

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2018

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

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

Commission file number: 001-38241



**OPTINOSE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State of other jurisdiction of incorporation or organization)

**42-1771610**

(I.R.S. Employer Identification Number)

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

(Address of principal executive offices, including zip code)

**(267) 364-3500**

(Registrant's telephone number including area code)

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

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

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

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

The number of shares of the registrant's common stock outstanding at November 9, 2018 was 41,227,530 shares.

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	<a href="#"><u>NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></a>	1
	<a href="#"><u>PART I — FINANCIAL INFORMATION</u></a>	
<a href="#"><u>Item 1.</u></a>		2
	<a href="#"><u>Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017</u></a>	2
	<a href="#"><u>Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017</u></a>	3
	<a href="#"><u>Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017</u></a>	4
	<a href="#"><u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017</u></a>	5
	<a href="#"><u>Notes to Unaudited Interim Consolidated Financial Statements</u></a>	6
<a href="#"><u>Item 2.</u></a>	<a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	16
<a href="#"><u>Item 3.</u></a>	<a href="#"><u>Qualitative and Quantitative Disclosure About Market Risk</u></a>	26
<a href="#"><u>Item 4.</u></a>	<a href="#"><u>Controls and Procedures</u></a>	26
	<a href="#"><u>PART II — OTHER INFORMATION</u></a>	27
<a href="#"><u>Item 1.</u></a>	<a href="#"><u>Legal Proceedings</u></a>	27
<a href="#"><u>Item 1A.</u></a>	<a href="#"><u>Risk Factors</u></a>	27
<a href="#"><u>Item 2.</u></a>	<a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	27
<a href="#"><u>Item 3.</u></a>	<a href="#"><u>Defaults Upon Senior Securities</u></a>	28
<a href="#"><u>Item 4.</u></a>	<a href="#"><u>Mine and Safety Disclosures</u></a>	28
<a href="#"><u>Item 5.</u></a>	<a href="#"><u>Other information</u></a>	28
<a href="#"><u>Item 6.</u></a>	<a href="#"><u>Exhibits</u></a>	29
	<a href="#"><u>Signatures</u></a>	30

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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.

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[Trademark Notice](#)

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

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the potential advantages of XHANCE, our other product candidates and our technologies;
- the potential benefits of our patient affordability 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 pursuit of a supplemental indication for chronic sinusitis with the first trial expected to be initiated in the fourth quarter of 2018 and the second trial expected to be initiated in 2019;
- our expectation that our GAAP operating expenses in 2018 will be between \$112 - \$115 million;
- the potential for XHANCE to be effected by the seasonality impact observed in the INS market;
- our expectation that the average net product revenues per prescription for XHANCE in the fourth quarter of 2018 will be lower than average net product revenues per prescription for XHANCE in the third quarter of 2018;
- future XHANCE prescription growth;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled “Item 1. Financial Statements,” and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by words such as “may,” “will,” “could,” “would,” “should,” “expect,” “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)

	September 30, 2018	December 31, 2017
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 221,491	\$ 234,854
Accounts receivable, net	2,923	—
Grants and other receivables	182	46
Inventory	7,009	2,013
Prepaid expenses and other current assets	1,850	1,254
Total current assets	233,455	238,167
Property and equipment, net	3,957	2,564
Other assets	210	405
Total assets	\$ 237,622	\$ 241,136
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 6,549	\$ 5,893
Accrued expenses	15,645	8,698
Deferred other income	168	186
Total current liabilities	22,362	14,777
Long-term debt, net	72,318	71,863
Other liabilities	212	—
Total liabilities	94,892	86,640
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 41,227,530 and 37,802,556 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	41	38
Additional paid-in capital	434,312	365,838
Accumulated deficit	(291,546)	(211,269)
Accumulated other comprehensive loss	(77)	(111)
Total stockholders' equity	142,730	154,496
Total liabilities and stockholders' equity	\$ 237,622	\$ 241,136

