimated third quarter 2020 new prescriptions of 23,000. In addition, the total estimated number of XHANCE new prescriptions was 24,600 in the fourth quarter of 2020, 25,900 in the first quarter of 2021 and 29,000 in the second quarter of 2021. Based on third-party prescription data, the INS market for new prescriptions increased 9% from the third quarter of 2020 to the third quarter of 2021 and decreased 4% from the second quarter of 2021 to the third quarter of 2021.

We track refill prescriptions and provide patient assistance to support refill programs that are administered by our PPN partners. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE refill prescriptions in the third quarter of 2021 was 58,400, which represents 27% growth for refill prescriptions when compared to estimated third quarter 2020 refill prescriptions of 46,100. In addition, the total estimated number of XHANCE refill prescriptions was 49,300 in the fourth quarter of 2020, 46,700 in the first quarter of 2021 and 53,900 in the second quarter of 2021.

- Prescribing Breadth and Depth. We track the number of physicians who prescribe XHANCE in a time period to evaluate the breadth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE in the third quarter of 2021 was 7,196, which represents 12% growth when compared to the estimated 6,443 physicians who had at least one patient fill a prescription for XHANCE in the third quarter of 2020. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 6,708 in the fourth quarter of 2020, 6,920 in the first quarter of 2021 and 7,188 in the second quarter of 2021.

We also track the number of prescriptions filled by a prescribing physician's patients in a time period to evaluate depth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients in the third quarter of 2021 was 1,459, which represents 27% growth when compared to the estimated 1,153 physicians who had more than 15 XHANCE prescriptions filled by their patients in the third quarter of 2020. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,275 in the fourth quarter of 2020, 1,285 in the first quarter of 2021 and 1,414 in the second quarter of 2021.

- **XHANCE Net Product Revenues per Prescription.** We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. Average XHANCE net product revenues per prescription were \$253 in the third quarter of 2021 which represents an approximately 13% increase when compared to the \$224 average XHANCE net product revenues per prescription in the third quarter of 2020. In addition, average XHANCE net revenues per prescription were \$211 in the fourth quarter of 2020, \$151 in the first quarter of 2021 and \$221 in the second quarter of 2021.

### **Sales, Marketing & Distribution**

We have established a commercial infrastructure designed to drive adoption and sales of XHANCE with healthcare professionals who treat patients with nasal polyps. 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.

**Customer Model.** We have a sales force of approximately 100 territory managers who target over 10,000 ENTs, allergists and "specialty-like" primary care physicians, and we target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers. In addition, we initiated a co-promotion agreement with kaléo in October 2020 to promote XHANCE to an audience of up to 6,000 prescribers, about half of whom are outside of our current called-on universe. Our sales team, and the sales team of our co-promotion partner, are equipped with educational materials demonstrating the benefit and safety profile of XHANCE. We have mutually agreed to terminate our co-promotion agreement with kaléo as of December 31, 2021. We believe that in the long term, direct-to-consumer (DTC) advertising could be an effective way to increase XHANCE prescription growth.

**XHANCE Co-Pay Savings Program.** We believe our co-pay savings program provides an affordability solution for patients that physicians will support. This program provides patient co-pay assistance including a first prescription for as little as no out-of-pocket cost (\$0 co-pay) to eligible commercially insured patients and low subsequent co-pays for refills ranging from \$0 to \$50 per XHANCE unit.

**Market Access.** Based on currently available third-party data and our internal analyses as of September 30, 2021, we believe that greater than 75% of commercially insured lives are currently in a plan that covers XHANCE. However, payors may change coverage levels for XHANCE, positively or negatively, at any time. Additionally, payors generally impose restrictions on access to or usage of XHANCE, such as by requiring prior authorizations or "step-edits". For example, insurers may require that a patient first use a generic INS prior to becoming eligible for coverage for XHANCE. Some healthcare providers may not complete the 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 may not gain access to XHANCE treatment. In our contract negotiations with payors we seek to balance patient access and affordability, breadth of coverage, payor utilization management and rebates levels. 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.

**Trade and Distribution** We currently sell XHANCE primarily to PPN partners. 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 and performing certain patient services such as patient insurance benefit verification. We also sell XHANCE to wholesale pharmaceutical distributors, who, in turn, sell XHANCE to retail pharmacies, hospitals and other customers. 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.

### ***XHANCE Development***

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 trial program in pursuit of a follow-on indication for the treatment of chronic sinusitis. We believe XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis. We expect the program will be comprised of two Phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018 and completed enrollment of approximately 330 subjects in July of 2021, and the second of which was initiated in the second quarter of 2019 and completed enrollment of approximately 210 subjects in October of 2021.

In April 2021, we completed a previously planned, blinded interim analysis to assess the variance in one of the two co-primary endpoints (change in Composite Score of Nasal Symptoms from baseline to week 4) in our first clinical trial for chronic sinusitis. The analysis was performed on blinded interim data from approximately half of the initial estimated enrollment of 378 patients. The result of this interim analysis was that the observed variance in this endpoint was lower than the variance assumed when we estimated sample size for statistical powering during the initial design of the trial.

In June 2021, we completed a previously planned, blinded interim analysis to assess the variance in the other co-primary endpoint (change in average percent opacification of volume by CT scan from baseline to week 24) in this trial. The analysis was performed on blinded interim data from approximately one-third of the initial estimated enrollment of 378 patients for whom 6-month CT scan data was available. The result of this interim analysis was that the observed variance in this endpoint was also lower than the variance assumed when we estimated sample size for statistical powering during the initial design of the study. Based on the results of these two interim analyses, and our assumptions and estimates relating to the trial, we anticipate that the initial targeted statistical power will be achieved with the approximately 330 patients currently enrolled in the trial.

In third quarter 2021, we completed previously planned, blinded interim analysis to assess the variance in the two co-primary endpoints in our second clinical trial for chronic sinusitis. The analysis was performed on blinded interim data from patients for whom data was available. For the Composite Score of Nasal Symptoms data was available for approximately one-half of the initial estimated enrollment of 399 patients and for the change in average percent opacification of volume by CT scan data was available for approximately one-third of the initial estimated enrollment of 399 patients. The result of these interim analyses was that the observed variance in these endpoints is lower than the variance assumed when we estimated sample size for statistical powering during the initial design of the study. Based on the results of these two interim analyses, and our assumptions and estimates relating to the trial, we anticipate that the initial targeted statistical power will be achieved with the approximately 210 patients currently enrolled in the trial.

For clarity, all of these interim analyses were blinded to treatment group and therefore could not evaluate the magnitude of difference, if any, between treatment groups. Accordingly, these interim analyses were not designed to, and do not, provide evidence regarding possible superiority of active treatment over placebo or success of the trials.

We expect top-line results from the first of our two ongoing Phase 3b chronic sinusitis clinical trials in the first quarter of 2022 and from the second clinical trial in the second quarter of 2022.

### ***OPN-019 Development Update***

In June 2020, we announced the initiation of development of a new product candidate, OPN-019, which combines our proprietary intranasal Exhalation Delivery System (EDS) device with an antiseptic.

We have performed in vitro testing against SARS-CoV-2 with a candidate formulation in which a 4-log reduction (a 99.99% reduction) in virus count was produced. In addition, we performed tests against other pathogens. For most pathogens tested, 3-log to 6-log reductions (99.9% to 99.9999% reductions) in virus count were observed.

In July 2021, we received approval from regulatory authorities in Mexico to conduct a randomized, proof-of-concept trial in Mexico in subjects who have tested positive for SARS-CoV-2 infection, who were recently infected, and who have mild or no symptoms. The trial is intended to evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019. Recruitment in this trial is currently paused while specimen-handling and laboratory procedures in Mexico undergo further evaluation.

Should proof-of-concept data suggest benefits, we expect to use the data to support pursuit of grants, partnerships, and/or other sources of capital that would be necessary to fund future development of OPN-019.

