## 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  $\mathbf{X}$ ACT OF 1934

## For the quarterly period ended June 30, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE 0 ACT OF 1934

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

Commission file number: 001-38241



OPTINOSE, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of other jurisdiction of incorporation or organization)

42-1771610

(I.R.S. Employer Identification Number)

1020 Stony Hill Road, Suite 300 Yardley, Pennsylvania 19067

(Address of principal executive offices, including zip code)

(267) 364-3500

(Registrant's telephone number including area code)

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 X No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes I No o

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.

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

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

The number of shares of the registrant's common stock outstanding at August 3, 2018 was 41,220,634 shares.

	NOTE REGARDING FORWARD-LOOKING STATEMENTS	1
	PART I — FINANCIAL INFORMATION	
<u>ltem 1.</u>		3
	Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017	3
	Consolidated Statements of Operations for the three and six months ended June 30, 2018 and 2017	4
	Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2018 and 2017	5
	Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and 2017	6
	Notes to Unaudited Interim Consolidated Financial Statements	7
<u>ltem 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
<u>Item 3.</u>	Qualitative and Quantitative Disclosure About Market Risk	27
<u>ltem 4.</u>	Controls and Procedures	27
	PART II — OTHER INFORMATION	28
<u>ltem 1.</u>	Legal Proceedings	28
<u>Item 1A.</u>	Risk Factors	28
<u>ltem 2.</u>	Unregistered Sales of Equity Securities and Use of Proceeds	29
<u>Item 3.</u>	Defaults Upon Senior Securities	29
ltem 4.	Mine and Safety Disclosures	29
<u>Item 5.</u>	Other information	29
<u>ltem 6.</u>	<u>Exhibits</u>	30
	<u>Signatures</u>	31

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<sup>®</sup> and XHANCE<sup>®</sup> 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 potential advantages of XHANCE and our product candidates;
- the potential benefits of our Xperience Program, our co-pay savings program and other patient support programs and their potential effect on XHANCE demand and financial results;
- our goal for 75% of commercially insured lives to have access to XHANCE in a Tier 3 formulary position with a low "hassle factor" by the end of 2018;
- our commercial initiatives and objectives related to XHANCE;
- our planned product development activities, studies and clinical trials, including our plans to initiate a clinical program of XHANCE in the fourth guarter of 2018 in pursuit of a supplemental indication for chronic sinusitis;
- our expectation that our operating expenses in 2018 will be in the range of \$117 \$121 million;
- the potential for XHANCE to be effected by the seasonality impact observed in the INS market;
- the potential for the additional number of XHANCE samples distributed in July to effect the number of XHANCE prescriptions in the third quarter of 2018; and
- our expectation that the average selling price (ASP) for XHANCE in the third quarter of 2018 will be similar to the ASP for XHANCE in the second quarter of 2018;
- future XHANCE prescription growth;
- our expectation that we will complete the transfer of manufacturing activities to another party prior to the effective date of the termination of our manufacturing services agreement with Ximedica, LLC and that our commercial supply will not be adversely impacted;

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 forwardlooking statements by words such as "may," "will," "could," "should," "expect," "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, 2017, 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 also contains estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning XHANCE, brand awareness, market access, the estimated size of markets, prescriptions, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. 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)

		June 30, 2018	D	ecember 31, 2017
	(ι	unaudited)		
Assets				
Current assets:				
Cash and cash equivalents	\$	244,990	\$	234,854
Accounts receivable, net		3,671		_
Grants and other receivables		211		46
Inventory		4,950		2,013
Prepaid expenses and other current assets		2,232		1,254
Total current assets		256,054		238,167
Property and equipment, net		3,596		2,564
Other assets		300		405
Total assets	\$	259,950	\$	241,136
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	6,951	\$	5,893
Accrued expenses		16,254		8,698
Deferred other income		8		186
Total current liabilities		23,213		14,777
Long-term debt, net		72,138		71,863
Other liabilities		267		_
Total liabilities		95,618		86,640
Stockholders' equity:				
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2018 and December 31, 2017; 41,121,557 and 37,802,556 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively		41		38
Additional paid-in capital		430,803		365,838
Accumulated deficit		(266,423)		(211,269)
Accumulated other comprehensive loss		(89)		(111)
Total stockholders' equity		164,332		154,496
Total liabilities and stockholders' equity	\$	259,950	\$	241,136

See accompanying notes to unaudited interim consolidated financial statements

## OptiNose, Inc. Consolidated Statements of Operations For the Three and Six Months Ended June 30, 2018 and 2017 (in thousands, except share and per share data) (Unaudited)

	Thr	Three Months Ended June 30,		Six Months E		Ended June 30,		
		2018		2017		2018		2017
Net product revenues	\$	1,274	\$	—	\$	2,139	\$	—
Cost of product sales		351				551		_
Gross margin		923		—		1,588		—
Operating expenses:								
Research and development		2,046		4,749		3,747		8,979
Selling, general and administrative		21,860		3,588		49,871		6,661
Total operating expenses		23,906		8,337		53,618		15,640
Loss from operations		(22,983)		(8,337)		(52,030)		(15,640)
Other (income) expense:								
Grant and other income		(145)		(44)		(333)		(93)
Interest income		(582)		(60)		(1,058)		(95)
Interest expense		2,301		—		4,494		862
Foreign currency (gains) losses		24		(25)		21		(31)
Net loss	\$	(24,581)	\$	(8,208)	\$	(55,154)	\$	(16,283)
Deemed dividend		_		4,083		_		7,150
Accretion to redemption value				546		—		1,074
Net loss attributable to common stockholders	\$	(24,581)	\$	(12,837)	\$	(55,154)	\$	(24,507)
Net loss per share of common stock								
basic	\$	(0.64)	\$	(3.16)	\$	(1.44)	\$	(6.02)
diluted	\$	(0.64)	\$	(3.16)	\$	(1.44)	\$	(6.02)
Weighted average common shares outstanding								
basic		38,688,366		4,067,717		38,271,101		4,067,717
diluted		38,688,366		4,067,717		38,271,101		4,067,717
			-					

See accompanying notes to unaudited interim consolidated financial statements

## OptiNose, Inc. Consolidated Statements of Comprehensive Loss For the Three and Six Months Ended June 30, 2018 and 2017 (in thousands) (Unaudited)

	 Three Months Ended June 30,				Six Mont Jun	ded	
	2018	2018 2017		2018			2017
Net loss	\$ (24,581)	\$	(8,208)	\$	(55,154)	\$	(16,283)
Other comprehensive (loss) income:							
Foreign currency translation adjustment	15		(5)		21		(6)
Comprehensive loss	\$ (24,566)	\$	(8,213)	\$	(55,133)	\$	(16,289)

See accompanying notes to unaudited interim consolidated financial statements

## OptiNose, Inc. Consolidated Statements of Cash Flows For the Six Months Ended June 30, 2018 and 2017 (in thousands) (Unaudited)

	Six Months E June 30,		
	2018		2017
Operating activities:			
Net loss	\$ (55,154)	\$	(16,283)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	172		66
Stock-based compensation	4,123		1,029
Amortization of debt discount and issuance costs	180		194
Loss on sale of equipment	1		—
Changes in operating assets and liabilities:			
Accounts receivable	(3,671)		—
Grants and other receivables	(165)		165
Prepaid expenses and other assets	(859)		1,893
Inventory	(2,723)		_
Accounts payable	2,917		(1,683)
Accrued expenses and other liabilities	7,686		985
Cash used in operating activities	 (47,493)		(13,634)
Investing activities:			
Purchases of property and equipment	(881)		(711)
Cash used in investing activities	(881)		(711)
Financing activities:			
Proceeds from the sale of Series D preferred stock	_		36,712
Proceeds from the sale of common stock	63,969		—
Cash paid for financing costs	(6,349)		(278)
Proceeds from the exercise of stock options	857		—
Cash provided by financing activities	 58,477		36,434
Effects of exchange rate changes on cash and cash equivalents	25		(6)
Net increase in cash, cash equivalents and restricted cash	10,128		22,083
Cash, cash equivalents and restricted cash at beginning of period	 234,875		36,847
Cash, cash equivalents and restricted cash at end of period	\$ 245,003	\$	58,930
Supplemental disclosure of noncash financing activities:			
Deemed dividend	\$ —	\$	7,150
Accretion to redemption value	\$ _	\$	1,074
Fixed asset purchases within accounts payable and accrued expenses	\$ 233	\$	_
Fixed asset additions acquired through tenant allowance	\$ 267	\$	_
Financing costs within accounts payable and accrued expenses	\$ 188	\$	1,507
Conversion of convertible notes payable and accrued interest into Series C-2 preferred stock	\$ _	\$	19,527

See accompanying notes to unaudited interim consolidated financial statements

## 1. Organization and Description of Business

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

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's first two products approved by the United States Food and Drug Administration (FDA) utilize its proprietary Exhalation Delivery Systems (EDS), which are capable of deep intranasal deposition of medication. OptiNose developed its first product, Onzetra<sup>®</sup> Xsail<sup>®</sup> (sumatriptan nasal powder) through the completion of Phase III clinical trials and subsequently out-licensed the product to Avanir Pharmaceuticals, Inc. (Avanir). Onzetra Xsail received FDA approval and was launched in the United States (US) in 2016. The Company's second FDA-approved product, XHANCE<sup>®</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic that utilizes the Company's EDS to deliver a topically-acting corticosteroid for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was launched commercially in the United States in March 2018.

XHANCE is also currently in development for the treatment of chronic sinusitis.

## 2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, preparing for and launching XHANCE. As of June 30, 2018, the Company had cash and cash equivalents of \$244,990.

On June 11, 2018, the Company and certain stockholders closed an underwritten public offering (the Offering) of 5,750,000 shares of Company common stock (Common Stock) at a price of \$22.25 per share. The Offering consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. As a result of the Offering, the Company received \$59,926 in net proceeds, after deducting discounts and commissions of \$3,678 and offering expenses of approximately \$364 payable by the Company.