See accompanying notes to unaudited interim consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net product revenues	\$ 1,902	\$ —	\$ 4,042	\$ —
Cost of product sales	319	—	870	—
Gross margin	<u>1,583</u>	<u>—</u>	<u>3,172</u>	<u>—</u>
Operating expenses:				
Research and development	2,989	6,641	6,736	15,620
Selling, general and administrative	22,086	6,553	71,957	13,214
Total operating expenses	<u>25,075</u>	<u>13,194</u>	<u>78,693</u>	<u>28,834</u>
Loss from operations	<u>(23,492)</u>	<u>(13,194)</u>	<u>(75,521)</u>	<u>(28,834)</u>
Other (income) expense:				
Grant and other income	(42)	(30)	(374)	(123)
Interest income	(680)	(61)	(1,738)	(156)
Interest expense	2,361	—	6,855	862
Foreign currency (gains) losses	(8)	(35)	13	(66)
Net loss	<u>\$ (25,123)</u>	<u>\$ (13,068)</u>	<u>\$ (80,277)</u>	<u>\$ (29,351)</u>
Deemed dividend	—	4,105	—	11,255
Accretion to redemption value	—	19	—	1,093
Net loss attributable to common stockholders	<u>\$ (25,123)</u>	<u>\$ (17,192)</u>	<u>\$ (80,277)</u>	<u>\$ (41,699)</u>
Net loss per share of common stock				
basic	<u>\$ (0.61)</u>	<u>\$ (4.23)</u>	<u>\$ (2.04)</u>	<u>\$ (10.25)</u>
diluted	<u>\$ (0.61)</u>	<u>\$ (4.23)</u>	<u>\$ (2.04)</u>	<u>\$ (10.25)</u>
Weighted average common shares outstanding				
basic	<u>41,207,167</u>	<u>4,067,717</u>	<u>39,260,903</u>	<u>4,067,717</u>
diluted	<u>41,207,167</u>	<u>4,067,717</u>	<u>39,260,903</u>	<u>4,067,717</u>

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Comprehensive Loss**  
**For the Three and Nine Months Ended September 30, 2018 and 2017**  
**(in thousands)**  
**(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$ (25,123)	\$ (13,068)	\$ (80,277)	\$ (29,351)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	13	(4)	34	(10)
Comprehensive loss	<u>\$ (25,110)</u>	<u>\$ (13,072)</u>	<u>\$ (80,243)</u>	<u>\$ (29,361)</u>

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Cash Flows**  
**For the Nine Months Ended September 30, 2018 and 2017**  
**(in thousands)**  
**(Unaudited)**

	Nine Months Ended September 30,	
	2018	2017
<b>Operating activities:</b>		
Net loss	\$ (80,277)	\$ (29,351)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
Depreciation and amortization	325	104
Stock-based compensation	6,325	1,800
Amortization of debt discount and issuance costs	291	194
Loss on sale of equipment	1	—
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(2,923)	—
Grants and other receivables	(136)	159
Prepaid expenses and other assets	(380)	2,513
Inventory	(4,686)	(241)
Accounts payable	2,566	(574)
Accrued expenses and other liabilities	7,271	3,518
Cash used in operating activities	<u>(71,623)</u>	<u>(21,878)</u>
<b>Investing activities:</b>		
Purchases of property and equipment	(1,450)	(1,210)
Cash used in investing activities	<u>(1,450)</u>	<u>(1,210)</u>
<b>Financing activities:</b>		
Proceeds from the sale of Series D preferred stock	—	36,494
Proceeds from the sale of common stock	63,969	—
Cash paid for financing costs	(6,464)	(781)
Proceeds from issuance of common stock under employee stock purchase plan	739	—
Proceeds from the exercise of stock options	1,418	—
Cash provided by financing activities	<u>59,662</u>	<u>35,713</u>
Effects of exchange rate changes on cash and cash equivalents	41	(18)
Net increase in cash, cash equivalents and restricted cash	<u>(13,370)</u>	<u>12,607</u>
Cash, cash equivalents and restricted cash at beginning of period	234,875	36,847
Cash, cash equivalents and restricted cash at end of period	<u>\$ 221,505</u>	<u>\$ 49,454</u>
<b>Supplemental disclosure of noncash financing activities:</b>		
Deemed dividend	\$ —	\$ 11,255
Accretion to redemption value	\$ —	\$ 1,093
Fixed asset purchases within accounts payable and accrued expenses	\$ 172	\$ —
Fixed asset additions acquired through tenant allowance	\$ 361	\$ —
Financing costs within accounts payable and accrued expenses	\$ 82	\$ 1,504
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



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

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

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and has facilities in Yardley, Pennsylvania, Ewing, New Jersey, 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 September 30, 2018, the Company had cash and cash equivalents of \$221,491.