## **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 \$21.8 million and \$15.4 million in net product revenues for the three months ended September 30, 2021 and 2020, respectively, and \$51.1 million and \$32.8 million for the nine months ended September 30, 2021 and 2020, respectively. 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 PPN partners, who collectively dispensed more than 85% of our total prescriptions (TRxs) in the period, our average net product revenues per prescription for the second quarter of 2021 was \$253, an increase compared to average net product revenues per prescription of \$221 in second quarter of 2021 and an increase compared to \$224 in the third quarter of 2020.

The increase in average net product revenues per prescription from the second quarter of 2021 to the third quarter of 2021 is a consequence of reduced co-pay support under our assistance programs as the result of patients' meeting their out-of-pocket expense thresholds and the effect of reduced rebate rates, including a one-time refund of disputed rebates.

The increase in average net product revenues per prescription from the third quarter of 2020 to the third quarter of 2021 is driven largely by changes in 2021 to our co-pay assistance plan that were intended to increase revenues per prescription by reducing the rate of growth in prescription fills by commercially insured patients in plans that do not cover XHANCE, while sustaining growth in covered plans, as well as the absence of a one-time co-pay assistance program that was available to new patients in the second quarter of 2020.

We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, 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 PPN 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 net product revenues per prescription.

We expect full year 2021 net product revenues to be \$71.0 to \$75.0 million. Previously, we expected full year 2021 net product revenues to be at least \$80 million. The reduction in our net product revenue expectations for 2021 is primarily the result of the continuing adverse impact of the COVID-19 pandemic on XHANCE prescription and XHANCE net product revenue growth rates.

We expect average net product revenues per prescription for the full year of 2021 will exceed \$210. Previously, we expected full year 2021 net product revenues per prescription to be greater than \$200. Factors supporting this expected growth include patients meeting their out-of-pocket expense thresholds, expected improvements in insurance coverage and continued strength in the proportion of prescription refills.

The duration and magnitude of the negative impact from the COVID-19 pandemic has, and is likely to continue to, affect our ability to remain in compliance with certain of the financial covenants in the Note Purchase Agreement, including the requirement to achieve at least \$80.0 million in consolidated XHANCE net product sales and royalties for the trailing twelve-month period ending December 31, 2021. If we do not achieve \$80.0 million in consolidated XHANCE net product sales and royalties for the trailing twelve-month period ending December 31, 2021 and we are unable to obtain a waiver or modification to this financial covenant, we will be in breach of a financial covenant of the Note Purchase Agreement, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the notes issued pursuant to the Note Purchase Agreement (the Pharmakon Senior Secured Notes) elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes, we may need to delay or curtail our operations. Our assets or cash flow may not be sufficient to fully repay our obligations under the Note Purchase Agreement if the obligations thereunder are accelerated upon any events of default.

### ***Licensing revenues***

In September 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into the Currax License Agreement. Under the terms of the Currax License Agreement, Currax paid us a \$3.7 million upfront payment in 2019, an additional \$0.8 million in December 2020 upon expiration of the escrow that was established for a limited period to cover potential indemnification obligations, and an additional \$1.0 million milestone payment in January 2021 upon the achievement of a specified regulatory milestone. We are not eligible to receive any further payments from Currax under the terms of the Currax License Agreement other than reimbursement for certain expenses.

### ***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***

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 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; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

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 as we continue the development of XHANCE for the treatment of chronic sinusitis and our other product candidates. Clinical trial costs associated with our chronic sinusitis program represent a substantial portion of our total research and development expenses. While we would expect to continue to incur regulatory and other development expenses after the conclusion of our chronic sinusitis clinical program, we expect the costs associated with the conduct of clinical trials to significantly decrease. Due to the inherently unpredictable nature of clinical development, compounded by the uncertainty introduced by the COVID-19 pandemic, the rate of subject enrollment, number of subjects required, and trial duration and outcome,



there is uncertainty as to the exact timing of when we expect our research and development costs related to the clinical development of XHANCE to significantly decrease.

### ***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, information technology, 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.

Sales and marketing expenses include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, samples, and marketing activities targeted towards health care providers, payors and patients/consumers, including initiatives and fees related to our co-promotion efforts. Additionally, sales and marketing-related expenses include fees paid to our PPN partners for services unrelated to traditional distribution functions, such as data fees, benefit claims adjudication and other enhanced services performed as part of our PPN.

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

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense is primarily related to the Note Purchase Agreement.

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

Other (income) expense consists primarily of foreign currency (income) losses due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

## **Consolidated Results of Operations**

### ***Comparison of three months ended September 30, 2021 and 2020***

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

	<b>Three Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Revenues:</b>		
Net product revenues	\$ 21,826	\$ 15,436
Licensing revenues	—	—
Total revenues	<u>21,826</u>	<u>15,436</u>
<b>Costs and expenses:</b>		
Cost of product sales	2,411	2,221
Research and development	6,654	6,524
Selling, general and administrative	25,801	24,575
Total operating expenses	<u>34,866</u>	<u>33,320</u>
Loss from operations	<u>(13,040)</u>	<u>(17,884)</u>
<b>Other (income) expense:</b>		
Interest (income) expense	4,063	3,319
Other (income) expense	14	11
Total other (income) expense	<u>4,077</u>	<u>3,330</u>
<b>Net loss</b>	<u>\$ (17,117)</u>	<u>\$ (21,214)</u>

### ***Net product revenues***

Net product revenues related to sales of XHANCE were \$21.8 million and \$15.4 million for the three months ended September 30, 2021 and 2020, respectively. Revenue growth is attributable primarily to an increase in units sold to customers as a result of a greater number of XHANCE prescriptions dispensed as well as an increase in our average net selling price during the three months ended September 30, 2021.

*Cost of product sales*

Cost of product sales related to XHANCE were \$2.4 million and \$2.2 million for the three months ended September 30, 2021 and 2020, respectively, with the increase attributed primarily to an increase in units sold to customers during the period.

*Research and development expense*

Research and development expense was \$6.7 million and \$6.5 million for the three months ended September 30, 2021 and 2020, respectively. The \$0.2 million increase was attributable primarily to a \$0.6 million increase in clinical expenses related to the conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis. This increase was offset by a \$0.4 million decrease in device development costs associated with our OPN-019 development program.

*Selling, general and administrative expense*

Selling, general and administrative expense was \$25.8 million and \$24.6 million for the three months ended September 30, 2021 and 2020, respectively. The \$1.2 million increase was due primarily to:

- a \$0.7 million increase in travel and meeting expenses as a result of COVID-19 restrictions starting to lift in 2021;
- a \$0.6 million increase in marketing and co-promotion costs; and
- a \$0.5 million increase in legal and professional fees, including D&O insurance.

This increase was offset by a decrease of \$0.6 million in payroll and related costs.

*Interest (income) expense, net*

Interest (income) expense, net, was \$4.1 million and \$3.3 million for the three months ended September 30, 2021 and 2020, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods. The increase was related to increased principal balance of the Pharmakon Senior Secured Notes.

**Comparison of nine months ended September 30, 2021 and 2020**

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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Revenues:</b>		
Net product revenues	\$ 51,143	\$ 32,770
Licensing revenues	1,000	—
Total revenues	52,143	32,770
<b>Costs and expenses:</b>		
Cost of product sales	6,576	5,276
Research and development	20,058	16,930
Selling, general and administrative	80,293	77,332
Total operating expenses	106,927	99,538
Loss from operations	(54,784)	(66,768)
<b>Other (income) expense:</b>		
Interest (income) expense	11,917	9,110
Other (income) expense	(29)	44
Total other (income) expense	11,888	9,154
<b>Net loss</b>	<b>\$ (66,672)</b>	<b>\$ (75,922)</b>

*Net product revenues*

Net product revenues related to sales of XHANCE were \$51.1 million and \$32.8 million for the nine months ended September 30, 2021 and 2020, respectively. Revenue growth is attributable primarily to an increase in units sold to



customers as a result of a greater number of XHANCE prescriptions dispensed as well as an increase in our average net selling price during the nine months ended September 30, 2021.

#### *Licensing revenues*

Licensing revenues were \$1.0 million for the nine months ended September 30, 2021 as a result of the milestone payment received under the terms of the Currax License Agreement. No licensing revenue was recognized during the nine months ended September 30, 2020.