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

## 3. 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 June 30, 2018 and its results of operations for the three and six months ended June 30, 2018 and 2017 and cash flows for the six months ended

June 30, 2018 and 2017. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. 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, 2017 contained in the Company's annual report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 13, 2018.

## 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.

## Fair value of financial instruments

At June 30, 2018 and December 31, 2017, the Company's financial instruments included cash and cash equivalents, accounts receivable, grants receivable, inventory, 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. The Company also believes the carrying value of long-term debt approximates fair value at June 30, 2018 as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At June 30, 2018 and December 31, 2017, there were no financial assets or liabilities measured at fair value on a recurring basis.

## Inventory

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

## **Revenue recognition**

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

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

#### Net Product Revenues

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

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

## Transaction Price, including Estimates of Variable Consideration

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

#### Components of Variable Consideration

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

## • Variable Consideration - Accounts Receivable Reductions

- Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Reserves for chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, as well as chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.
- <u>Trade Discounts and Allowances.</u> The Company generally provides Customers with discounts that include incentive fees which are explicitly stated in the Company's contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized. In addition, the Company reimburses (through discounts and allowances) its Customers for sales order management, data and distribution services.



## • Variable Consideration - Current Liabilities

- <u>Product Returns.</u> Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the goods to a patient. The Company estimates the amount of its products that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company considers several factors in the estimation process, including expiration dates of product shipped to specialty pharmacies and wholesalers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.
- <u>Government Rebates</u>. The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. For Medicaid, accruals are based on estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. To estimate the cost to the Company of this Medicare coverage gap responsibility, the Company estimates the number of patients in the prescription drug coverage gap for whom it will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of the reporting period.
- <u>Payer Rebates.</u> The Company contracts with certain third-party payers, 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.
- <u>Other Incentives.</u> Other incentives that the Company offers include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers and coupon programs for cash payers. The calculation of the accruals for this assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

## Net income (loss) per common share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to Common Stock holders by the weighted average common shares outstanding during the period. For the three and six months ended June 30, 2018 and 2017, the outstanding Common Stock options and Common Stock warrants have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

Diluted net loss per common share for the periods presented do not reflect the following potential common shares, as the effect would be antidilutive:

	June	9 30,
	2018	2017
Stock options	6,126,560	4,397,949
Common stock warrants	1,878,660	1,890,489
Convertible preferred stock	—	25,068,556
Total	8,005,220	31,356,994

#### 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 six months ended June 30, 2018 and 2017, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of June 30, 2018 and December 31, 2017, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

In December 2017, the Tax Cuts and Jobs Act (TCJA) was signed into law. Due to the timing of and the substantial changes made by the TCJA, the Staff of the SEC issued Staff Accounting Bulletin No. 118 (SAB 118) which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA. Accordingly, the Company's preliminary estimate of the impact of the TCJA and the re-measurement of its deferred tax assets and liabilities is subject to finalization of its analysis of certain matters, such as developing interpretations of the TCJA provisions, changes to certain estimates and the filing of its tax returns. US Treasury regulations, administrative interpretations or court decisions interpreting the TCJA may require adjustments to the Company's initial estimates. The final determination of the TCJA provisions and re-measurement of the Company's deferred tax assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the TCJA.

## Recent accounting pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation - Scope of Modification Accounting*. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The adoption of ASU 2017-09 did not have a material impact on the Company's results of operations, financial position, cash flows and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)*. ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new standard is effective for fiscal years beginning after December 15, 2017. The Company adopted ASU 2016-18 in the first quarter of 2018, and the guidance has been retrospectively applied to all periods presented. As of June 30, 2018 and December 31, 2017, the restricted cash balance included in prepaid expenses and other assets was \$13 and \$20, respectively.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The FASB issued the update to require the recognition of lease assets and liabilities on the balance sheet of lessees. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. Early adoption is

permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU-2014-09, which replaced numerous requirements in US GAAP, including industry-specific requirements. This guidance provides a five-step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The new standard also defines accounting for certain costs related to origination and fulfillment of contracts with customers, including whether such costs should be capitalized.

This statement requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance and assets recognized from costs incurred to obtain or fulfill a contract. The guidance was effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. An entity could elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented — referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings — referred to as the modified retrospective method.

The Company assessed the impact that ASU No. 2014-09 had on its financial statements and related disclosures. Through the January 1, 2018 adoption date, the Company has derived its revenues from a single licensing agreement with Avanir (the AVP-825 License Agreement). The consideration the Company has received to date includes an upfront payment, research and development funding and development milestone payments. Additionally, the Company is eligible to receive sales milestone payments and royalties in the future once net product sales exceed a certain threshold. The Company analyzed the performance obligations under the AVP-825 License Agreement, and the consideration received to date and that the Company may receive in the future, as part of its analysis of the impact of ASU 2014-09 on this arrangement.

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

## 4. Inventory

Inventory consisted of the following:

	June 30, 2018		December 31, 2017		
Raw materials	\$ 1,780	\$	1,385		
Work-in-process	2,262		628		
Finished goods	908		—		
Total inventory	\$ 4,950	\$	2,013		

Inventories are stated at the lower of cost or net realizable value, as determined on a first-in, first-out, basis. The approximate shelf life of finished goods is two years from the date manufacturing is completed.

## 5. Property and Equipment

Property and equipment, net, consisted of:

	J	June 30, 2018		mber 31, 2017
Computer equipment and software	\$	800	\$	307
Furniture and fixtures		287		89
Machinery and equipment		2,629		2,495
Leasehold improvements		48		28
Construction in process		525		—
		4,289		2,919
Less: accumulated depreciation		(693)		(355)
	\$	3,596	\$	2,564

Depreciation expense was \$16 and \$34 for the three months ended June 30, 2018 and 2017 and \$172 and \$66 for the six months ended June 30, 2018 and 2017, respectively. In addition, depreciation expense of \$158 and \$15 is included within inventory and prepaid expenses and other assets, respectively, as of June 30, 2018, which represents depreciation expense related to equipment involved in the manufacturing process.

## 6. Accrued Expenses

Accrued expenses consisted of:

	June 30, 2018	December 31, 2017
Selling, general and administrative expenses	\$ 6,954	\$ 3,463
Research and development expenses	237	80
Bonus expense	2,574	4,163
Payroll and benefit expenses	2,732	448
Employee contributions withheld	998	185
Product revenue allowances	1,613	—
Interest expense	356	45
Other	790	314
	\$ 16,254	\$ 8,698

## 7. AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra<sup>®</sup> Xsail<sup>®</sup>), a product combining a low-dose powder form of sumatriptan with the Company's EDS, for the acute treatment of migraines in adults and any follow-on products under development that consist of a formulation that contains triptans as the sole active ingredient. Through June 30, 2018, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of \$70,000 in connection with the initial signing and the achievement of certain development milestones. Under the terms of the License Agreement, the Company is eligible to receive up to \$50,000 upon the achievement of sales milestones as well as tiered low double-digit royalty payments on net sales in the US, Canada and Mexico after such cumulative sales exceed a certain threshold.

The Company analyzed the performance obligations under the AVP-825 License Agreement, the consideration received to date and the consideration the Company may receive in the future as part of its analysis of the impact of ASU 2014-09 on this arrangement. The consideration the Company has received to date, which includes an upfront payment, research and development funding and development milestone payments has all been recognized in prior years, and all of the Company's performance obligations pursuant to the arrangement have been completed. Future revenues that the Company is entitled to receive, which include sales milestone payments and royalties should net product sales exceed a certain threshold, will be recognized when earned. See Note 3 for additional information on ASU 2014-09.

The Company did not recognize any licensing revenue under the arrangement during the three and six months ended June 30, 2018 and 2017.

#### 8. Long-term Debt

On December 29, 2017, the Company entered into a Senior Secured Note Purchase Agreement (the Senior Secured Notes) with Athyrium Opportunities III Acquisition LP. The Senior Secured Notes provided the Company with up to \$100,000 in capital, of which \$75,000 was issued immediately. The remaining \$25,000 (the Delayed Draw Notes) may be issued between April 1, 2019 and August 14, 2019, subject to the Company achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Senior Secured Note Purchase Agreement) of \$15,000 and a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00, and certain other conditions.

The Senior Secured Notes bear interest at 9.0% plus the three-month London Inter-bank Offered Rate (LIBOR) rate, subject to a 1.0% floor and are scheduled to mature on June 29, 2023. The interest rate was 11.375% at June 30, 2018. The Senior Secured Notes bore front-end fees of 1.0% of the aggregate principal amount, which were paid at issuance. The Company is also required to pay an exit fee of 2.0% of any principal payments (whether mandatory, voluntary, or at maturity) made throughout the term of the Senior Secured Note Purchase Agreement.

The Company recorded interest expense of \$2,301 and \$4,494 during the three and six months ended June 30, 2018, respectively, in conjunction with the Senior Secured Notes. Interest expense included total coupon interest, exit fees, front end fees and the amortization of debt issuance costs. The front-end fees of \$1,000 were recorded as debt discount at issuance and are being amortized to interest expense over the 5.5 year term of the Ioan. Additionally, back end fees of \$2,000 are being amortized to interest expense and are recorded as an increase in the carrying amount throughout the term of the Senior Secured Notes. The Company also incurred \$2,181 in debt issuance costs during the year ended December 31, 2017, which are also being amortized to interest expense over the term of the Senior Secured Notes.

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

	June 30, 2018		De	cember 31, 2017
Face amount	\$	75,000	\$	75,000
Front end fees		(943)		(999)
Debt issuance costs		(2,056)		(2,139)
Back end fees		137		1
Long-term debt, net	\$	72,138	\$	71,863

## 9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of June 30, 2018, approximately \$171 is recorded in accrued liabilities related to the Company match applicable to 2018 employee contributions. The Company's contributions are made in cash.