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

The Company may need to secure additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under the Company's outstanding Senior Secured Notes, 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 September 30, 2018 and its results of operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months

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

ended September 30, 2018 and 2017. Operating results for the three and nine months ended September 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 September 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 September 30, 2018 as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At September 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.

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

### Net Product Revenues

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

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

- Variable Consideration - Current Liabilities

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

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

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

	September 30,	
	2018	2017
Stock options	6,138,373	4,583,148
Common stock warrants	1,866,831	1,890,489
Employee stock purchase plan	18,507	—
Convertible preferred stock	—	25,068,556
<b>Total</b>	<b>8,023,711</b>	<b>31,542,193</b>

### **Income taxes**

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2018 and 2017, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 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 August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU 2018-15 requires that certain implementation costs incurred in a cloud computing arrangement be deferred and recognized over the term of the arrangement. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 resulted in certain modifications to fair value measurement disclosures, primarily related to level 3 fair value measurements. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation - Scope of Modification Accounting*. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for fiscal years beginning after December

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

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 September 30, 2018 and December 31, 2017, the restricted cash balance included in prepaid expenses and other assets was \$15 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, with early adoption permitted. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. The Company is currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures. The Company expects that most of its operating lease commitments will be subject to the update and anticipates recognition of additional assets and corresponding liabilities related to these leases on our consolidated balance sheet.

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.

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

**4. Inventory**

Inventory consisted of the following:

	September 30, 2018	December 31, 2017
Raw materials	\$ 1,900	\$ 1,385
Work-in-process	2,613	628
Finished goods	2,496	—
Total inventory	<u>\$ 7,009</u>	<u>\$ 2,013</u>

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

**5. Property and Equipment**

Property and equipment, net, consisted of:

	September 30, 2018	December 31, 2017
Computer equipment and software	\$ 848	\$ 307
Furniture and fixtures	370	89
Machinery and equipment	2,678	2,495
Leasehold improvements	609	28
Construction in process	383	—
	<u>4,888</u>	<u>2,919</u>
Less: accumulated depreciation	<u>(931)</u>	<u>(355)</u>
	<u>\$ 3,957</u>	<u>\$ 2,564</u>

Depreciation expense was \$153 and \$37 for the three months ended September 30, 2018 and 2017 and \$325 and \$104 for the nine months ended September 30, 2018 and 2017, respectively. In addition, depreciation expense of \$238 and \$23 is included within inventory and prepaid expenses and other assets, respectively, as of September 30, 2018, which represents depreciation expense related to equipment involved in the manufacturing process.

**6. Accrued Expenses**

Accrued expenses consisted of:

	September 30, 2018	December 31, 2017
Selling, general and administrative expenses	\$ 7,268	\$ 3,463
Research and development expenses	515	80
Bonus expense	3,120	4,163
Payroll and benefit expenses	757	448
Employee contributions withheld	341	185
Product revenue allowances	2,424	—
Interest expense	308	45
Other	912	314
	<u>\$ 15,645</u>	<u>\$ 8,698</u>

**7. AVP-825 License Agreement**

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra® Xsail®), a product combining a low-dose powder form of sumatriptan with the Company's EDS, 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

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

ingredient. Through September 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 nine months ended September 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 September 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 \$2,361 and \$6,855 during the three and nine months ended September 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 loan. Additionally, back end fees of \$2,000 are being amortized to interest expense and are recorded as an increase in the carrying amount throughout the term of the Senior Secured Notes. The Company also incurred \$2,181 in debt issuance costs during the year ended December 31, 2017, which are also being amortized to interest expense over the term of the Senior Secured Notes.