#### *Cost of product sales*

Cost of product sales related to XHANCE were \$6.6 million and \$5.3 million for the nine months ended September 30, 2021 and 2020, respectively, with the increase attributed primarily to an increase in units sold to customers during the period.

#### *Research and development expense*

Research and development expense was \$20.1 million and \$16.9 million for the nine months ended September 30, 2021 and 2020, respectively. The \$3.2 million increase was attributable primarily to a \$4.0 million increase in clinical expenses related to the conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis. This increase was offset by a \$0.8 million decrease in personnel costs and device development costs associated with our OPN-019 development program.

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

Selling, general and administrative expense was \$80.3 million and \$77.3 million for the nine months ended September 30, 2021 and 2020, respectively. The \$3.0 million increase was due primarily to:

- a \$1.7 million increase in marketing, travel and meeting expenses as a result of COVID-19 restrictions starting to lift in 2021;
- a \$1.6 million increase in volume-based PPN administrative fees and co-promotion costs; and
- a \$1.0 million increase in legal and professional fees, including D&O insurance.

This increase was offset by a \$1.3 million decrease in personnel expenses.

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

Interest (income) expense, net, was \$11.9 million and \$9.1 million for the nine months ended September 30, 2021 and 2020, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods. The increase was primarily related to increased principal balance of the Pharmakon Senior Secured Notes as well as a decrease in interest income earned on cash deposits.

#### **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 \$66.7 million and \$75.9 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$594.4 million. We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues. As of September 30, 2021, we had \$84.2 million in cash and cash equivalents.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Net cash used in operating activities	\$ (60,219)	\$ (67,050)
Net cash used in investing activities	(38)	(460)
Net cash provided by financing activities	310	63,502
Effects of exchange rates on cash and cash equivalents	2	(11)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (59,945)</u>	<u>\$ (4,019)</u>

#### *Operating activities*

Cash used in operating activities decreased by \$6.9 million, from \$67.1 million for the nine months ended September 30, 2020 to \$60.2 million for the nine months ended September 30, 2021. The decrease in cash used in operating activities was attributable to an increase in revenue, offset by an increase in expenses and net working capital. The increase in expenses was primarily attributable to an increase in clinical trial-related expenses in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis, and the increase in net working capital was due to an increase in inventory production during the nine months ended September 30, 2021.

*Investing activities*

Cash used in investing activities decreased by \$0.4 million from the nine months ended September 30, 2020 to the nine months ended September 30, 2021. Purchases of equipment during the nine months ended September 30, 2020 of \$0.5 million decreased in the nine months ended September 30, 2021 to \$0.2 million, which was offset by \$0.1 million of proceeds from the sale of manufacturing equipment.

*Financing activities*

Cash provided by financing activities was \$0.3 million for the nine months ended September 30, 2021. Cash provided by financing activities was \$63.5 million for the nine months ended September 30, 2020. Cash provided by financing activities for the nine months ended September 30, 2020 was primarily driven by the receipt of \$30.0 million from the issuance of the First Delayed Draw Notes under the Pharmakon Senior Secured Notes and \$33.6 million from the sale of common stock. Cash provided by financing activities for the nine months ended September 30, 2021 was driven by proceeds from the issuance of common stock under the 2017 Plan.

*Senior Secured Note Purchase Agreement*

On September 12, 2019 (the Closing Date), we entered into the Note Purchase Agreement (the Note Purchase Agreement) with funds managed by Pharmakon, the investment manager of BioPharma. The Note Purchase Agreement provided us with \$130.0 million in debt financing, of which \$80.0 million was issued on the Closing Date, \$30.0 million was issued on February 13, 2020 and \$20.0 million was issued on December 1, 2020.

On August 13, 2020, we entered into a letter agreement (the Pharmakon Letter Agreement) to the Note Purchase Agreement. The Pharmakon Letter Agreement provided us with the option to issue additional Pharmakon Senior Secured Notes, subject to us achieving specified consolidated XHANCE net sales and royalties for the quarter ended June 30, 2021 and certain other conditions. As consideration for the Pharmakon Letter Agreement, we issued 44,643 shares of Common Stock to Pharmakon. The aggregate fair value of \$250,000 was recorded as debt issuance costs and is being amortized to interest expense over the five-year term of the Pharmakon Senior Secured Notes. We are no longer eligible for the additional Pharmakon Senior Secured Notes as the requisite conditions were not satisfied as of June 30, 2021.

On March 2, 2021, we entered into the first amendment (the First Amendment) to the Note Purchase Agreement. The First Amendment revised certain minimum trailing twelve-month consolidated XHANCE net sales and royalties we are required to achieve. As consideration for the First Amendment, we will pay an amendment fee of \$1.3 million upon the earlier of the prepayment of the Pharmakon Senior Secured Notes and September 12, 2024.

The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). We are required to make quarterly interest payments until the Maturity Date. We are also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that we may, at our election, postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain minimum trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved.

We are required to repay the Pharmakon Senior Secured Notes in full upon the occurrence of a change of control (as defined in the Note Purchase Agreement). In addition, we may make voluntary prepayments in whole or in part. All mandatory and voluntary prepayments are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the third anniversary of the Closing Date, an amount equal to 2% of the principal prepaid, (ii) if prepayment occurs on or after the third anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, an amount equal to 1% of the principal prepaid; and (iii) if prepayment occurs on or after the fourth anniversary of the Closing Date, no prepayment premium is required. We are also required to pay a "make-whole" amount in respect of any principal prepayments (whether mandatory or voluntary) made prior to the 30-month anniversary of the issuance of the applicable Pharmakon Senior Secured Note, in an amount equal to the interest that would have accrued through the 30-month anniversary in respect of such note but for such principal prepayment.

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of our assets and 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, technologies 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 least \$30.0 million of cash and cash equivalents.

The Note Purchase Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the Pharmakon Senior Secured Notes.

#### *Projected 2021 operating expenses*

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2021 will be between \$132.0 million and \$137.0 million, of which approximately \$10.0 million is expected to be non-cash stock-based compensation expense. As a result, total GAAP operating expenses, excluding non-cash stock-based compensation expense, are expected to be between \$122.0 million and \$127.0 million. An increase in expenses from 2020 to 2021 is anticipated due primarily to an increase in fees paid to our PPN partners associated with higher projected XHANCE prescription volumes and an increase in research and development expenses related to our clinical trial program in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis.

#### *Future funding requirements*

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

- maintain our sales force and the commercial infrastructure to support the sales and marketing for XHANCE;
- 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 an FDA-mandated post-marketing pediatric study and clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- continue research and development activities for additional product candidates, including OPN-019;
- continue to contract to manufacture XHANCE and our other product candidates;
- maintain, expand and protect our patent portfolio;
- service our debt obligations under the Pharmakon Senior Secured Notes issued in September 2019, February 2020 and December 2020, including in connection with any potential events of default and subsequent acceleration of payment in full;
- maintain infrastructure necessary to operate as a publicly-traded, FDA-regulated commercial-stage company; and
- hire additional staff and add operational, financial and information systems to execute our business plan.

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

- duration and impact of COVID-19 pandemic on our business;
- 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 maintain 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 of maintaining our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including the outcome, timing and cost of an FDA-mandated post-marketing pediatric study 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 and annuity fees relating to issued patents;
- the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates, including OPN-019;
- the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies; and
- maintain infrastructure necessary to operate as a publicly-traded, FDA-regulated commercial-stage company.

Although it is difficult to predict our future liquidity requirements, we will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under our outstanding Pharmakon Senior Secured Notes, including repayment, and to carry out our planned development and commercial activities. We believe that our existing cash and cash equivalents will be sufficient to maintain the minimum cash balance required under the Note Purchase Agreement and to fund our operations for at least twelve months from the filing date of this Quarterly Report on Form 10-Q if, in the event of a default, the holders of the Pharmakon Senior Secured Notes do not elect to accelerate repayment of all unpaid principal and accrued interest under the Note Purchase Agreement; however, we will likely require additional capital to fund operations beyond twelve months and to continue to service our debt obligations under the Note Purchase Agreement. Financial capital, secured through equity 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. Furthermore, if we do not achieve \$80 million of consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 and we are unable to obtain a waiver or modification to this financial covenant, we will be in breach of a financial covenant under the Note Purchase Agreement, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the Pharmakon Senior Secured Notes elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes we may need to delay or curtail our operations. These factors raise substantial doubt about our ability to continue as a going concern. Additionally, we may fail to satisfy our financial covenants in the future, may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis.