For Norway and UK employees, the Company maintains defined contribution pension plans which meet statutory requirements of those jurisdictions. The Company incurred costs of \$7 and \$38 for the three months ended June 30, 2018 and 2017 and \$69 and \$43 related to the pension plans for the six months ended June 30, 2018 and 2017, respectively.

## 10. Stockholders' Equity

#### **Common Stock**

On June 11, 2018, the Company and certain stockholders closed the Offering of 5,750,000 shares of Common Stock at a price of \$22.25 per share. The Offering consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. As a result of the Offering, the Company received \$59,926 in net proceeds, after deducting discounts and commissions of \$3,678 and offering expenses of approximately \$364 payable by the Company.

In October 2017, the Company increased the number of authorized Common Stock from 10,624,486 to 200,000,000 and completed an initial public offering (IPO) of its Common Stock, selling 8,625,000 shares at \$16.00 per share. As a result of the IPO, the Company received \$125,471 in net proceeds, after deducting discounts and commissions of \$9,660 and offering expenses of approximately \$2,869 payable by the Company.

Each share of Common Stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of Common Stock are entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through June 30, 2018.

## **Common Stock warrants**

As of June 30, 2018, the Company had warrants outstanding to purchase 1,878,660 shares of Common Stock with an exercise price of \$8.16. The warrants expire on November 1, 2020.

## 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 six months ended June 30, 2018 and 2017:

	1	Three Months Ended June 30,			 Six Months I	l June 30,	
		2018		2017	2018		2017
Cost of product sales	\$	2	\$	_	\$ 3	\$	_
Research and development		166		130	405		508
General and administrative		1,932		177	3,715		521
	\$	2,100	\$	307	\$ 4,123	\$	1,029

In addition, stock-based compensation expense of \$56 and \$6 is included within inventory and prepaid expenses and other assets, respectively, as of June 30, 2018, which represents the total stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples during the period.

## Stock Options

The Company has issued serviced-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. 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 June 30, 2018, all of the performance conditions related to performance-based stock options issued by the Company have been achieved.

The following table summarizes the activity related to stock option grants to employees and nonemployees for the six months ended June 30, 2018:

	Shares	e	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2017	6,251,576	\$	9.34	6.67
Granted	358,192		19.98	
Exercised	(446,367)		2.28	
Expired	_		_	
Forfeited	(36,841)		6.49	
Outstanding at June 30, 2018	6,126,560	\$	10.50	6.91
Exercisable at June 30, 2018	3,114,397	\$	6.80	4.74
Vested and expected to vest at June 30, 2018	6,126,560	\$	10.50	6.91

During the six months ended June 30, 2018, stock options to purchase 358,192 shares of Common Stock were granted to employees and directors and generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$13.26. During the six months ended June 30, 2017, stock options to purchase 334,993 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 \$3.39.

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:

	Six Months Ended June 30,			
	2018	2017		
Risk free interest rate	2.69%	2.07%		
Expected term (in years)	5.90			
Expected volatility	74.92%	73.93%		
Annual dividend yield	0.00%	0.00%		
Fair value of common stock	\$ 19.98	\$ 5.14		

At June 30, 2018, the unrecognized compensation cost related to unvested stock options expected to vest was \$23,539. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 3.09 years.

## 2017 Employee Stock Purchase Plan

Under the 2017 Plan, shares of Common Stock may be purchased by 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 \$123 and \$279 during the three and six months ended June 30, 2018, respectively, related to the 2017 Plan.

In July 2018, the Company issued 53,137 shares of Common Stock related to the offering periods ended June 30, 2018.



## 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, 2017, filed with the Securities and Exchange Commission (SEC) on March 13, 2018.

#### **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 lead product, XHANCE<sup>®</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids (INS), which have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS.

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

## **XHANCE Commercialization Update**

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

- <u>Commercial Supply Chain</u>. We have entered into commercial supply agreements with our key suppliers, spent significant time with our suppliers to oversee product production and quality management, and manufactured our initial commercial supply of XHANCE. We have contracted with a third-party logistics partner and our distribution partners.
- <u>Brand Awareness</u>. We have executed a broad, multi-channel awareness campaign leveraging digital, non- personal promotion and journal advertising and have already reached over 10,000 ENT physicians and allergists with disease state and branded messages. From November 2017 through April 2018, we deployed a nurse educator team of approximately 85 nurse professionals who called on approximately 5,000 ENT physicians and allergists and delivered over 16,000 presentations. The focus of their interactions with healthcare professionals included: (i) introducing Optinose and highlighting the unmet medical need and limitations of current treatments, (ii) increasing awareness about XHANCE along with providing education on the mechanism of action and the differences associated with the Optinose EDS, and (iii) familiarizing healthcare professionals with the proper administration of XHANCE. Based on our market research as of July 2018, aided brand awareness (meaning awareness of XHANCE or Optinose when specifically asked about the product and company) amongst a survey of 100 ENT and allergy physicians is 94 percent, which achieves our objective of 85 percent brand awareness during the launch phase.
- <u>Customer Model</u>. We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENTs, allergists and "specialty like" primary care physicians and have deployed a

hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target customer universe. We prioritized approximately 80 territories within our sales force footprint to deploy at launch based upon an expectation that we will achieve an estimated 65% commercial market access within each of those territories. The initial 80 territory managers completed training and were deployed in March 2018 engaging approximately 8,000 ENTs, allergists and "specialty like" primary care physician targets to promote XHANCE for the treatment of nasal polyps.

- XHANCE Patient Support Programs. In March 2018, we introduced the XHANCE Xperience program to offer physicians and their patients an opportunity to gain initial experience with XHANCE. As part of this program, patients receive up to two XHANCE prescriptions at no out of pocket cost to them (\$0 co-pay). In order to receive the second prescription, patients are required to complete a brief survey regarding their use of XHANCE. Initial survey results have been encouraging and provide physicians with the opportunity to receive feedback on early patient responses to treatment. As planned, Optinose closed Xperience to new enrollments at the end of June 2018. We believe this program has the potential to improve demand for XHANCE during the early phases of product launch. Through July 27, 2018, more than 2,600 unique physicians have prescribed XHANCE and more than 12,000 prescriptions have been written by physicians for patients. Following the end of the Xperience program, Optinose introduced a new co-pay savings program in order to encourage further patient trial and adoption of XHANCE. Following the end of the Xperience program, we observed an increase in demand for samples to be distributed to physician offices. A sample unit of XHANCE contains the same amount of product as the unit available by prescription (120 metered-dose sprays). In response to this market dynamic, we updated our co-pay savings program to provide the first prescription at no out-of-pocket cost (\$0 co-pay) to commercially insured patients and low subsequent co-pays for refills, and expect to reduce product sample distribution.
  - <u>Market Access</u>. Payers leverage various strategies to manage utilization of branded pharmaceutical products. An increasing number of payers are employing "new-to-market blocks" for launch brands until they have the opportunity to make a coverage decision based upon their internal review of the product's clinical and pharmacoeconomic data. When a product is not covered, the patient is responsible to pay the full price for the medication which significantly limits utilization of the product. If a payer decides to cover a medication, payers will classify products based upon Tiers. Tiers determine the out-of-pocket costs for a patient. For example, a product that is covered on Tier 2 typically requires a co-pay by the patient of between \$20 to \$40 and Tier 3 typically requires a co-pay by the patient of between \$60 to \$80.

Payers will also use controls to manage the prescribing of products that they cover. These tools include passive management techniques, such as "step edits," which minimize the internal resources payers need to apply to ensure a medication is primarily used in the intended manner. A step edit requires prior use of another medication, usually a generic or preferred brand, prior to approving coverage for the product in question. This confirmation can be performed at the pharmacy level and includes an electronic look-back. If the pharmacist is unable to confirm prior utilization of the "step medication," the pharmacist will need to contact the physician to obtain either a verbal or written confirmation of prior use of the "step medication." Payers will also use more active, aggressive management techniques such as Prior Authorizations (PAs). PAs require a physician to submit a written prior authorization form to be reviewed by the payer clinical staff prior to granting reimbursement for a prescription medication. A PA can sometimes be as simple as a physician checking a box documenting that a patient has previously tried a generic or preferred brand without benefit or as complex as a multipage form requiring a detailed medical history of a patient.

We have engaged with health plans representing over 85% of US commercial lives. In meeting with potential payers, we have shared what we believe is our compelling economic value proposition. Our analyses suggest that XHANCE will have a comparatively low pharmacy budget impact and our clinical trial data suggest that XHANCE may produce an offsetting benefit by helping reduce the rate of surgery with its related costs. For an insurance plan, this could represent a potential overall cost reduction for the population of patients with nasal polyps, as the overall cost of XHANCE could be less than the offsetting costs related to the reduction in surgeries. During clinical studies, XHANCE was also associated with an improvement in reported work productivity in treated patients, which should be valued by employers and patients. Further, we believe the cost of XHANCE to insurance plans will likely be significantly less than the projected costs of monoclonal antibodies that are currently in development for the treatment of nasal polyps.

Based on currently available third party data and our internal analyses, we believe that approximately 76% of commercially insured lives are in a plan in which XHANCE is covered in a Tier 3 formulary position, and approximately 60% of commercially insured lives are in a plan that covers XHANCE in a Tier 3 formulary position that is either unrestricted or requires a single step edit or simple PA for prior use of an over-the-counter or generic intranasal steroid. However, payers may change coverage levels for XHANCE or controls such as step edits and PAs, positively or negatively, at any time. We have also contracted with the Centers for Medicare and Medicaid Services for coverage of certain government covered lives, and over time intend to pursue future coverage for other government-insured populations. Further, we have introduced a co-pay assistance program and plan to implement other patient affordability programs to appropriately support patient access to XHANCE.

As we seek to increase the number of lives covered by commercial payers, it is our objective to continue to seek Tier 3 coverage that involves a low "hassle factor" for physicians and patients. We use the term "hassle factor" to characterize the level of difficulty that physicians and patients must overcome to prescribe and fill XHANCE. We define a low "hassle factor" as Tier 3 unrestricted, Tier 3 single step edit, or Tier 3 with a simple PA requiring prior use of an over-the-counter or generic intranasal steroid - although we acknowledge that any step edit or PA involves a level of burden for physicians and patients that could negatively impact XHANCE utilization. Our goal is for 75% of commercially insured lives to have access to XHANCE in a Tier 3 formulary position with a low "hassle factor" by the end of 2018.