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

	September 30, 2018	December 31, 2017
Face amount	\$ 75,000	\$ 75,000
Front end fees	(908)	(999)
Debt issuance costs	(1,979)	(2,139)
Back end fees	205	1
Long-term debt, net	<u>\$ 72,318</u>	<u>\$ 71,863</u>



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

## 9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of September 30, 2018, approximately \$139 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 \$6 and \$6 for the three months ended September 30, 2018 and 2017 and \$75 and \$50 related to the pension plans for the nine months ended September 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 \$59,917 in net proceeds, after deducting discounts and commissions of \$3,678 and offering expenses of approximately \$373 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 September 30, 2018.

### Common Stock warrants

As of September 30, 2018, the Company had warrants outstanding to purchase 1,866,831 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 nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of product sales	\$ 3	\$ —	\$ 6	\$ —
Research and development	329	411	734	919
General and administrative	1,870	360	5,585	881
	\$ 2,202	\$ 771	\$ 6,325	\$ 1,800

In addition, stock-based compensation expense of \$72 and \$6 is included within inventory and prepaid expenses and other assets, respectively, as of September 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.

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

**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 September 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 nine months ended September 30, 2018:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2017	6,251,576	\$ 9.34	6.67
Granted	423,892	20.35	
Exercised	(491,654)	3.22	
Expired	—	—	
Forfeited	(45,441)	8.81	
Outstanding at September 30, 2018	6,138,373	\$ 10.60	6.71
Exercisable at September 30, 2018	3,228,993	\$ 6.91	4.70
Vested and expected to vest at September 30, 2018	6,138,373	\$ 10.60	6.71

During the nine months ended September 30, 2018, stock options to purchase 423,892 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 \$20.35. During the nine months ended September 30, 2017, stock options to purchase 524,147 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 \$5.90.

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

	Nine Months Ended September 30,	
	2018	2017
Risk free interest rate	2.71%	2.01%
Expected term (in years)	5.93	6.08
Expected volatility	74.61%	74.06%
Annual dividend yield	0.00%	0.00%
Fair value of common stock	\$ 13.50	\$ 3.90

At September 30, 2018, the unrecognized compensation cost related to unvested stock options expected to vest was \$22,269. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.90 years.

**2017 Employee Stock Purchase Plan**

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. The Company recognized stock-based compensation expense of \$84 and \$363 during the three and nine months ended September 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 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. XHANCE was made widely available through retail channels in April 2018.

### XHANCE Commercialization Update

Since FDA approval of our NDA for XHANCE, we focused on executing our integrated launch plan and achieving our objective of making XHANCE widely available through retail pharmacies. Key strategies in our integrated launch plan include: (i) building a robust commercial supply chain network and quality management system, (ii) driving awareness and appreciation of the clinical differentiation of XHANCE, (iii) designing and deploying our customer facing model, (iv) engaging commercial payers with the objective of securing tier 3 coverage, and (v) developing 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:

- **Commercial Supply Chain and Distribution Channel.** We have entered into commercial supply agreements with our key suppliers and spent significant time with our suppliers to oversee product production and quality management. Initial production of product for commercial supply was completed and shipped to our third party logistics partner in February 2018. Replenishment to ensure we have protected our demand forecasts has occurred throughout the year, with frequent business and quality reviews with our key manufacturing and distribution partners occurring as necessary. Additionally, to complement the availability of XHANCE through the traditional retail pharmacy channel, we have contracted with certain mail-order pharmacies (referred to as our 'pharmacy network') to provide convenience and optionality to patients and healthcare providers.
- **Brand Awareness / Promotion.** Prior to the launch of XHANCE, we executed a broad, multi-channel awareness campaign including digital, non-personal promotion, journal advertising, and a field team of 85 nurse educators directly calling on ENT and allergy specialists. We believe that the combined impact of these initiatives was an increase in XHANCE unaided brand awareness from 28% in September 2017 to 87% in April 2018, which was based on our quantitative market research amongst a survey of 100 ENT and allergy specialists. We continue to promote XHANCE within the ENT / allergy specialties through multiple channels, including our sales force (see "Customer Model" below), peer-to-peer education programs, and digital / non-personal promotion.
- **Customer Model.** We have defined a sales force footprint of approximately 120 territories targeting approximately 14,000 ENTs, allergists and "specialty like" primary care physicians and have deployed a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target health care provider (HCP) customer universe. We prioritized approximately 80 territories within our sales force footprint to deploy at launch based upon pre-launch expectations regarding where we could achieve an estimated 65% commercial market access within each territory. The initial 80 territory managers completed training in February 2018 and were deployed in March 2018 to actively