#### **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.

**Contractual obligations and commitments**

The following table summarizes our contractual obligations at September 30, 2021:

	Total	Less than 1 year	1-3 years (in thousands)	3-5 years	More than 5 years
Operating leases <sup>(1)</sup>	\$ 2,747	\$ 1,080	\$ 1,667	\$ —	\$ —
Long-term debt <sup>(2)</sup>	161,395	14,169	145,926	1,300	—
<b>Total</b>	<b>\$ 164,142</b>	<b>\$ 15,249</b>	<b>\$ 147,593</b>	<b>\$ 1,300</b>	<b>\$ —</b>

<sup>(1)</sup> Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey and Oslo, Norway and leases of certain other equipment.

<sup>(2)</sup> Reflects principal, interest obligations and exit fees pursuant to the Note Purchase Agreement entered into on September 12, 2019 (the Closing Date). The Pharmakon Senior Secured Notes bear interest at 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). We are required to make quarterly interest payments until the Maturity Date. Principal payments are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that we may, at our election and upon achieving certain minimum trailing four-quarter consolidated XHANCE net sales and royalties, postpone any such amortization payment until the Maturity Date. The Note Purchase Agreement includes events of default customary for financings of this type (including, among others, failure to comply with affirmative, negative and financial covenants), in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the Pharmakon Senior Secured Notes.

We are also party to a manufacturing services agreement with one of our suppliers pursuant to which we are obligated to purchase a minimum number of products per month or potentially be subject to a payment of \$5,000 per week for any month in which we do not purchase such minimum number of products.

**Critical accounting policies**

The Critical Accounting Policies and Significant Judgments and Estimates included in our annual report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 3, 2021, have not materially changed.

**Recent accounting pronouncements**

See Note 3 to our unaudited interim consolidated financial statements of this Form 10-Q 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.

**ITEM 3. 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 4. 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 Securities Exchange Act of 1934, as amended, (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 information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, 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 September 30, 2021.

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

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II

### ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

#### ITEM 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors previously disclosed in Part I, "Item 1A, Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 3, 2021.

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

##### **We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.**

As of September 30, 2021, we had cash and cash equivalents of \$84.2 million. Our accumulated deficit as of September 30, 2021 was \$594.4 million. We have incurred significant net losses since inception and also expect to incur substantial losses in future periods. Our continuation as a going concern is dependent on our ability to maintain compliance with our financial covenants under that certain Note Purchase Agreement dated as of September 12, 2019, as amended pursuant to that certain letter agreement dated as of August 13, 2020 and as further amended by that certain first amendment to the Note Purchase Agreement dated as of March 2, 2021 (the Note Purchase Agreement) that we entered into with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit Funds (BioPharma) and our ability to generate sufficient cash flows from operations to meet our obligations and/or obtain additional financing from our stockholders or other sources, as may be required. In March 2021, the Note Purchase Agreement was amended to revise certain covenants relating to minimum trailing twelve-month consolidated XHANCE net sales and royalties, including the requirement to achieve at least \$80.0 million for the trailing twelve-month period ending December 31, 2021.

As of the filing of this quarterly report on Form 10-Q, we expect consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 to be between \$71.0 million and \$75.0 million. If we do not achieve \$80.0 million of consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 and we are unable to obtain a waiver or modification to this financial covenant, we will be in breach of a financial covenant of the Note Purchase Agreement as of December 31, 2021, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the senior secured notes issued pursuant to the Note Purchase Agreement (Pharmakon Senior Secured Notes) elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes as described below, we may be forced to delay or reduce the scope of our development programs and clinical trials, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. These factors raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Future reports of our independent registered public accounting firm may contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

##### **Our failure to comply with the covenants or other terms of the Note Purchase Agreement, including but not limited to 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 September 12, 2019 (the Closing Date), we entered into the Note Purchase Agreement that provided for the issuance of up to \$150.0 million of the Pharmakon Senior Secured Notes, of which \$80.0 million were issued on the Closing Date, \$30.0 million were issued on February 13, 2020, and \$20.0 million were issued on December 1, 2020. An additional \$20.0 million was available to us, but we did not meet the requirements to issue those additional Pharmakon Senior Secured Notes. On August 13, 2020, we entered into a letter agreement to the Note Purchase Agreement that provided us with the option to issue an additional \$20.0 million of Pharmakon Senior Secured Notes, subject to achieving \$26.0 million in consolidated XHANCE net sales and royalties in the quarter ended June 30, 2021 and certain other conditions. We are no longer eligible for the additional Pharmakon Senior Secured Notes as the requisite conditions were not satisfied as of June 30, 2021.



The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). We are required to make quarterly interest payments until the Maturity Date. We are also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that we may elect to postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain minimum trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved. The Pharmakon Senior Secured Notes are guaranteed by OptiNose, Inc. and our subsidiaries and are secured by a pledge of substantially all of our and their assets.

The Note Purchase Agreement, as amended, contains various covenants that limit our ability to engage in specified types of transactions without our lenders' prior consent, as well as financial covenants that require us to maintain at least \$30.0 million of cash and cash equivalents in certain deposit accounts and require us to achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis. We are currently required to achieve consolidated XHANCE net sales and royalties of \$80.0 million for the trailing twelve-month period ending December 31, 2021; \$90.0 million, \$98.75 million, \$102.5 million, and \$106.25 million for the trailing twelve-month periods ending March 31, June 30, September 30 and December 31, 2022, respectively; and increasingly higher quarterly requirements for calendar year 2023.

As of the filing of this quarterly report on Form 10-Q, we expect consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 to be between \$71.0 million and \$75.0 million. If we do not achieve \$80.0 million of consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 and we are unable to obtain a waiver or modification to this financial covenant, we will be in breach of a financial covenant of the Note Purchase Agreement as of December 31, 2021, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the Pharmakon Senior Secured Notes elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes, as described in the next paragraph, we may be forced to delay or reduce the scope of our development programs and clinical trials, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. These factors raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment.

Each holder of the Pharmakon Senior Secured Notes may elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes 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 Pharmakon Senior Secured Notes;
- our breach of the restrictive covenants or other terms of the Pharmakon Senior Secured Notes;
- our breach of reporting obligations;
- our failure to properly maintain the collateral;
- any circumstance that could reasonably be expected to have a material adverse effect (as defined in the Note Purchase Agreement) on us;
- certain regulatory and/or commercial actions that causes an ongoing delay in commercialization of XHANCE; and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Pharmakon Senior Secured Notes, all amounts outstanding with respect to the Pharmakon Senior Secured Notes (principal and accrued interest), as well as any applicable prepayment premiums or interest "make-whole" payments, would become due and payable immediately upon an event of default at a default interest rate of 13.75%. Our assets or cash flow may not be sufficient to fully repay our obligations under the Pharmakon Senior Secured Notes if the obligations thereunder are accelerated upon any events of default. The duration and magnitude of the negative impact from the COVID-19 pandemic on XHANCE net revenues has previously affected, and could affect in the future, our ability to meet the consolidated XHANCE net product sales and royalties threshold to remain in compliance with our financial covenants. Further, if we are unable to repay, refinance or restructure our obligations under the Pharmakon Senior Secured Notes, or obtain a waiver or modification to the financial covenants under the Note Purchase Agreement, the holders of such Pharmakon Senior Secured Notes could proceed to protect and enforce their rights under the Pharmakon Senior Secured Notes by exercising such remedies (including foreclosure on the assets securing our obligations under the Pharmakon Senior Secured Notes and the Note Purchase Agreement) 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 Pharmakon Senior Secured Notes or in aid of the exercise of any power granted in the Pharmakon Senior Secured Notes. Any such action would materially and adversely affect the ongoing viability of our business.