<u>Infrastructure</u>. We continue to develop our internal capabilities and grew from 21 employees as of January 1, 2017 to 94 employees as of August 3, 2018 to support the commercialization of XHANCE. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have also implemented a robust healthcare compliance program to guide our staff's and our partners' compliance with rules and regulations regarding pharmaceutical sales. And in managing our growth, we have remained focused on fostering our One Mission culture.

## **XHANCE Development Update**

In addition to XHANCE's existing indication for nasal polyps, we plan to initiate a clinical program to seek a supplemental indication for the treatment of chronic sinusitis in the U.S. in order to broaden our market opportunity. We prepared draft clinical trial protocols and submitted them to the FDA in conjunction with a meeting request to discuss key elements of the program. That meeting was held in June 2018 and we expect to initiate the clinical program in the fourth quarter of 2018.

## **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 revenue

Sales of XHANCE generated \$2.1 million in net revenue through the six months ended June 30, 2018. XHANCE revenue for the three months ended June 30, 2018 was \$1.3 million, generated primarily through the Xperience program. In accordance with GAAP, we estimated the average selling price (ASP) for XHANCE, with specific assumptions for units sold into the retail channel as well as units dispensed through the Xperience program.

The Xperience program was a limited-time program and an important component of our launch strategy. The Xperience program was designed to encourage early trial and adoption of XHANCE by lowering barriers to initial trial. As expected, most early prescriptions were filled through this program as opposed to retail channels. Patients in the Xperience program were eligible to receive two months of treatment at no cost to them through our payment of any out-of-pocket expense incurred by the patient at the time the prescription was filled as a result of co-pays or non-coverage. As a result, the ASP for XHANCE units sold through the Xperience program was significantly lower than the ASP for XHANCE sold through the retail channel.

As planned, the Xperience program was the primary source of demand for XHANCE in second quarter of 2018. While there were modest levels of prescriptions and shipments into retail, we were focused on driving demand of XHANCE through the Xperience program as we believe it will accelerate long-term product uptake and the acquisition of product experience that drives future demand. Because of this program, the ASP and gross profit margin percentages in the three months ended June 30, 2018 were lower than what they were in the first quarter.

Following the end of the Xperience program we observed an increase in demand for samples to be distributed to physician offices (approximately 2,000 additional XHANCE samples were distributed in the last three weeks of July as compared to average weekly samples distributed during May and June). A sample unit of XHANCE contains the same amount of product as the unit available by prescription (120 metered-dose sprays). In response to this market dynamic, we updated our co-pay savings program to include the first prescription at no cost (\$0 co-pay) to commercially insured patients and expect to reduce product sample distributed in July may have an effect on XHANCE prescriptions in the third quarter of 2018.

In addition, historical data suggests that the INS market exhibits a seasonal decline in the summer months. We believe approximately one-third of the total INS prescriptions are coded for the treatment of chronic rhinosinusitis (including nasal polyps) and the balance is primarily for the treatment of rhinitis, especially allergic rhinitis. From May to July, based on 2016-2017 historical prescription data, the average decline in INS prescription volumes was approximately 23%, with month-over-month growth following July for the balance of the year. Although the underlying disease that we are treating is chronic and causes symptoms year-round, we believe the variation in patient flow through the offices of relevant specialists, and seasonality in disease flare-ups, may have an impact on the number of patients that present themselves and who are therefore available for prescribing a new medication like XHANCE. We continue to believe that patients can benefit from consistent treatment, and that as the product becomes more mature this seasonality effect may be reduced. However, in the launch phase when new patient starts are the majority of prescriptions, we believe XHANCE prescribing may be subject to a seasonal effect.

Based on third party prescription data and data from a contracted mail order pharmacy partner, monthly XHANCE prescriptions for March, April, May and June 2018 were 806, 2,225, 3,191 and 3,450, respectively, and weekly XHANCE prescriptions for the weeks ended July 6, July 13, July 20 and July 27, 2018 were 639, 664, 712 and 749, respectively. The July data represents an approximately 14% decline in average weekly reported XHANCE prescriptions through July 27th compared to June. We believe this decline is the result of (1) the termination of the Xperience program in which the first two prescriptions of XHANCE were available at \$0 co-pay for commercially insured patients, (2) the approximately 2,000 additional 30-day samples distributed to physicians during the last three weeks of July as compared to the average weekly number of samples distributed in May and June and (3) the seasonality impact of the INS market which declined approximately 11% during the same period from June to July. Given the continued strong physician interest, evidence for good patient outcomes, and the influence of our updated co-pay savings program offering the first prescription for a \$0 co-pay for all commercially insured patients and low subsequent co-pays for refills, and given that data suggest that the seasonality impact will turn positive in the next few months, we believe XHANCE will return to a positive prescription growth trend in the coming months. Additionally, we expect ASP for XHANCE in the third quarter of 2018 to be similar to the ASP for XHANCE in the second quarter of 2018 because a substantial number of patients remain eligible for a second prescription through the Xperience program at a \$0 co-pay and we expect our updated co-pay savings program to apply to a large number of eligible patients.

Our ability to generate additional net revenue and become profitable depends largely upon our ability to successfully commercialize XHANCE without the support provided by the Xperience program and other patient support programs, as well as our ability to broaden our market opportunity by successfully developing XHANCE for the treatment of chronic sinusitis.

## Costs of product sales

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

## Research and development expense

Prior to the FDA approval of XHANCE in September 2017, research and development expense consisted primarily of costs incurred in connection with the development and pursuit of regulatory approval for XHANCE for the treatment of nasal polyps. Post-FDA approval of XHANCE, research and development expense consists primarily of expenses incurred to prepare for 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 research 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 preclinical studies and clinical trials;

- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses
  prior to regulatory approval of products for commercial sale and the cost of acquiring and manufacturing preclinical study and clinical
  trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA prior to regulatory approval of products for commercial sale;
- costs incurred to maintain, expand and protect our patent portfolio as it relates to product candidates in development; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

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

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

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

#### Selling, general and administrative expense

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

Sales and marketing related expenses consist of expenses related to building brand awareness through advertising and the deployment of our nurse educator team, developing and deploying our contract sales force and securing market access for XHANCE as well as salaries and related benefits for employees focused on such efforts.

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

#### Interest (income) expense

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

## Other (income) expense

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

## **Consolidated Results of Operations**

## Comparison of three months ended June 30, 2018 and 2017

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

	 Three Months Ended June 30,			
	2018		2017	
Net product revenues	\$ 1,274	\$	—	
Cost of product sales	351		_	
Gross margin	 923		—	
Operating expenses:				
Research and development	2,046		4,749	
Selling, general and administrative	21,860		3,588	
Total operating expenses	 23,906		8,337	
Loss from operations	 (22,983)		(8,337)	
Other (income) expense:				
Interest (income) expense	1,719		(60)	
Other (income) expense	(121)		(69)	
Total other (income) expense	 1,598		(129)	
Net loss	\$ (24,581)	\$	(8,208)	

#### Net product revenues

Net product revenues were \$1.3 million for the three months ended June 30, 2018 and were related primarily to sales of XHANCE through the Xperience program. We did not record any net product revenues during the three months ended June 30, 2017.

#### Cost of product sales

Cost of product sales were \$0.4 million for the three months ended June 30, 2018 and consisted of XHANCE inventory sold during the period. We did not record any cost of product sales during the three months ended June 30, 2017.

## Research and development expense

Research and development expense was \$2.0 million and \$4.7 million for the three months ended June 30, 2018 and 2017, respectively. The \$2.7 million decrease was attributable primarily to:

- a \$2.1 million decrease in regulatory and medical affairs expenses, including personnel, bonus and administrative expenses, as a
  result of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of
  XHANCE in September 2017; and
- a \$0.8 million decrease related to the substantial completion of the preparation of contract manufacturing capabilities prior to the receipt of FDA approval of XHANCE in September of 2017 in anticipation of the expected commercial launch of XHANCE in the US for the treatment of nasal polyps.

## These decreases were offset by:

a \$0.2 million increase in clinical expenses related to our early research programs and the preparation for our planned clinical trials of XHANCE for a follow-on indication for the treatment of chronic sinusitis and FDA-mandated pediatric studies.

#### Selling, general and administrative expense

Selling, general and administrative expense was \$21.9 million and \$3.6 million for the three months ended June 30, 2018 and 2017, respectively. The \$18.3 million increase was due primarily to:

- a \$8.2 million increase in sales and marketing expenses related to our preparation for the commercial launch of XHANCE for the treatment of nasal polyps, of which:
  - \$4.8 million related to our contracted nurse educator team and the deployment of our contract sales force; and

- \$3.4 million related primarily to marketing expenses for XHANCE;
- a \$4.8 million increase in personnel and bonus expenses due to increases in headcount;
- a \$2.1 million increase in regulatory and medical affairs expenses, including personnel, bonus, and administrative expenses, as a result
  of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of
  XHANCE in September 2017;
- a \$1.1 million increase in insurance and facilities expenses and professional fees to support our expanding infrastructure to prepare for the commercial launch of XHANCE and operate as a public company; and
- a \$1.8 million increase in stock-based compensation expense.

#### These increases were offset by:

a \$0.5 million decrease in patent and consultancy expenses.

#### Interest (income) expense, net

Interest (income) expense, net, was \$1.7 million and \$(0.1) million for the three months ended June 30, 2018 and 2017, respectively. The increase in interest (income) expense, net, for the three months ended June 30, 2018 was related to \$2.3 million in interest expense on our long-term debt, offset by \$0.6 million in interest income. Interest income increased \$0.5 million during the three months ended June 30, 2018, as compared to the three months ended June 30, 2017 as a result of higher cash balances. We did not record any interest expense for the three months ended June 30, 2017.