engage approximately 8,000 ENTs, allergists and "specialty like" primary care physician targets to promote XHANCE for the treatment of nasal polyps.

- **XHANCE Patient Affordability Programs.** During the early launch phase of XHANCE, we introduced the XHANCE Xperience program to offer physicians and their patients an opportunity to gain initial experience with XHANCE. As part of this program, patients received up to two XHANCE prescriptions at no out-of-pocket cost to them (\$0 co-pay). In order to receive the second prescription, patients were required to complete a brief survey regarding their use of XHANCE. The survey results are encouraging and also provided physicians an opportunity to receive individual feedback on early patient responses to treatment. As planned, we closed the Xperience program to new enrollments at the end of June 2018. Between July and late-August (post-Xperience), we offered an interim co-pay assistance program which provided a maximum patient benefit of \$120, with patients responsible for the first \$30 of any copay. Starting in late August, we implemented an updated co-pay savings program. We believe this updated program, with an indefinite duration, is a solution for patients that physicians will support. The model currently provides for co-pay assistance terms including a first prescription at no out-of-pocket cost (\$0 co-pay) to commercially insured patients and low subsequent co-pays for refills. Our data suggests these programs have the potential to accelerate demand for XHANCE, particularly as they become more widely understood in the prescribing community.
- **XHANCE Prescriptions.** Based on third-party prescription data as well as data from mail order pharmacy partners, more than 3,800 unique health care providers have prescribed XHANCE through November 2, 2018, and we have continued to grow the number of weekly prescribers since the beginning of the third quarter of 2018. Based on this same data, monthly XHANCE prescriptions for July, August, September and October 2018 were 3,081, 3,440, 3,360, and 4,880, respectively. In addition, XHANCE prescriptions grew 22% for the 4-week period ended October 5, 2018, compared to the 4-week period ended September 7, 2018, and XHANCE prescriptions grew 28% for the 4-week period ended November 2, 2018, compared to the 4-week period ended October 5, 2018. The INS market increased 9% for the 4-week period ended October 5, compared to the 4-week period ended September 7, and decreased 2% for the 4-week period ended November 2, compared to the 4-week period ended October 5 based on third party prescription data. XHANCE prescriptions in October 2018 increased 42% versus prescriptions in August 2018. In that same time frame, prescriptions in the INS market increased 10%. We believe the prescription growth of XHANCE is the result, in part, of changes implemented in the second half of August 2018 including (1) updated physician messaging targeted at quantitatively-identified patient types to improve the ability of our sales team to help doctors identify the most appropriate patients for XHANCE, (2) updated physician marketing materials focused on the efficacy of XHANCE, and (3) the updated patient affordability program. In addition, XHANCE prescribing may be subject to a seasonal effect historically observed in the INS market. 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.
- **Market Access.** In meeting with potential payers, we share what we believe is a compelling economic value proposition. Our analyses suggest that XHANCE will have a comparatively low pharmacy budget impact and our clinical trial data suggest that XHANCE may produce an offsetting benefit by helping reduce the rate of surgery and therefore, surgery-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 trials, XHANCE was also associated with an improvement in reported work productivity in treated patients, which should be valued by employers and patients. Further, we believe the cost of XHANCE to insurance plans will likely be significantly less than the projected costs of monoclonal antibodies that are currently in development for the treatment of nasal polyps, including dupilumab, for which the completion of Phase 3 clinical trials was recently publicly announced.