## Risks Related to COVID-19

### **The coronavirus (COVID-19) pandemic has and may continue to adversely affect our business, results of operations and financial condition.**

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic (the "COVID-19 pandemic"), which continues to spread throughout the U.S. and worldwide. On March 13, 2020, the then-President of the United States announced a national emergency relating to the COVID-19 pandemic.

Government authorities in the U.S. have recommended or imposed various social distancing, quarantine, and isolation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. These measures have changed, and will continue to change, based on the severity and uncertainties of the COVID-19 pandemic.

In March 2020, we modified our business practices and transitioned to a full-time, virtual work environment in which all employees were encouraged to work from their place of residence if their job functions allowed, and all work-related travel was temporarily discontinued. A significant portion of the physicians' offices in which our territory managers detail XHANCE either were closed, had reduced patient flow or temporarily stopped sales representatives' visits, which has hindered our ability to detail XHANCE to physicians' offices. Late in the first quarter of 2020, we began to observe an adverse impact of the COVID-19 pandemic on XHANCE prescription growth and net revenues, and we subsequently withdrew our previous XHANCE revenue guidance for 2020. This adverse impact on our revenues was most pronounced during the "shelter-in-place" mitigation efforts that were prevalent from late-March through May 2020. Where permitted by governmental requirements and the policies of physician offices, our territory managers began to return to in-person detailing of physicians in May and June 2020, however, many restrictions remain and some physicians' offices are still not accepting visits from sales representatives and others are limiting or placing restrictions on visits, which has negatively impacted our ability to drive prescription growth from the physicians targeted by our sales representatives. If our territory managers continue to have a limited ability to meet in person with physicians and if patients' visits to doctors continue to be limited, XHANCE prescription growth and net revenues will continue to be adversely impacted. We expect these impacts of the COVID-19 pandemic to negatively impact XHANCE product revenues for the remainder of 2021 and into 2022. In addition, reduced patients visiting physician offices, changes in insurance coverage or reimbursement levels by governmental authorities, private health insurers and other third-party payors, or in the type of such coverage held by patients, due to the impacts of the COVID-19 pandemic, including the impact on U.S. unemployment rates, may also negatively impact XHANCE prescription growth and net revenues.

The duration and magnitude of the negative impact from the COVID-19 pandemic on XHANCE net revenues could also affect our ability to remain in compliance with our financial covenants. As of the filing of this quarterly report on Form 10-Q, we expect consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 to be between \$71.0 million and \$75.0 million. If we do not achieve \$80.0 million of consolidated XHANCE net sales and royalties for the trailing twelve-month period ending December 31, 2021 and we are unable to obtain a waiver or modification to this financial covenant, we will be in breach of a financial covenant of the Note Purchase Agreement as of December 31, 2021, which will constitute an event of default under the terms of the Note Purchase Agreement. If the holders of the Pharmakon Senior Secured Notes elect to accelerate the repayment of all unpaid principal and accrued interest under such holder's Pharmakon Senior Secured Note, we may be forced to delay or reduce the scope of our development programs and clinical trials, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. Furthermore, capital markets in the U.S. and around the world have also been negatively impacted by COVID-19; if market conditions continue to be volatile, it may harm our business, including our ability to obtain future financing.

Our ability to enroll patients and retain principal investigators and site staff for our ongoing clinical trials have been, and could continue to be, impaired due to the COVID-19 outbreak in their geographic areas, the prioritization of medical resources toward the COVID-19 pandemic, or as a result of quarantines and other restrictions that interrupt healthcare services. For example, previous guidance related to the expected timing of results from our ongoing chronic sinusitis trials indicated that top-line results from both trials would be available in the second half of 2021. Pauses or delays in patient enrollment due to factors related to COVID-19 have had, and may continue to have, varying effects in different geographies and over time have led to a change in our projected timeline for initial data availability and may lead to additional changes in the future. We now expect top-line from the first of our two ongoing Phase 3b chronic sinusitis trials in the first quarter of 2022 and from the second clinical trial in the second quarter of 2022. For those subjects currently participating in these studies, procedures to facilitate ongoing treatment and capture of data during periods of in-person care restrictions have been put in place. Furthermore, patients, investigators, or site staff have been and may continue to be unwilling or unable to comply with clinical trial protocols due to COVID-19 illness, concerns about the pandemic, or quarantines or other restrictions that impede

their movement. Any interruption in the supply of the study drug might also delay our ability to complete our ongoing clinical trials within our expected timelines. Significant delays in the completion of our ongoing clinical trials are costly and could adversely affect our business and financial condition.

COVID-19 may also have an adverse impact on our contract manufacturers, suppliers, PPN partners, wholesalers, distributors and third party logistic provider as a result of employees or other key personnel becoming infected, preventive and precautionary measures that governments or such third parties are taking, such as social distancing, quarantines, and other restrictions, and shortages of supplies necessary for the manufacture of XHANCE. Any of these circumstances could adversely impact the ability of third parties on which we rely to manufacture and distribute adequate volumes of XHANCE. For example, in April 2020, our contract manufacturer for the formulation and assembly of finished XHANCE drug product implemented a reduced work schedule in response to the pandemic which resulted in temporary delays relating to the assembly of XHANCE finished goods.

The extent to which COVID-19 impacts our business, our customers, and the third parties on whom we rely, such as our contract manufacturers, suppliers, PPN partners, wholesalers, distributors, third party logistics, contract research organizations, investigators for our clinical trials and other vendors, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and any resurgence, new information that may emerge concerning the severity of the coronavirus, the actions to contain the coronavirus or treat its impact, and the speed with which and the extent to which normal economic and operating conditions resume, among others.

## ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

### INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1	<a href="#">Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).</a>
3.2	<a href="#">Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).</a>
10.1	<a href="#">Open Market Sale Agreement (the Sale Agreement), dated August 11, 2021, between the Company and Jefferies LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 2021 (File No. 001-38241), as filed with the SEC on August 11, 2021).</a>
31.1 *	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
31.2 *	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
32.1 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.</a>
32.2 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.</a>
101.SCH *	Inline XBRL Taxonomy Extension Schema Document.
101.CAL *	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF *	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB *	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104 *	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

\* Filed herewith.

**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.

Date: November 15, 2021

**OPTINOSE, INC.**

By: /s/ KEITH A. GOLDAN

Name: Keith A. Goldan

Title: *Chief Financial Officer*

*(Principal Financial and Accounting Officer)*

OPEN MARKET SALE AGREEMENT<sup>SM</sup>

August 11, 2021

JEFFERIES LLC  
520 Madison Avenue  
New York, New York 10022

Ladies and Gentlemen:

OptiNose, Inc., a Delaware corporation (the “**Company**”), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the “**Agent**”), shares of the Company’s common stock, par value \$0.001 per share (the “**Common Shares**”), on the terms set forth in this agreement (this “**Agreement**”).

**Section 1. DEFINITIONS**

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

“**Affiliate**” of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first- mentioned Person. The term “control” (including the terms “controlling,” “controlled by” and “under common control with”) means the possession, direct or indirect, 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.

“**Agency Period**” means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

“**Commission**” means the U.S. Securities and Exchange Commission.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

“**Floor Price Limitation**” means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less than \$1.00 without the prior written consent of the Agent, which may be withheld in the Agent’s sole discretion.

“**Issuance Amount**” means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

**“Issuance Notice”** means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President, Chief Financial Officer or Chief Legal Officer.

**“Issuance Notice Date”** means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

**“Issuance Price”** means the Sales Price less the Selling Commission.

**“Maximum Program Amount”** means Common Shares with an aggregate Sales Price of the least of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company’s authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), and (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).

**“Person”** means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

**“Principal Market”** means The Nasdaq Global Select Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

**“Rule 462(b) Registration Statement”** means any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Shares.

**“Sales Price”** means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

**“Securities Act”** means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

**“Selling Commission”** means up to three percent (3.0%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

**“Settlement Date”** means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

**“Shares”** shall mean the Company’s Common Shares issued or issuable pursuant to this Agreement.

“**Trading Day**” means any day on which the Principal Market is open for trading.