## Other (income) expense, net

Other income, net was \$0.1 million for the three months ended June 30, 2018 and 2017. The income in both periods was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

## Comparison of six months ended June 30, 2018 and 2017

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

	 Six Months Ended June 30,			
	2018	2017		
Net product revenues	\$ 2,139	\$		
Cost of product sales	551			
Gross margin	 1,588		_	
Operating expenses:				
Research and development	3,747		8,979	
Selling, general and administrative	49,871		6,661	
Total operating expenses	 53,618		15,640	
Loss from operations	(52,030)		(15,640)	
Other (income) expense:				
Interest (income) expense	3,436		767	
Other (income) expense	(312)		(124)	
Total other (income) expense	3,124		643	
Net loss	\$ (55,154)	\$	(16,283)	

#### Net revenue

Net revenue were \$2.1 million for the six months ended June 30, 2018, related directly to the commercial launch of XHANCE. As planned, the majority of the net revenue was related to XHANCE sales through the Xperience program, with the balance generated through the traditional retail channel. We did not record any net revenue during the six months ended June 30, 2017.

## Cost of product sales

Cost of product sales related to the sale of XHANCE were \$0.6 million for the six months ended June 30, 2018. We did not record any cost of product sales during the six months ended June 30, 2017.

#### Research and development expense

Research and development expense was \$3.7 million and \$9.0 million for the six months ended June 30, 2018 and 2017, respectively. The \$5.3 million decrease was attributable primarily to:

- a \$3.8 million decrease in regulatory and medical affairs expenses, including personnel, bonus and administrative expenses, as a
  result of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of
  XHANCE in September 2017; and
- a \$1.8 million decrease related to the substantial completion of the preparation of contract manufacturing capabilities prior to the receipt of FDA approval of XHANCE in September of 2017 in anticipation of the expected commercial launch of XHANCE in the US for the treatment of nasal polyps.

These decreases were offset by:

 a \$0.5 million increase in clinical expenses related to our early research programs and the preparation for our planned clinical trials of XHANCE for a follow-on indication for the treatment of chronic sinusitis and FDA-mandated pediatric studies.

#### Selling, general and administrative expense

Selling, general and administrative expense was \$49.9 million and \$6.7 million for the six months ended June 30, 2018 and 2017, respectively. The \$43.2 million increase was due primarily to:

- a \$23.6 million increase in sales and marketing expenses related to our preparation for the commercial launch of XHANCE for the treatment of nasal polyps, of which:
  - \$14.3 million related to our contracted nurse educator team and the deployment of our contract sales force; and
  - \$9.3 million related primarily to marketing expenses for XHANCE;
- a \$9.0 million increase in personnel and bonus expenses due to increases in headcount;
- a \$3.8 million increase in regulatory and medical affairs expenses, including personnel, bonus, and administrative expenses, as a result
  of a shift in departmental focus from research and development to commercialization activities as a result of the FDA approval of
  XHANCE in September 2017;
- a \$2.0 million increase in facilities expense, professional fees and consultancy expenses to support our expanding infrastructure to
  prepare for the commercial launch of XHANCE and operate as a public company; and
- a \$3.2 million increase in stock-based compensation expense.

#### Interest (income) expense, net

Interest (income) expense, net, was \$3.4 million and \$0.8 million for the six months ended June 30, 2018 and 2017, respectively. The increase in interest (income) expense, net, for the six months ended June 30, 2018 was related to \$4.5 million in interest expense on our long-term debt, offset by \$1.1 million in interest income. Interest income increased \$1.0 million during the six months ended June 30, 2018, as compared to the six months ended June 30, 2017 as a result of higher cash balances. Interest expense for the six months ended June 30, 2017 was related to our convertible notes, which were converted to shares of preferred stock in March 2017.

#### Other (income) expense, net

Other income, net, was \$0.3 million and \$0.1 million for the six months ended June 30, 2018 and 2017, respectively. The income in both periods was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

#### Liquidity and Capital Resources

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We incurred net losses of \$55.2 million and \$16.3 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had an accumulated deficit of \$266.4 million.

We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues received under the terms of the AVP-825 License Agreement. As of June 30, 2018, we had \$245.0 million in cash and cash equivalents.

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

		Six Months Ended June 30,			
	2018 20			2017	
Net cash used in operating activities	\$	\$ (47,493) \$ (		(13,634)	
Net cash used in investing activities		(881)		(711)	
Net cash provided by financing activities		58,477		36,434	
Effects of exchange rates on cash and cash equivalents		25		(6)	
Net increase in cash and cash equivalents	\$	10,128 \$ 22,0		22,083	

#### **Operating activities**

Cash used in operating activities increased by \$33.9 million, from \$13.6 million for the six months ended June 30, 2017 to \$47.5 million for the six months ended June 30, 2018. The increase in cash used in operating activities was attributable primarily to the increase in our net loss from \$16.3 million for the six months ended June 30, 2017 to \$55.2 million for the six months ended June 30, 2018. The increase in net loss is attributable primarily to our preparation and ongoing efforts to support the commercial launch of XHANCE.

#### Investing activities

Cash used in investing activities increased \$0.2 million from \$0.7 million for the six months ended June 30, 2017 to \$0.9 million for the six months ended June 30, 2018. The increase was related primarily to purchases of equipment in connection with infrastructure expansion activities to support the commercial launch of XHANCE and our transition to a public company.

#### Financing activities

Cash provided by financing activities was \$58.5 million for the six months ended June 30, 2018, driven by net proceeds of \$59.9 million as a result of a June 2018 underwritten public offering (the Offering) of 5,750,000 shares of Company common stock (Common Stock) at a price of \$22.25 per share, which consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. This receipt was partially offset by \$2.5 million of cash paid for financing costs during the six months ended June 30, 2018 related to our IPO and debt offering in the fourth quarter of 2017. Cash provided by financing activities was \$36.4 million for the six months ended June 30, 2017, driven by the receipt of \$36.4 million in net proceeds from the sale of our Series D Preferred Stock.

### Projected 2018 operating expenses

We now expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2018 will be in the range of \$117.0 - \$121.0 million (previous estimate of \$119.0 - \$125.0 million.)

#### Future funding requirements

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

- maintain and expand our commercial infrastructure to support the sales and marketing for XHANCE;
- maintain and expand our contract specialty sales force, which currently consists of approximately 80 territory managers, to market XHANCE for the treatment of nasal polyps;
- continue advertising and other promotional activities to support the commercialization of XHANCE;
- continue to provide co-pay and other patient support programs;
- continue clinical development activities for XHANCE, including FDA-mandated pediatric studies and clinical trials for a supplemental indication for the treatment of chronic sinusitis;
- hire additional staff and add operational, financial and information systems to execute our business plan;

- maintain, expand and protect our patent portfolio;
- continue to contract to manufacture XHANCE and our other product candidates;
- service our debt obligations under the Senior Secured Notes issued in December 2017;
- continue research and development activities for additional product candidates; and
- maintain infrastructure necessary to operate as a public company.

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

- the success of our commercialization of XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to obtain adequate insurance coverage and reimbursement for XHANCE;
- the cost and timing of commercialization activities for XHANCE, including product manufacturing, marketing, sales and distribution;
- net revenue received from commercial sales of XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the supplemental indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- potential future licensing revenue from the AVP-825 License Agreement;
- fluctuations in the three-month LIBOR-based floating interest rate of our Senior Secured Notes;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates; and
- the extent to which we in-license, acquire or otherwise partner in development of other products, product candidates or technologies.

It is difficult to predict future liquidity requirements and the Company may need to secure additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources in order to service the Company's existing obligations under outstanding Senior Secured Notes, including repayment, and to carry out all of the Company's planned development and commercial activities. Additional capital, if required, may not be available on a timely basis, on favorable terms, or at all, and such capital, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If additional capital is not secured when required, the Company may need to delay or curtail its operations until such funding is received. If we cannot expand our operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received. Additionally, we may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

## 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 June 30, 2018:

	 Total		Less than 1 year		1-3 years		3-5 years		More than 5 years	
				(in the	ousands)					
Operating leases <sup>(1)</sup>	\$ 2,675	\$	897	\$	1,778	\$	_	\$	_	
Long-term debt <sup>(2)</sup>	\$ 120,104		8,697		17,276		94,131		_	
Purchase obligations <sup>(3)</sup>	\$ 9,339		9,339		_		_		_	
Total	\$ 132,118	\$	18,933	\$	19,054	\$	94,131	\$	_	

<sup>(1)</sup> Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England. In January 2018, we amended our existing office lease agreement for our headquarters in Yardley, PA (the Lease Amendment). Under the terms of the Lease Amendment, our leased office space was increased from approximately 20,050 square feet to approximately 30,000 square feet and the term of the lease was extended from March 31, 2018 to May 31, 2021 (the Extended Term). The rent payments during the Extended Term will be approximately \$2.7 million in the aggregate and we will also be required to pay our proportionate share of certain operating costs and property taxes applicable to the leased premises.

<sup>(2)</sup> Reflects principal, interest obligations and exit fees pursuant to the Note Purchase Agreement entered into on December 29, 2017. The Senior Secured Notes bear interest at 9.0% plus the three-month LIBOR rate, subject to a 1.0% floor. The Company is required to make quarterly, interest only payments until the maturity date. Interest amounts included above are calculated at the quarterly rate as of June 30, 2018.

<sup>(3)</sup> Reflects non-cancellable services under an agreement we entered into in November 2017 with a contract sales organization for the recruitment, deployment and management of a contract sales force to market XHANCE in the U.S. Subject to certain limited exceptions, we may not terminate this agreement until after the first anniversary of the deployment of the sales force (which deployment occurred in March 2018). We estimate the expenses related to the non-cancellable services during this period to be approximately \$9.3 million. Thereafter, we may terminate the agreement subject to potential early termination fees ranging from \$0.1 million to \$0.7 million.