Based on currently available third-party data and our internal analyses, we believe that greater than 75% of commercially insured lives are currently in a plan in which XHANCE is covered in a Tier 3 formulary position, and approximately 60% of commercially insured lives are in a plan that covers XHANCE in a "low hassle factor" position. However, payers may change coverage levels for XHANCE or controls such as step edits and prior authorization (PAs), positively or negatively, at any time. We use the term "hassle factor" to characterize the level of difficulty that physicians and patients must overcome to prescribe and fill XHANCE. We define a low "hassle factor" as Tier 3 unrestricted, Tier 3 single step edit, or Tier 3 with a simple PA

requiring, for example, only the prior use of an over-the-counter or generic 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.

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

- **Infrastructure.** We continue to develop our internal capabilities in a manner commensurate with having become a fully integrated and publicly traded commercial-stage specialty pharmaceutical company. As of October 31, 2018, we had 102 employees. We have implemented an enterprise resource planning system to expand our operational and commercial finance capabilities. We have also implemented a robust healthcare compliance program to guide our staff's and our partners' compliance with rules and regulations regarding pharmaceutical sales. In managing our growth, we have remained focused on fostering our One Mission culture.

## **XHANCE Development Update**

In addition to XHANCE's existing indication for the treatment of nasal polyps, in order to broaden our U.S. market opportunity, we plan to initiate a clinical research program in pursuit of a supplemental indication for the treatment of chronic sinusitis in the U.S. We anticipate conducting two clinical trials and expect that the first trial will be initiated in the fourth quarter of 2018 and the second trial in 2019.

## **Financial Operations Overview**

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

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

Sales of XHANCE generated \$4.0 million and \$1.9 million in net product revenues through the nine months and three months, respectively, ended September 30, 2018. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payer rebates.

Based on available XHANCE prescription data purchased from third parties and data from our pharmacy network, our average net product revenues per prescription for the third quarter of 2018 was approximately \$191, which is favorable compared to our average net product revenues per prescription of approximately \$144 in the second quarter of 2018. We calculate average net product revenues per prescription by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. As a result, average net product revenues per prescription is subject to variability. That variability is impacted by factors that do not necessarily reflect a change in the price that is paid for an individual unit of XHANCE, including but not limited to ordering patterns and inventory levels for our wholesale customers and mail-order pharmacy network, patient utilization rates of affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. With respect to third quarter 2018 average net product revenues per prescription, the favorability was driven primarily by lower rates of utilization of patient affordability programs than occurred in the second quarter of 2018. For the fourth quarter of 2018, we expect the average net product revenues per prescription of XHANCE to be lower than the average net product revenues per prescription realized in the third quarter of 2018 due to an anticipated increase in the utilization of our co-pay assistance programs.

### ***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 clinical development performed by third parties, including pursuant to agreements with contract research organizations (CROs), as well as investigative sites and consultants that conduct or support our nonclinical studies and clinical trials;
- expenses associated with the continued development of our Exhalation Delivery System;
- expenses related to the continued development of our product sample portfolio;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA prior to regulatory approval of products for commercial sale;
- costs incurred to maintain, expand and protect our patent portfolio as it relates to product candidates in development; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

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

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

We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of XHANCE for the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, 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.

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

Selling, general and administrative expenses have increased in 2018 as compared to 2017 as a result of an expanded infrastructure and an increased headcount to support the commercial launch of XHANCE. We have also incurred 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 September 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 September 30,	
	2018	2017
Net product revenues	\$ 1,902	\$ —
Cost of product sales	319	—
Gross margin	1,583	—
Operating expenses:		
Research and development	2,989	6,641
Selling, general and administrative	22,086	6,553
Total operating expenses	25,075	13,194
Loss from operations	(23,492)	(13,194)
Other (income) expense:		
Interest (income) expense	1,681	(61)
Other (income) expense	(50)	(65)
Total other (income) expense	1,631	(126)
Net loss	\$ (25,123)	\$ (13,068)

**Net product revenues**

Net product revenues related to sales of XHANCE were \$1.9 million for the three months ended September 30, 2018. We did not record any net product revenues during the three months ended September 30, 2017.