## **Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY**

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date with respect to which the Company is required to deliver a certificate pursuant to Section 4(o) and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a “**Representation Date**”), except as may be disclosed in the Registration Statement or the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed or will file with the Commission a shelf registration statement on Form S-3 that contains a base prospectus (the “**Base Prospectus**”). Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements on Form S-3 from time to time that will contain a base prospectus (in which case all references herein to the Base Prospectus shall be to the base prospectus in such additional registration statement) and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the “**Registration Statement**,” and the Base Prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the “**Prospectus**,” except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term “**Prospectus**” shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally becomes effective is herein called the “**Original Registration Statement**.” As used in this Agreement, the terms “amendment” or “supplement” when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or

included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date. The Company's obligations under this Agreement to furnish, provide or deliver or make available (and all other reference of like import) copies of any report or statement shall be deemed satisfied if the same is filed with or furnished to the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("EDGAR").

At the time the Original Registration Statement was or will be declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. The Original Registration Statement and any Rule 462(b) Registration Statement have been or will be declared effective by the Commission under the Securities Act prior to the issuance and sale of Shares pursuant to this Agreement. The Company has complied or will comply, to the Commission's satisfaction, with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied or will comply in all material respects with the Securities Act and, if filed with the Commission by electronic transmission pursuant to EDGAR, was or will be identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "**Time of Sale Information**") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the

Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Ineligible Issuer Status. The Company is not an “ineligible issuer” in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. The representations and warranties set forth in the immediately preceding sentence do not apply to statements made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 6 below. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent’s prior consent, which consent shall not be unreasonably withheld, conditioned or delayed, prepare, use or refer to, any Free Writing Prospectus.

(d) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(e) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied and will comply in all material respects with the requirements of the Exchange Act, and, when



read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Time of Sale (as defined below), as the case may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) This Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(g) Authorization of the Shares. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(h) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly satisfied or waived.

(i) No Material Adverse Change. Except as otherwise disclosed or incorporated by reference in the Registration Statement and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change being referred to herein as a “**Material Adverse Change**”); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with their business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, and have not entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(j) Independent Accountants. To the knowledge of the Company, Ernst & Young LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act and the rules of the Public Company

Accounting Oversight Board (“PCAOB”), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(k) Financial Statements. The financial statements filed with the Commission as a part of, or incorporated by reference into, the Registration Statement and the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of the dates indicated and the results of their operations, changes in stockholders’ equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus. The interactive data in eXtensible Business Reporting Language incorporated by reference into the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission’s rules and guidelines applicable thereto. All disclosures contained or incorporated by reference in the Registration Statement or the Prospectus and any free writing prospectus, that constitute non-GAAP financial measures (as defined by the rules and regulations under the Securities Act and the Exchange Act) comply, in all material respects, with Regulation G under the Exchange Act and Item 10 of Regulation S-K under the Securities Act, as applicable. To the Company’s knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(l) Company’s Accounting System. The Company and each of its subsidiaries make and keep books and records that are accurate in all material respects and maintain a system of internal accounting controls designed to, and which the Company believes is sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management’s general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles as applied in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference into the Registration Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission’s rules and guidelines applicable thereto.

(m) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure

controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(n) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described or incorporated by reference in the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the Commonwealth of Pennsylvania and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or in good standing would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change.

(o) Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized and is validly existing as a corporation or other entity in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described or incorporated by reference in the Registration Statement and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or to be in good standing would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. None of the outstanding capital stock in any subsidiary was issued in violation of preemptive or similar rights of any securityholder of such subsidiary. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit

21 to the Company's most recent Annual Report on Form 10-K. OptiNose UK Ltd. is not a "significant subsidiary" (as defined in Rule 405 under the Securities Act).

(p) Capitalization and Other Capital Stock Matters. The authorized, issued and outstanding capital stock of the Company is as set forth in the Company's latest financial statements, audited or unaudited, as applicable, incorporated by reference in the Registration Statement and the Prospectus (other than for subsequent issuances, if any, including pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case as described or incorporated by reference in the Registration Statement and the Prospectus). The Common Shares (including the Shares, when issued pursuant to the terms of this Agreement) conform in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding Common Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all applicable federal and state securities laws. None of the outstanding Common Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described or incorporated by reference in the Registration Statement and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth or incorporated by reference in the Registration Statement and the Prospectus accurately and fairly present, in all material respects, the information required to be shown with respect to such plans, arrangements, options and rights.

(q) Stock Exchange Listing. The Common Shares are registered pursuant to Section 12(b) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Principal Market.

(r) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws, or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "**Existing Instrument**"), except for such Defaults in Existing Instruments as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change. The Company's execution, delivery and performance of this Agreement, consummation of the transactions

contemplated hereby and by the Registration Statement and the Prospectus and the issuance and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement and the Prospectus under the caption “Use of Proceeds”) (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company’s execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the Financial Industry Regulatory Authority, Inc. (“**FINRA**”). As used herein, a “**Debt Repayment Triggering Event**” means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder’s behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(s) Compliance with Laws. The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change.

(t) No Material Actions or Proceedings. There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Change or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Change. No material labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent.

(u) Intellectual Property Rights. The Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described or incorporated by reference in the Registration Statement and the Prospectus as being owned or licensed by them or which, to the Company's knowledge, are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted in the Registration Statement and the Prospectus (collectively, "**Intellectual Property**"). To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except (A) for a security interest in favor of BPCR Limited Partnership, (B) the licenses of Intellectual Property to Inexia Limited and Currax Pharmaceuticals LLC disclosed or incorporated by reference in the Registration Statement and the Prospectus, and (C) for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed or incorporated by reference in the Registration Statement and the Prospectus as licensed to the Company or one or more of its subsidiaries, and the Company and its subsidiaries have taken all reasonable steps necessary to secure their interests in the Intellectual Property from their employees and contractors; (ii) there is no infringement by third parties of any Intellectual Property; (iii) the Company is not infringing the intellectual property rights of third parties; (iv) the Company is the sole owner of the Intellectual Property owned by it, except for a security interest in favor of BPCR Limited Partnership, and has the valid right to use the Intellectual Property; (v) there are no material defects in any of the patents or patent applications included in the Intellectual Property; (vi) the duties of candor and good faith required by the United States Patent and Trademark Office during the prosecution of the United States patents and patent applications included in the Intellectual Property have been complied with, and all such requirements in foreign offices having similar requirements applicable to the Company and its subsidiaries have been complied with; and (vii) no employee of the Company is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others, that would reasonably be expected to have a Material Adverse Change on the Company: (A) challenging the Company's rights in or to any Intellectual Property; (B) challenging the validity, enforceability or scope of any Intellectual Property; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described or incorporated by reference in the Registration Statement or the Prospectus as under development, infringe, misappropriate or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others. The Company and its subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. The product candidates described or incorporated by reference in the Registration Statement and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or any subsidiary.

(v) All Necessary Permits, etc. The Company and its subsidiaries possess such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described or incorporated by reference in the Registration Statement or the Prospectus (“**Permits**”). Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit.

(w) Title to Properties. Neither the Company nor any Subsidiary owns any real property. The Company and its subsidiaries have good and marketable title to all of the personal property and other assets reflected as owned in the financial statements referred to in Section 2(k) above (or elsewhere in the Registration Statement or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except for a security interest in favor of BPCR Limited Partnership, and except as would not reasonably be expected, individually or in the aggregate, to materially affect the value of such property or materially interfere with the use thereof. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(x) Tax Law Compliance. The Company and its subsidiaries have filed all necessary federal, state and foreign income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 2(k) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined.

(y) Insurance. Each of the Company and its subsidiaries are insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as the Company reasonably believes are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Change. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(z) Compliance with Environmental Laws. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, “**Hazardous Materials**”) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, “**Environmental Laws**”); (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements; (iii) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries; and (iv) there are no orders for clean-up or remediation, or an action, suit or proceeding pending or, to the knowledge of the Company threatened, by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(aa) ERISA Compliance. The Company and its subsidiaries and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “**ERISA**”)) established or maintained by the Company, its subsidiaries or, to the knowledge of the Company, their “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “**ERISA Affiliate**” means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the “**Code**”) of which the Company or such subsidiary is a member. No “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any material liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any “employee benefit plan” or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would reasonably be expected to cause the loss of such qualification.