## **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, 2017, as filed with the SEC on March 13, 2018, have not materially changed, with the exception of the revenue recognition policy pursuant to the adoption of ASC 606, *Revenue from Contracts with Customers*, which is described in Note 3 to our unaudited interim consolidated financial statements of this Form 10-Q.

## **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

There have been no material changes to our market risk since December 31, 2017.

## **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 management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

## **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 June 30, 2018 that have 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**

You should carefully consider the risk factors described under the caption "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 13, 2018. There have been no material changes to the risk factors disclosed in our Form 10-K, with the exception of the following:

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

Approximately 12% and 41% of our XHANCE net revenue during the three and six months ended June 30, 2018, respectively, were to the three largest pharmaceutical wholesalers. If any of these wholesalers ceases to purchase our product for any reason, then unless and until the remaining wholesalers increase their purchases of XHANCE or alternative distribution channels are established:

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

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

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Issuances of Unregistered Securities

None.

## Use of Proceeds

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

On October 17, 2017 we received proceeds from the IPO of \$128.3 million, which was net of underwriting discounts and commissions of approximately \$9.7 million. Of this amount, we paid offering expenses of approximately \$2.8 million.

There has been no material change in the use of proceeds from the IPO as described in the final prospectus for the IPO filed with the SEC on October 12, 2017 (Final Prospectus). During the period from the closing of our IPO to June 30, 2018, we used \$69.9 million of the proceeds as follows:

- approximately \$44.8 million to support the planned launch of XHANCE, including investments in marketing and sales, inventory and our commercial infrastructure;
- approximately \$4.7 million to fund further development efforts for XHANCE; and
- approximately \$20.4 million to fund other working capital and general corporate purposes, including costs of operating as a public company.

The foregoing amounts represent the Company's reasonable estimate of the amount of net offering proceeds applied to such activities instead of the actual amount of net offering proceeds used. The balance of the funds totaling approximately \$55.6 million are expected to be used in a manner consistent with the use of proceeds described in the Final Prospectus.

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

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **ITEM 5. OTHER INFORMATION**

On August 14, 2018, we delivered a written notice of termination to Ximedica, LLC (Ximedica) providing for the termination of that certain manufacturing services agreement, dated as of August 30, 2017, by and between us and OptiNose UK Ltd., OptiNose AS and Ximedica (Manufacturing Services Agreement). The Manufacturing Services Agreement has an initial term of two years from September 18, 2017 and provides for the manufacture of the liquid delivery sub-assembly of XHANCE. Pursuant to our rights to terminate the Manufacturing Services Agreement at any time and pursuant to our notice of termination to Ximedica, the Manufacturing Services Agreement will terminate effective as of February 14, 2019. The termination of this agreement was in connection with an initiative to reduce XHANCE manufacturing costs. We do not expect the termination of this agreement to adversely impact commercial supply and expect to complete the transfer of the manufacturing activities to another party prior to the effective date of the termination.

## **ITEM 6. EXHIBITS**

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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	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).
3.2	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).
10.1 *	Form of Indemnification Agreement+
31.1 *	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange</u> <u>Act.</u>
31.2 *	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange</u> <u>Act.</u>
32.1 *	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2 *	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.INS *	XBRL Instance Document.
101.SCH *	XBRL Taxonomy Extension Schema Document.
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Filed herewith.

+ Indicates management contract or compensatory plan.

## 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: August 14, 2018

## OPTINOSE, INC.

By:

/s/ KEITH A. GOLDAN Name: Keith A. Goldan Title: Chief Financial Officer (Principal Financial and Accounting Officer)

## **INDEMNIFICATION AGREEMENT**

This Indemnification Agreement (this "<u>Agreement</u>") is made as of \_\_\_\_\_\_, 201\_\_\_ by and between OptiNose, Inc., a Delaware corporation (the "<u>Corporation</u>"), in its own name and on behalf of its direct and indirect subsidiaries, and \_\_\_\_\_\_, an individual ("<u>Indemnitee</u>"). This Agreement supersedes and replaces any and all previous Agreements between the Corporation and Indemnitee covering the subject matter of this Agreement.

## RECITALS:

**WHEREAS**, directors, officers, employees, controlling persons, fiduciaries and other agents ("<u>Representatives</u>") in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the corporation or business enterprise itself;

**WHEREAS**, the Board of Directors of the Company (the "<u>Board</u>") believes that highly competent persons have become more reluctant to serve corporations as Representatives unless they are provided with adequate protection through insurance and adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation or business enterprise;

**WHEREAS**, the Board has determined that the increased difficulty in attracting and retaining highly competent persons is detrimental to the best interests of the Corporation and its stockholders and that the Corporation should act to assure such persons that there will be increased certainty of protection against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the Corporation;

**WHEREAS**, it is reasonable, prudent and necessary for the Corporation contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Corporation free from undue concern regarding such risks;

**WHEREAS**, (a) the Amended and Restated Bylaws of the Corporation (the "<u>Bylaws</u>") require indemnification of the officers and directors of the Corporation, (b) Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware, as it may be amended from time to time (the "<u>DGCL</u>") and (c) the Bylaws and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive and thereby contemplate that contracts may be entered into between the Corporation and its Representatives with respect to indemnification;

**WHEREAS**, this Agreement is a supplement to and in furtherance of the Bylaws and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefore, nor to diminish or abrogate any rights of Indemnitee thereunder; and

**WHEREAS**, (a) Indemnitee does not regard the protection available under the Bylaws and insurance as adequate in the present circumstances, (b) Indemnitee may not be willing to serve or continue to serve as a Representative without adequate protection, (c) the Corporation desires Indemnitee to serve or continue to serve in such capacity and (d) Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Corporation on the condition that he/she be so indemnified.

#### AGREEMENT:

**NOW, THEREFORE**, in consideration of the premises and the covenants contained herein, the Corporation and Indemnitee do hereby covenant and agree as follows:

Section 1. <u>Definitions</u>.

(a) As used in this Agreement:

"<u>Agreement</u>" shall have the meaning ascribed to such term in the Preamble hereto.

"<u>Beneficial Owner</u>" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act (as defined below); provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Corporation approving a merger of the Corporation with another entity.

"Board" shall have the meaning ascribed to such term in the Recitals hereto.

"Bylaws" shall have the meaning ascribed to such term in the Recitals hereto.

"Certificate of Incorporation" shall mean the Fourth Amended and Restated Certificate of Incorporation of the Corporation.

A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below), other than the Sponsor Entities (as defined below), is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Corporation representing fifteen percent (15%) or more of the combined voting power of the Corporation's then outstanding securities, unless the change in relative Beneficial Ownership of the Corporation's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Corporation to effect a transaction described herein) whose election by the Board or nomination for election by the Corporation's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Corporation with any other entity, other than a merger or consolidation which would result in the voting securities of the Corporation outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity in any such transaction) more than fifty percent (50%) of the combined voting power of the voting securities of such surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;

iv. Liquidation. The approval by the stockholders of the Corporation of a complete liquidation of the Corporation or an agreement for the sale or disposition by the Corporation of all or substantially all of the Corporation's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Corporation is then subject to such reporting requirement.

"Corporate Status" describes the status of an individual who is or was a Representative of an Enterprise.

"<u>Corporation</u>" shall have the meaning ascribed to such term in the Preamble hereto.

"<u>DGCL</u>" shall have the meaning ascribed to such term in the Recitals hereto.

"<u>Enterprise</u>" shall mean the Corporation and any other Person, employee benefit plan, joint venture or other enterprise of which Indemnitee is or was serving at the request of the Corporation as a Representative.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time, and the rules and regulations thereunder.

"Expenses" shall include all reasonable costs, expenses, fees and charges, including, without limitation, attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include, without limitation, (i) expenses incurred in connection with any appeal resulting from any Proceeding, including, without limitation, the premium, security for, and other costs relating to any cost bond, supersedes bond, or other appeal bond or its equivalent, (ii) for purposes of Section 12(d) only, expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise, (iii) any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement (on a grossed up basis), (iv) excise taxes and penalties under the Employee Retirement Income Security Act of 1974, and (v) any interest, assessments or other charges in respect of the foregoing.

"Indemnitee" shall have the meaning ascribed to such term in the Preamble hereto.

"<u>Indemnity Obligations</u>" shall mean all obligations of the Corporation to Indemnitee under this Agreement, including, without limitation, the Corporation's obligations to provide indemnification to Indemnitee and advance Expenses to Indemnitee under this Agreement.

"<u>Independent Counsel</u>" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five (5) years has been, retained to represent: (i) the Corporation or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements) or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder; <u>provided</u>, <u>however</u>, that the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Corporation or Indemnitee in an action to determine Indemnitee's rights under this Agreement.

"<u>Liabilities</u>" shall mean all claims, liabilities, damages, losses, judgments, orders, fines, penalties and other amounts payable in connection with, arising out of, in respect of, relating to or occurring as a direct or indirect consequence of, any Proceeding, including, without limitation, amounts paid in whole or partial settlement of any Proceeding, all Expenses incurred in complying with any judgment, order or decree issued or entered in connection with any Proceeding or any settlement agreement, stipulation or consent decree entered into or issued in settlement of any Proceeding, and any consequential damages resulting from any Proceeding or the settlement, judgment, or result thereof.

"<u>Person</u>" shall mean any individual, corporation, partnership, limited partnership, limited liability company, trust, governmental agency or body or any other legal entity.

"<u>Proceeding</u>" shall include any threatened, pending or completed action, claim, suit, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, formal or informal hearing, inquiry or investigation, administrative hearing or any other actual, threatened or completed judicial, administrative or arbitration proceeding (including, without limitation, any such proceeding under the Securities Act of 1933, as amended, or the Exchange Act or any other federal law, statute or regulation), whether brought in the right of the Corporation or otherwise, and whether of a civil, criminal, administrative legislative or

investigative nature, including any appeal therefrom, in which Indemnitee was, is or will be, or is threatened to be, involved as a party, potential party, non-party witness or otherwise (i) by reason of the fact that Indemnitee is or was a Representative of the Corporation, (ii) by reason of any actual or alleged action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee's part while acting as Representative of the Corporation or (iii) by reason of the fact that Indemnitee is or was serving at the request of the Corporation as a Representative of another Person, whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

"Representative" shall have the meaning ascribed to such term in the Recitals hereto.