**Cost of product sales**

Cost of product sales related to XHANCE were \$0.3 million for the three months ended September 30, 2018. We did not record any cost of product sales during the three months ended September 30, 2017.

**Research and development expense**

Research and development expense was \$3.0 million and \$6.6 million for the three months ended September 30, 2018 and 2017, respectively. The \$3.6 million decrease was attributable primarily to:

- a \$3.0 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 \$1.4 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 in 2018.

These decreases were offset by:

- a \$0.9 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 \$22.1 million and \$6.6 million for the three months ended September 30, 2018 and 2017, respectively. The \$15.5 million increase was due primarily to:

- a \$8.1 million increase in sales and marketing expenses related to the commercialization of XHANCE for the treatment of nasal polyps, of which:
  - \$4.9 million related to our contracted nurse educator team and the deployment of our contract sales force; and
  - \$3.2 million related primarily to marketing expenses for XHANCE;
- a \$2.4 million increase in personnel and bonus expenses due to increases in headcount;
- a \$3.0 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 \$0.5 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 \$1.5 million increase in stock-based compensation expense.

These increases were offset by:

- a \$0.4 million decrease in consultancy expenses.

*Interest (income) expense, net*

Interest (income) expense, net, was \$1.7 million and \$(0.1) million for the three months ended September 30, 2018 and 2017, respectively. The increase in interest (income) expense, net, for the three months ended September 30, 2018 was related to \$2.4 million in interest expense on our long-term debt, offset by \$0.7 million in interest income. Interest income increased \$0.6 million during the three months ended September 30, 2018, as compared to the three months ended September 30, 2017 as a result of higher cash balances. We did not record any interest expense for the three months ended September 30, 2017.

*Other (income) expense, net*

Other (income) expense, net was \$(0.1) million for the three months ended September 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 nine months ended September 30, 2018 and 2017**

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

	Nine Months Ended September 30,	
	2018	2017
Net product revenues	\$ 4,042	\$ —
Cost of product sales	870	—
Gross margin	3,172	—
Operating expenses:		
Research and development	6,736	15,620
Selling, general and administrative	71,957	13,214
Total operating expenses	78,693	28,834
Loss from operations	(75,521)	(28,834)
Other (income) expense:		
Interest (income) expense	5,117	706
Other (income) expense	(361)	(189)
Total other (income) expense	4,756	517
Net loss	\$ (80,277)	\$ (29,351)

*Net product revenues*

Net product revenues related to sales of XHANCE were \$4.0 million for the nine months ended September 30, 2018. We did not record any net product revenues during the nine months ended September 30, 2017.

*Cost of product sales*

Cost of product sales related to XHANCE were \$0.9 million for the nine months ended September 30, 2018. We did not record any cost of product sales during the nine months ended September 30, 2017.

*Research and development expense*

Research and development expense was \$6.7 million and \$15.6 million for the nine months ended September 30, 2018 and 2017, respectively. The \$8.9 million decrease was attributable primarily to:

- a \$6.8 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 \$3.3 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 in 2018.

These decreases were offset by:

- a \$1.5 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 \$72.0 million and \$13.2 million for the nine months ended September 30, 2018 and 2017, respectively. The \$58.8 million increase was due primarily to:

- a \$31.2 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:
  - \$18.8 million related to our contracted nurse educator team and the deployment of our contract sales force; and
  - \$12.4 million related primarily to marketing expenses for XHANCE;
- a \$11.4 million increase in personnel and bonus expenses due to increases in headcount;

- a \$6.8 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 \$2.3 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 \$4.7 million increase in stock-based compensation expense.

*Interest (income) expense, net*

Interest (income) expense, net, was \$5.1 million and \$0.7 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in interest (income) expense, net, for the nine months ended September 30, 2018 was related to \$6.9 million in interest expense on our long-term debt, offset by \$1.7 million in interest income. Interest income increased \$1.6 million during the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017 as a result of higher cash balances. Interest expense for the nine months ended September 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) expense, net, was \$(0.4) million and \$(0.2) million for the nine months ended September 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 \$80.3 million and \$29.4 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$291.5 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 September 30, 2018, we had \$221.5 million in cash and cash equivalents.