(bb) Company Not an “Investment Company.” The Company is not, and will not be, either after receipt of payment for the Shares or after the application of the proceeds therefrom as described under “Use of Proceeds” in the Registration Statement or the Prospectus, required to register as an “investment company” under the Investment Company Act of 1940, as amended (the “**Investment Company Act**”).

(cc) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Shares or of any “reference security” (as defined in Rule 100 of Regulation M under the Exchange Act (“**Regulation M**”)) with respect to the Common Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(dd) Related-Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required under Item 404 of Regulation S-K to be described or incorporated by reference in the Registration Statement or the Prospectus that have not been described as required.

(ee) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its counsel, its officers and directors and, to the knowledge of the Company, the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with FINRA’s rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct. The Company meets the definition of the term “experienced issuer” specified in FINRA Rule 5110(j)(6).

(ff) Statistical and Market-Related Data. All statistical, demographic and market-related data included or incorporated by reference in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(gg) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company’s knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any applicable law or of the character required to be disclosed in the Registration Statement or the Prospectus.

(hh) Anti-Corruption Laws. None of the Company, any of its subsidiaries or any of their respective affiliates, directors or officers, employees or, to the Company’s knowledge, any of the Company or its subsidiaries respective agents, representatives or other persons associated with or acting on behalf of the Company or any of its subsidiaries or their respective affiliates has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful

expenses relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any domestic government official, “foreign official” (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the “FCPA”)) or government employee, including of any government-owned or controlled entity or a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the FCPA or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act of 2010 of the United Kingdom, or any other applicable non-U.S. anti-bribery or anti-corruption laws; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful or improper bribe, rebate, payoff, influence payment, kickback or other unlawful payment or benefit; and the Company and its subsidiaries and, to the Company’s knowledge, its affiliates have conducted their respective businesses in compliance with applicable anti-bribery and anti-corruption laws and have instituted and maintain and continue to maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance with such laws and with the representation and warranty contained herein.

(ii) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Money Laundering Laws**”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(jj) Sanctions Laws. Neither the Company nor its subsidiaries, or any of their respective directors, officers or employees or, to the knowledge of the Company, any agent, affiliate or other person associated with or acting on behalf of the Company or its subsidiaries is currently subject to or the target of any U.S. sanctions administered by the U.S. Government (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a “specially designated national” or “blocked person”), the United Nations Security Council, the European Union, Her Majesty’s Treasury or other relevant sanctions authority (collectively, “**Sanctions**”), nor is the Company or its subsidiaries located, organized or resident in a country or territory that is subject to or the target of Sanctions, including, without limitation, Crimea, Cuba, Iran, North Korea and Syria (each, a “**Sanctioned Country**”); and the Company and its subsidiaries will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity, for the purpose of (i) financing or facilitating the activities of or business with any person that currently is subject to or the target of any Sanctions, (ii) financing or facilitating any activities of

or business in any Sanctioned Country or (iii) financing or using such proceeds in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, each of the Company and its subsidiaries has not engaged in, is not now engaged in, and will not engage in, any dealings or transactions with any person that at the time of the dealing or transaction is or was subject to or the target of Sanctions or with any Sanctioned Country.

(kk) Brokers. Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company or its subsidiaries any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(ll) Forward-Looking Statements. Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained or incorporated by reference in the Registration Statement or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

(mm) No Outstanding Loans or Other Extensions of Credit. The Company does not have any outstanding extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

(nn) Emerging Growth Company Status. The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act.

(oo) Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to or incorporated by reference in the Registration Statement or the Prospectus; the Company and its subsidiaries have made all such filings and obtained all such approvals as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "**Regulatory Agencies**"), except where such failure or non-compliance would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change; neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency

requiring the termination, suspension or modification of any clinical trials that are described or referred to or incorporated by reference in the Registration Statement or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

(pp) Compliance with Health Care Laws. The Company and its subsidiaries are, and at all times have been, in compliance with all Health Care Laws, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change. For purposes of this Agreement, “**Health Care Laws**” means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.) and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Laws (42 U.S.C. Section 1320a-7a), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), all applicable federal, state, local and foreign criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. Section 1320a-7), the statutes, regulations and directives of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes; (iii) the Physician Payments Sunshine Act (42 U.S.C. Section 1320-7h); (iv) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the data privacy and security regulations promulgated thereunder; (v) the Patient Protection and Affordable Care Act of 2010 (Pub. Law 111-148), as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (Pub. Law 111-152), the regulations promulgated thereunder; (vi) the U.S. Controlled Substances Act (21 U.S.C. Section 801 et seq.); (vii) quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies, including, but not limited to, all laws applicable to ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company; and (viii) all other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company or its subsidiaries. Neither the Company nor its subsidiaries have received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws nor, to the Company’s knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, the Company and its subsidiaries have filed, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company nor its subsidiaries are a party to any corporate integrity agreements, monitoring agreements, consent

decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, its subsidiaries nor any of their respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that would reasonably be expected to result in debarment, suspension, or exclusion.

(qq) Compliance with Data Privacy Laws. To the Company's knowledge, the Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations (collectively, the "**Privacy Laws**"), except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change. Except where failure to do so would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, the Company and its subsidiaries have in place, comply with, and take commercially reasonable steps reasonably designed to comply in all respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (as defined below) (the "**Policies**"). Except where failure to do so would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, the Company and its subsidiaries have at all times made all disclosures to users or customers required by the Privacy Laws, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any Privacy Laws in any respect. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, the Company further certifies that neither it nor any subsidiary: (i) has received written notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement from or with a governmental or regulatory authority or agency that imposes any obligation or liability under any Privacy Law.

(rr) Cybersecurity. Except where failure to do so would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, to the Company's knowledge, the Company's and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all respects as required in connection with, the operation of the business of the Company and its subsidiaries as currently conducted, free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. Except where failure to do so would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, the Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "**Personal Data**" means (i) a natural person's name, street address, telephone number, e-mail address, photograph,

social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) if applicable to the Company, "personal data" as defined by EU General Data Protection Regulation ("GDPR"); (iv) if applicable to the Company, any information which would qualify as "protected health information" under HIPAA; and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, to the Company's knowledge, there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Change.

(ss) No Contract Terminations. Neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in any preliminary prospectus, the Prospectus or any free writing prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(tt) Dividend Restrictions. No subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary, except, in each case, for such restrictions or prohibitions imposed under applicable laws or pursuant to the Company's note purchase agreement entered into with funds managed by Pharmakon Advisors, LP disclosed or incorporated by reference in the Registration Statement and the Prospectus.

(uu) No Indebtedness. Except as otherwise disclosed or incorporated by reference in the Registration Statement and the Prospectus, the Company and its subsidiaries have no outstanding indebtedness other than intercompany debt.

(vv) Duties, Transfer Taxes, Etc. No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by the Agent in the United

States or any political subdivision or taxing authority thereof or therein in connection with the execution, delivery or performance of this Agreement by the Company or the sale and delivery by the Company of the Shares.

(ww) Other Underwriting Agreements. The Company is not a party to any agreement with another agent or underwriter for any other “at the market” or continuous equity transaction.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(o) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

### **Section 3. ISSUANCE AND SALE OF COMMON SHARES**

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; provided, however, that (A) in no event may the Company deliver an Issuance Notice to the extent that the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by email to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the

information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in negotiated transactions with the consent of the Company or (B) by any other method permitted by law deemed to be an “**at the market offering**” as defined in Rule 415(a)(4) under the Securities Act, including block transactions, sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clause (A) above) the method of placement of any Shares by the Agent shall be at the Agent’s discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee’s account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a “**Time of Sale**”).