"<u>Sponsor Entities</u>" shall mean funds affiliated with Avista Capital Partners and any of their respective Affiliates who beneficially own shares of common stock, par value \$0.001 per share, of the Corporation, and any securities into which such shares of common stock shall have been changed or any securities resulting from any reclassification or recapitalization of such shares of common stock from time to time; <u>provided</u>, <u>however</u>, that neither the Corporation nor any of its subsidiaries shall be considered Sponsor Entities hereunder.

"Submission Date" shall have the meaning ascribed to such term in Section 11(a).

(b) For the purpose hereof, references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Corporation" shall include any service as a Representative of the Corporation which imposes duties on, or involves services by, such Representative with respect to an employee benefit plan, its participants or beneficiaries; and a Person who acted in good faith and in a manner he/she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in manner "not opposed to the best interests of the Corporation" as referred to in this Agreement.

Section 2. <u>Indemnity in Third-Party Proceedings</u>. The Corporation shall indemnify and hold harmless Indemnitee, to the fullest extent permitted by applicable law, from and against all Liabilities and Expenses suffered or incurred by Indemnitee or on Indemnitee's behalf in connection with or as a consequence of any Proceeding (other than any Proceeding brought by or in the right of the Corporation to procure a judgment in its favor which shall be governed by the provisions set forth in Section 3 below), if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in, or not opposed to, the best interests of the Corporation and, in the case of a criminal proceeding, had no reasonable cause to believe that his conduct was unlawful. For the avoidance of doubt, a finding, admission or stipulation that an Indemnitee has not met such applicable standard of conduct or that Indemnitee acted with gross negligence or recklessness shall not, of itself, be a defense to any action pursuant to this Agreement or create a presumption that such Indemnitee has failed to meet the standard of conduct required for indemnification in this Section 2.

Section 3. Indemnity in Proceedings by or in the Right of the Corporation. The Corporation shall indemnify and hold harmless Indemnitee, to the fullest extent permitted by applicable law, from and against all Liabilities and Expenses suffered or incurred by Indemnitee or on Indemnitee's behalf in connection with or as a consequence of any Proceeding brought by or in the right of the Corporation to procure a judgment in its favor, or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in, or not opposed, to the best interests of the Corporation. No indemnification for Liabilities and Expenses shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Corporation, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability, but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such Liabilities and Expenses which the Court of Chancery or such other court shall deem proper. For the avoidance of doubt, a finding, admission or stipulation that an Indemnitee has not met such applicable standard of conduct or that Indemnitee acted with gross negligence or recklessness shall not, of itself, be a defense to any action pursuant to this Agreement or create a presumption that such Indemnitee has failed to meet the standard of conduct required for indemnification in this Section 3.

Section 4. <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provisions of this Agreement, and without limiting the rights of Indemnitee under any other provision hereof, to the extent that Indemnitee is a party to (or a participant in) any Proceeding and is successful on the merits or otherwise (including,

without limitation, settlement thereof), as to one or more but less than all claims, issues or matters in such Proceeding, in whole or in part, then the Corporation shall indemnify Indemnitee, to the fullest extent permitted by applicable law, against all Liabilities and Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf, in connection with or as a consequence of each successfully resolved claim, issue or matter. For purposes of this Section 4 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 5. <u>Partial Indemnification</u>. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Corporation for some or a portion of Expenses, but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 6. <u>Indemnification for Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Liabilities and Expenses suffered or incurred by him or on his behalf in connection therewith.

### Section 7. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 2, 3, 4 or 5, the Corporation shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to, or threatened to be made a party to, any Proceeding (including, without limitation, a Proceeding by or in the right of the Corporation to procure a judgment in its favor), by reason of Indemnitee's Corporate Status.

(b) For purposes of Section 7(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

(i) to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to, or replacement of, the DGCL, and

(ii) to the fullest extent authorized or permitted by any amendments to, or replacements of, the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 8. <u>Exclusions</u>. Notwithstanding any provision in this Agreement, the Corporation shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) subject to Section 14, for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Corporation within the meaning of Section 16(b) of the Exchange Act (as defined in Section 1(a) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Corporation by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Corporation pursuant to Section 304 of the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Corporation of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Corporation by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section 13(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Corporation or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the Corporation under applicable law.

Section 9. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 13(d)), the Corporation shall advance, to the fullest extent permitted by law, Expenses incurred by Indemnitee in connection with any Proceeding (or part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board, and such advancement shall be made within ten (10) days after the receipt by the Corporation of a statement or statements requesting such advances from time to time, whether prior to, or after, final disposition of any Proceeding. Advances shall be unsecured and interest free. Indemnitee shall be entitled to continue to receive advancement of Expenses pursuant to this Section 9 unless and until the matter of Indemnitee's entitlement to indemnification hereunder has been finally adjudicated by court order or judgment from which no further right or appeal exists. Advances shall be made without regard to Indemnitee's ability to repay Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 13(d), advances shall include any and all Expenses incurred pursuing an action to enforce this right of advancement, including, without limitation, Expenses incurred preparing and forwarding statements to the Corporation to support the advances claimed. Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Corporation. No other form of undertaking shall be required other than the execution of this Agreement. This Section 9 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 8.

### Section 10. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Corporation in writing of any Proceeding with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Corporation shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Corporation a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. Any delay or failure by Indemnitee to notify the Corporation hereunder will not relieve the Corporation from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, nor shall such delay or failure constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Corporation shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) In the event Indemnitee seeks indemnification and/or advancement of Expenses with respect to any Proceeding, Indemnitee may, at Indemnitee's option, (i) retain legal counsel selected by Indemnitee and approved by the Corporation (which approval shall not to be unreasonably withheld, conditioned or delayed) to defend Indemnitee in such Proceeding, at the sole expense of the Corporation or (ii) have the Corporation assume the defense of Indemnitee in the Proceeding, in which case the Corporation shall assume the defense of such Proceeding with legal counsel selected by the Corporation and approved by Indemnitee (which approval shall not be unreasonably withheld, conditioned or delayed) within ten (10) days of the Corporation's receipt of written notice of Indemnitee's election to cause the Corporation to do so. If the Corporation is required to assume the defense of any such Proceeding, it shall engage legal counsel for such defense, and shall be solely responsible for all Expenses of such legal counsel and otherwise of such defense. Such legal counsel may represent both Indemnitee and the Corporation (and/or any other party or parties entitled to be indemnified by the Corporation with respect to such matter) unless, in the reasonable opinion of legal counsel to Indemnitee, there is a conflict of interest between Indemnitee and the Corporation (or any other such party or parties) or there are legal defenses available to Indemnitee that are not available to the Corporation (or any such other party or parties). Notwithstanding either party's assumption of responsibility for defense of a Proceeding, each party shall have the right to engage separate legal counsel at its own expense. The party having responsibility for defense of a Proceeding shall provide the other party and its legal counsel with all copies of pleadings and material correspondence relating to the Proceeding. Indemnitee and the Corporation shall reasonably cooperate in the defense of any Proceeding with respect to which indemnification is sought hereunder, regardless of whether the Corporation or Indemnitee assumes the defense thereof. Indemnitee may not settle or compromise any Proceeding without the prior written consent of the Corporation (which consent shall not be unreasonably withheld, conditioned or delayed). The Corporation may not settle or compromise any Proceeding without the prior written consent of Indemnitee (which consent shall not be unreasonably withheld, conditioned or delayed).

Section 11. Procedure Upon Application for Indemnification.

(a) Upon receipt of a written request by Indemnitee for indemnification pursuant to Section 10(a) (the "Submission Date"), if any determination by the Corporation is required by applicable law with respect to Indemnitee's ultimate entitlement to indemnification, such determination shall be made (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Corporation. If it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the Person(s) making such determination with respect to Indemnitee's entitlement to indemnification, including, without limitation, providing to such Person(s), upon reasonable advance request, any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Expenses incurred by Indemnitee in so cooperating with the Person(s) making such determination shall be borne by the Corporation (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Corporation hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Corporation will not deny any written request for indemnification hereunder made in good faith by Indemnitee unless a determination as to Indemnitee's entitlement to such indemnification described in this Section 11(a) has been made. The Corporation agrees to pay Expenses of the Independent Counsel referred to above and to fully indemnify the Independent Counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(b) In the event that the determination of entitlement to indemnification is to be made by the Independent Counsel pursuant to Section 11(a) hereof, the Independent Counsel shall be selected as provided in this Section 11(b). If a Change in Control has not occurred, the Independent Counsel shall be selected by the Board, and the Corporation shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control has occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Corporation advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Corporation, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Corporation or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1(a) of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court of Chancery has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 10(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Corporation or Indemnitee may petition the Delaware Court of Chancery for resolution of any objection which shall have been made by the Corporation or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 11(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 13(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

#### Section 12. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the Person(s) making such determination shall, to the fullest extent permitted by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Corporation shall, to the fullest extent permitted by law, have the burden of proof to overcome that presumption with clear and convincing evidence in connection with the making by any Person(s) of any determination contrary to that presumption. Neither the failure of the Corporation (including, without limitation, by its directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met

the applicable standard of conduct, nor an actual determination by the Corporation (including, without limitation, by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 12(e), if the Person(s) empowered or selected under Section 10 hereof to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Corporation of the request therefore, the requisite determination of entitlement to indemnification shall, to the fullest extent permitted by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent a prohibition of such indemnification under applicable law; <u>provided</u>, <u>however</u>, that such sixty (60) day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if (i) the determination is to be made by the Independent Counsel and there is an objection to the selection of the Independent Counsel and (ii) the Person(s) making such determination requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 12(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 11(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Corporation of the request for such determination the Board has resolved to submit such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he/she reasonably believed to be in, or not opposed to, the best interests of the Corporation or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