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

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (71,623)	\$ (21,878)
Net cash used in investing activities	(1,450)	(1,210)
Net cash provided by financing activities	59,662	35,713
Effects of exchange rates on cash and cash equivalents	41	(18)
Net (decrease) increase in cash and cash equivalents	<u>\$ (13,370)</u>	<u>\$ 12,607</u>

*Operating activities*

Cash used in operating activities increased by \$49.7 million, from \$21.9 million for the nine months ended September 30, 2017 to \$71.6 million for the nine months ended September 30, 2018. The increase in cash used in operating activities was attributable primarily to the increase in our net loss from \$29.4 million for the nine months ended September 30, 2017 to \$80.3 million for the nine months ended September 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 \$0.3 million from \$1.2 million for the nine months ended September 30, 2017 to \$1.5 million for the nine months ended September 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 \$59.7 million for the nine months ended September 30, 2018, driven primarily by net proceeds to us of \$59.9 million as a result of a June 2018 underwritten public offering (the Offering) of 5,750,000 shares of our common stock (Common Stock) at a price of \$22.25 per share, which consisted of 2,875,000 shares of Common Stock sold by us 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 nine months ended September 30, 2018 related to our IPO and debt financing in the fourth quarter of 2017. Cash provided by financing activities was \$35.7 million for the nine months ended September 30, 2017, driven primarily by the receipt of \$36.5 million in net proceeds from the sale of our Series D Preferred Stock.

### *Projected 2018 operating expenses*

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2018 will be between \$112.0 - \$115.0 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 affordability 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 of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from commercial sales of XHANCE;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including FDA-mandated pediatric studies and clinical trials for the supplemental indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights;

- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- fluctuations in the three-month LIBOR-based floating interest rate of our 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 our future liquidity requirements and we may need to secure additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources in order to meet our debt service obligations under our Senior Secured Notes, including repayment, and to carry out all of our 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 meet our debt service obligations or enable us to continue to implement our long-term business strategy. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received. Additionally, we may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

### Off-balance sheet arrangements

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

### Contractual obligations and commitments

The following table summarizes our contractual obligations at September 30, 2018:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(in thousands)				
Operating leases <sup>(1)</sup>	\$ 2,478	\$ 931	\$ 1,547	\$ —	\$ —
Long-term debt <sup>(2)</sup>	117,876	8,626	17,299	91,951	—
Purchase obligations <sup>(3)</sup>	5,837	5,837	—	—	—
Total	<u>\$ 126,191</u>	<u>\$ 15,394</u>	<u>\$ 18,846</u>	<u>\$ 91,951</u>	<u>\$ —</u>

<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. We are required to make quarterly, interest only payments until the maturity date. Interest amounts included above are calculated at the quarterly rate as of September 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 \$5.8 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 September 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 38% and 39% of our XHANCE net revenue during the three and nine months ended September 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 September 30, 2018, we used \$94.6 million of the proceeds as follows:

- approximately \$58.8 million to support the planned launch of XHANCE, including investments in marketing and sales, inventory and our commercial infrastructure;
- approximately \$7.0 million to fund further development efforts for XHANCE; and
- approximately \$28.8 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 \$30.8 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**

None.

**ITEM 6. EXHIBITS**

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

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1	<a href="#">Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).</a>
3.2	<a href="#">Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).</a>
31.1 *	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
31.2 *	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
32.1 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.</a>
32.2 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.</a>
101.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.



## SIGNATURES

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

Date: November 13, 2018

**OPTINOSE, INC.**

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

**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: November 13, 2018

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

**CERTIFICATION UNDER SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. 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: November 13, 2018

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

**CERTIFICATION UNDER SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Peter K. Miller, Chief Executive Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the period ending September 30, 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: November 13, 2018

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

**CERTIFICATION UNDER SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, Chief Financial Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge

1. the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 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: November 13, 2018

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