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; provided, however, that (A) such suspension and termination shall not affect or impair either party’s obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto



acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "**Blue Sky Survey**" or memorandum and a "Canadian wrapper", and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable and documented fees and disbursements of the Agent's counsel, including the reasonable and documented fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; (ix) the costs and expenses of the Company

relating to investor presentations on any “road show” undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of Agent’s counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) \$50,000 in connection the execution of this Agreement and (B) \$15,000 in connection with each Triggering Event Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 4(o).

#### **Section 4. ADDITIONAL COVENANTS**

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an “**Interim Prospectus Supplement**”), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or, to the knowledge of the Company, of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its reasonable best

efforts to obtain the lifting of such order as soon as reasonably practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its commercially reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the reasonable opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and Section 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 4(d) and Section 4(f). Notwithstanding the foregoing, the Company shall not be required to file such amendment or supplement if there is no pending Issuance Notice and the Company believes that it is in its best interests not to file such amendment or supplement.

(d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent (which shall not be unreasonably withheld, conditioned or delayed), insofar as such proposed amendment or supplement relates to the transactions contemplated hereby, and the Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Use of Free Writing Prospectus. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

(f) Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent, such consent not to be unreasonably withheld, conditioned or delayed. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent, such consent not to be unreasonably withheld, conditioned or delayed.

(g) Filing of Agent Free Writing Prospectuses. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

(h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an

untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its reasonable best efforts to obtain the withdrawal thereof as soon as reasonably practicable.

(j) Earnings Statement. As soon as practicable, the Company will use its reasonable best efforts to make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(k) Listing; Reservation of Shares. (a) The Company will use its reasonable best efforts to maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(l) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Registration Statement or Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii) (B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as

necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) confirming that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o), dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurance letter and the written legal opinion of Hogan Lovells US LLP, counsel to the Company, the Company's intellectual property counsel and the Company's Norwegian counsel, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided, however, that the Company shall be required to furnish no more than one opinion and negative assurance letter hereunder per each filing of an annual report on Form 10-K or a quarterly report on Form 10-Q. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

(q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Ernst & Young LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the

Agent, the Company shall also cause a comfort letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter hereunder per each filing of an annual report on Form 10-K or a quarterly report on Form 10-Q.

(r) Secretary's Certificate. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(u) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall use commercially reasonable efforts to cause each of its affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall use commercially reasonable efforts to cause each of its affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

(v) Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise



dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, or effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Common Shares, during the period beginning at the time at which any Issuance Notice is delivered to the Agent hereunder and ending on the earlier of (A) the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice and (B) the date such Issuance Notice is cancelled if no Shares have been sold pursuant to such Issuance Notice; and will not directly or indirectly enter into any other “at the market” or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company’s (i) issuance or sale of Common Shares, options to purchase Common Shares, restricted stock units or Common Shares issuable upon the exercise or settlement of options, restricted stock units or other equity awards, as applicable, pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Principal Market rules or other compensation plan of the Company or its subsidiaries, (ii) issuance or sale of Common Shares issuable upon exchange, conversion, settlement or redemption of securities or the exercise, vesting or settlement of warrants, options, restricted stock units or other equity awards, (iii) issuance or sale of Common Shares or securities convertible into or exchangeable for Common Shares as consideration for mergers, acquisitions, other business combinations, joint ventures or strategic alliances and other business transactions (including, without limitation, collaborations or arrangements involving research and/or development activities) occurring after the date of this Agreement; provided, however, that the aggregate number of Common Shares issued, or issuable pursuant to the conversion or exchange of securities convertible into or exchangeable for Common Shares, under this subsection (iii) does not exceed 5% of the aggregate number of Common Shares outstanding immediately prior to giving effect to such issuance or sale; and (iv) modification of any outstanding options, warrants or any rights to purchase or acquire Common Shares.

#### **Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT**

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

(i) Accuracy of the Company’s Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to

Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).

(ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(iii) Material Adverse Changes. Except as disclosed in the Registration Statement or Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or the FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a

certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President, Chief Financial Officer or Chief Legal Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate as required to be delivered pursuant to Section 4(o) (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Agent Counsel Legal Opinion. Agent shall have received from Cooley LLP, counsel for Agent, such opinion or opinions, on or before the date on which the delivery of the Company counsel legal opinion is required pursuant to Section 4(p), with respect to such matters as Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for enabling them to pass upon such matters.

## **Section 6. INDEMNIFICATION AND CONTRIBUTION**

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, and to reimburse the Agent and each such officer, employee and controlling person for any and all reasonable and documented expenses (including the reasonable and documented fees and disbursements of one counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss,

claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in subsection (b) below. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), that arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus, and to reimburse the Company and each such director, officer and controlling person for any and all reasonable and documented expenses (including the reasonable and documented fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party

under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section 6(b) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have

reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any legal or other fees or expenses documented and reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(c) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this Section 6(e), the Agent shall not be required to contribute any amount in excess of the Selling Commission received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

#### **Section 7. TERMINATION & SURVIVAL**

(a) Term. Subject to the provisions of this Section 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

(i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 3(d), Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.

(ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

#### **Section 8. MISCELLANEOUS**

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K, Quarterly Report on Form 10-Q or Annual Report on Form 10-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good

faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules and, for the avoidance of doubt, the disclosure required pursuant to Section 4(a) of this Agreement in the Company's quarterly reports on Form 10-Q or annual reports on Form 10-K. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC



520 Madison Avenue  
New York, NY 10022  
Facsimile: (646) 786-5719  
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Cooley LLP  
55 Hudson Yards  
New York, NY 10001  
Attention: Daniel I. Goldberg, Esq.  
Facsimile: (212) 479-6275

If to the Company:

OptiNose, Inc.  
1020 Stony Hill Road, Suite 300  
Yardley, Pennsylvania 19067  
Facsimile: (267) 395-2119  
Attention: Chief Executive Officer and Chief Legal Officer

with a copy (which shall not constitute notice) to:

Hogan Lovells US LLP  
1735 Market Street, 23rd Floor  
Philadelphia, Pennsylvania, 19103  
Facsimile: (267) 675-4671  
Attention: Steven J. Abrams

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

(e) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(f) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(g) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the “**Specified Courts**”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docuSign.com). This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

*[Signature Page Immediately Follows]*

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

**OPTINOSE, INC.**

By: /s/ Keith A. Goldan  
Name: Keith A. Goldan  
Title: Chief Financial Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

**JEFFERIES LLC**

By: /s/ Michael Magarro  
Name: Michael Magarro  
Title: Managing Director

**EXHIBIT A**  
ISSUANCE NOTICE

[Date]

Jefferies LLC  
520 Madison Avenue  
New York, New York 10022

Attn: [\_\_\_\_\_]

Reference is made to the Open Market Sale Agreement<sup>SM</sup> between OptiNose, Inc. (the “**Company**”) and Jefferies LLC (the “**Agent**”) dated as of August 11, 2021. The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)):

\_\_\_\_\_

Issuance Amount (equal to the total Sales Price for such Shares):

\$\_\_

Number of days in selling period: \_\_

First date of selling period: \_\_

Last date of selling period: \_\_

Settlement Date(s) if other than standard T+2 settlement:

\_\_

Floor Price Limitation (in no event less than \$1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent’s sole discretion): \$ \_\_\_\_ per share

Comments: \_\_\_\_

\_\_

By: \_\_  
Name:

Title:

**Schedule A**

**Notice Parties**

The Company.

Peter K. Miller ([•])

Ramy A. Mahmoud ([•])

Keith Goldan ([•])

Michael Marino ([•])

The Agent

Michael Magarro ([•])

Donald Lynaugh ([•])

**CERTIFICATION UNDER SECTION 302 OF THE**

**SARBANES-OXLEY ACT OF 2002**

I, Peter K. Miller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. 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: November 15, 2021

/s/ Peter K. Miller  
Peter K. Miller  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION UNDER SECTION 302 OF THE**

**SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. 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: November 15, 2021

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

**CERTIFICATION UNDER 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 Quarterly Report on Form 10-Q of the Company for the period ending September 30, 2021 (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: November 15, 2021

/s/ Peter K. Miller  
Peter K. Miller  
Chief Executive Officer  
(Principal Executive Officer)



**CERTIFICATION UNDER 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 Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2021 (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: November 15, 2021

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