(d) <u>Reliance as Safe Harbor</u>. For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise, or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. The provisions of this Section 12(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) <u>Actions of Others</u>. The knowledge and/or actions, or failure to act, of any Representative (other than Indemnitee) of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

#### Section 13. Remedies of Indemnitee.

(a) Subject to Section 12(d), in the event that (i) a determination is made pursuant to Section 11 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 9 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 11(a) of this Agreement within ninety (90) days after the Submission Date, (iv) payment of indemnification is not made pursuant to Section 4, 5, 6 or 11(a) of this Agreement within ten (10) days after receipt by the Corporation of a written request therefore, (v) payment of indemnification pursuant to Section 2, 3 or 7 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or (vi) in the event that the Corporation or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, Indemnitee, the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification and/or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within one hundred and eighty (180) days following the date on which Indemnitee first has the right to

commence such proceeding pursuant to this Section 13(a). The Corporation shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 11 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 13 shall be conducted in all respects as a *de novo* trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 13, the Corporation shall have the burden of proving by clear and convincing evidence Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 11 of this Agreement that Indemnitee is entitled to indemnification, the Corporation shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 13, absent (i) a misstatement by the Indemnitee of a material fact, or an omission by the Indemnitee of a material fact necessary to make the Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Corporation shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 13 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Corporation is bound by all the provisions of this Agreement. It is the intent of the Corporation that, to the fullest extent permitted by law, Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to Indemnitee hereunder. In addition, the Corporation shall, to the fullest extent permitted by law, indemnity Indemnitee against any and all such Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Corporation of a written request therefore) advance, to the fullest extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Corporation under this Agreement or under any directors' and officers' liability insurance policies maintained by the Corporation if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only in connection with each successfully resolved claim, issue or matter, or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding; <u>provided</u>, that in absence of any such determination with respect to such Proceeding, the Corporation shall pay Liabilities and advance Expenses with respect to such Proceeding as if Indemnitee has been determined to be entitled to indemnification and advancement of Expenses with respect to such Proceeding.

### Section 14. Non-Exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders, a resolution of directors or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in applicable law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation, the Bylaws and/or this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) The Corporation hereby acknowledges that Indemnitee may have certain rights to indemnification, advancement of Expenses and/or insurance provided by one or more Persons with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity). The Corporation hereby acknowledges and agrees that

(i) the Corporation shall be the indemnitor of first resort with respect to any Proceeding, Expense, Liability or matter that is the subject of the Indemnity Obligations, (ii) the Corporation shall be primarily liable for all Indemnity Obligations and any indemnification afforded to Indemnitee in respect of any Proceeding, Expense, Liability or matter that is the subject of Indemnity Obligations, whether created by law, organizational or constituent documents, contract (including, without limitation, this Agreement) or otherwise, (iii) any obligation of any other Persons with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) to indemnify Indemnitee and/or advance Expenses to Indemnitee in respect of any proceeding shall be secondary to the obligations of the Corporation hereunder, (iv) the Corporation shall be required to indemnify Indemnitee and advance Expenses to Indemnitee hereunder to the fullest extent provided herein without regard to any rights Indemnitee may have against any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or insurer of any such Person and (v) the Corporation irrevocably waives, relinquishes and releases any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) from any claim of contribution, subrogation or any other recovery of any kind in respect of amounts paid by the Corporation hereunder. In the event that any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or their insurers advances or extinguishes any liability or loss which is the subject of any Indemnity Obligation owed by the Corporation or payable under any insurance policy provided under this Agreement, such payor shall have a right of subrogation against the Corporation or its insurer or insurers for all amounts so paid which would otherwise be payable by the Corporation or its insurer or insurers under this Agreement. In no event will payment of an Indemnity Obligation of the Corporation under this Agreement by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) or their insurers, affect the obligations of the Corporation hereunder or shift primary liability for any Indemnity Obligation to any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity). Any indemnification and/or insurance or advancement of Expenses provided by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity), with respect to any liability arising as a result of Indemnitee's Corporate Status or capacity as an officer or director of any Person, is specifically in excess of any Indemnity Obligation of the Corporation or valid and any collectible insurance (including, without limitation, any malpractice insurance or professional errors and omissions insurance) provided by the Corporation under this Agreement, and any obligation to provide indemnification and/or insurance or advance Expenses provided by any other Person with whom or which Indemnitee may be associated (including, without limitation, any Sponsor Entity) shall be reduced by any amount that Indemnitee collects from the Corporation as an indemnification payment or advancement of Expenses pursuant to this Agreement.

(c) The Corporation shall use its best efforts to obtain and maintain in full force and effect an insurance policy or policies providing liability insurance for Representatives of the Corporation or of any other Enterprise, and Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such Representative under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Corporation maintains an insurance policy or policies providing liability insurance for Representatives of the Corporation or of any other Enterprise, the Corporation shall give prompt notice of the commencement of such Proceeding to the insurers in accordance with the procedures set forth in the respective policy or policies. The Corporation shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies. In the event of a Change in Control or the Corporation's becoming insolvent, the Corporation shall maintain in force any and all insurance policies then maintained by the Corporation in providing insurance (directors' and officers' liability, fiduciary, employment practices or otherwise) in respect of Indemnitee for a period of six years thereafter.

(d) In the event of any payment under this Agreement, the Corporation shall not be subrogated to, and hereby waives any rights to be subrogated to, any rights of recovery of Indemnitee, including, without limitation, rights of indemnification provided to Indemnitee from any other Person or entity with whom Indemnitee may be associated (including, without limitation, any Sponsor Entity) as well as any rights to contribution that might otherwise exist; <u>provided</u>, <u>however</u>, that the Corporation shall be subrogated to the extent of any such payment of all rights of recovery of Indemnitee under insurance policies of the Corporation or any of its subsidiaries, and the Indemnitee shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Corporation to brings suit to enforce such rights.

(e) The indemnification and contribution provided for in this Agreement will remain in full force and effect regardless of any investigation made by or on behalf of Indemnitee.

Section 15. <u>Duration of Agreement; Not Employment Contract</u>. This Agreement shall continue until and terminate upon the latest of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a Representative of the Corporation or any other Enterprise and (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 13 of this Agreement relating thereto. This Agreement shall be binding upon the Corporation and its successors and assigns and shall inure to the benefit of Indemnitee and Indemnitee's heirs, executors and administrators. The Corporation shall require and cause any direct or indirect successor (whether by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Corporation, by written agreement, expressly or to assume and agree to perform this agreement in the same manner and to the same extent that the Corporation (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Corporation (or any of its subsidiaries or any Enterprise), if any, is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Corporation (or any of its subsidiaries or any Enterprise), using a will, and Indemnitee and the Corporation (or any of its subsidiaries or any Enterprise), if any, is at will, and Indemnitee and the Corporation (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a Representative of the Corporation, by the Certificate of Incorporation, Bylaws and the DGCL.

Section 16. <u>Severability</u>. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable) shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

#### Section 17. Enforcement.

(a) The Corporation expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a Representative of the Corporation, and the Corporation acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a Representative of the Corporation.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; <u>provided</u>, <u>however</u>, that this Agreement is a supplement to and in furtherance of the Bylaws and applicable law, and shall not be deemed a substitute therefore, nor to diminish or abrogate any rights of Indemnitee thereunder.

(c) The Corporation shall not seek from a court, or agree to, a "bar order" which would have the effect of prohibiting or limiting the Indemnitee's right to receive advancement of expenses under this Agreement.

Section 18. <u>Modification and Waiver</u>. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties thereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver. The failure of any party to enforce any of the provisions of this Agreement shall in no way be construed as a waiver of such provisions and shall not affect the right of such party thereafter to enforce each and every provision of this Agreement in accordance with its terms.

Section 19. <u>Notices</u>. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Corporation.

(b) If to the Corporation to:

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

or to any other address as may have been furnished to Indemnitee by the Corporation.

Section 20. <u>Contribution</u>. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Corporation, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of the Proceeding in order to reflect (a) the relative benefits received by the Corporation and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (b) the relative fault of the Corporation (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 21. <u>Applicable Law and Consent to Jurisdiction</u>. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 13(a), the Corporation and Indemnitee hereby irrevocably and unconditionally (a) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court of Chancery, and not in any other state or federal court in the United States of America or any court in any other country, (b) consent to submit to the exclusive jurisdiction of the Delaware Court of Chancery for purposes of any action or proceeding arising out of or in connection with this Agreement, (c) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court of Chancery and (d) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court of Chancery has been brought in an improper or inconvenient forum.

Section 22. <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Section 23. Third-Party Beneficiaries. The Sponsor Entities are intended third-party beneficiaries of this Agreement.

Section 24. <u>Miscellaneous</u>. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

OPTINOSE, INC.

Name: Peter Miller Title: Chief Executive Officer

[Signature Page to Indemnification Agreement]

INDEMNITEE:

[]

[Signature Page to Indemnification Agreement]

# Schedule to Exhibit 10.1

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.1 except as to the name of the signatory and the date of each signatory's Indemnification Agreement, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

INDEMNITEE	DATE
Peter K. Miller	October 2, 2017
Ramy A. Mahmoud, M.D., M.P.H.	October 2, 2017
Thomas E. Gibbs	October 2, 2017
Keith A. Goldan	October 2, 2017
Michael F. Marino	October 2, 2017
William F. Doyle	October 1, 2017
Sriram Venkataraman	September 29, 2017
Joshua A. Tamaroff	September 29, 2017
Joseph C. Scodari	October 5, 2017
Wilhelmus Groenhuysen	October 5, 2017
Sandra K. Helton	February 22, 2018
Robert P. O'Neil	June 7, 2018

### **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. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2018

<u>/s/ Peter K. Miller</u> 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. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2018

<u>/s/ Keith A. Goldan</u> 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 June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: August 14, 2018

<u>/s/ Peter K. Miller</u> 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 June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: August 14, 2018

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