NovaBay Pharmaceuticals, Inc.
Form 10-Q
November 14, 2018

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

OR

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

For the transition period from _____ to _____

Commission File Number: 001-33678

NOVABAY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0454536**

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

2000 Powell Street, Suite 1150, Emeryville, CA 94608

(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (510) 899-8800

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 (§231.405 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. (Check one):

Large accelerated filer Accelerated filer Emerging growth company
Non-accelerated filer Smaller reporting 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 Exchange Act).
Yes No

As of November 9, 2018, there were 17,089,304 shares of the registrant's common stock outstanding.

NOVABAY PHARMACEUTICALS, INC.

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Unless the context requires otherwise, all references in this report to "we," "our," "us," the "Company" and "NovaBay" refer to NovaBay Pharmaceuticals, Inc.

NovaBay®, NovaBay Pharma®, Avenova®, NeutroPhase®, CelleRx®, intelli-Case™, AgaNase®, Aganocide®, AgaDerm®, Neutrox® and Going Beyond Antibiotics® are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value amounts)

	September 30, 2018 (Unaudited)	**December 31, 2017** See Note 2
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,207	$ 3,199
Accounts receivable, net of allowance for doubtful accounts ($9 and $13 at September 30, 2018 and December 31, 2017, respectively)	2,612	3,629
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $124 and $140 at September 30, 2018 and December 31, 2017, respectively	390	504
Prepaid expenses and other current assets	1,319	1,663
Total current assets	9,528	8,995
Property and equipment, net	271	471
Other assets	566	613
TOTAL ASSETS	$ 10,365	$ 10,079
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 564	$ 466
Accrued liabilities	2,751	1,672
Deferred revenue	62	2,841
Total current liabilities	3,377	4,979

Deferred revenues - non-current	-	534
Deferred rent	213	286
Warrant liability	518	1,489
Other liabilities	198	197
Total liabilities	4,306	7,485
Stockholders' equity:		
Preferred stock: 5,000 shares authorized; none outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value; 50,000 and 240,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 17,089 and 15,385 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	171	154
Additional paid-in capital	119,601	113,514
Accumulated deficit	(113,713)	(111,074)
Total stockholders' equity	6,059	2,594
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 10,365	$ 10,079

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018,* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

The accompanying notes are an integral part of these consolidated financial statements.

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Sales:				
Product revenue, net	$3,142	$4,080	$8,870	$11,868
Other revenue, net	-	11	13	46
Total net sales	3,142	4,091	8,883	11,914
Product cost of goods sold	332	521	1,062	1,807
Gross profit	2,810	3,570	7,821	10,107
Research and development	45	132	152	264
Sales and marketing	3,230	3,296	9,603	10,412
General and administrative	1,344	2,311	4,326	7,134
Total operating expenses	4,619	5,739	14,081	17,810
Operating loss	(1,809)	(2,169)	(6,260)	(7,703)
Non-cash gain (loss) on changes in fair value of warrant liability	267	(281)	971	(501)
Other income (expense), net	4	3	13	9
Loss before provision for income taxes	(1,538)	(2,447)	(5,276)	(8,195)
Provision for income tax	-	-	(1)	(1)
Net loss and comprehensive loss	$(1,538)	$(2,447)	$(5,277)	$(8,196)
Net loss per share attributable to common stockholders, basic	$(0.09)	$(0.16)	$(0.31)	$(0.54)
Net loss per share attributable to common stockholders, diluted	$(0.11)	$(0.16)	$(0.37)	$(0.54)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock				
Basic	17,089	15,324	16,864	15,306
Diluted	17,148	15,324	17,056	15,306

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018,* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

The accompanying notes are an integral part of these consolidated financial statements.

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities:		
Net loss	$(5,277)	$(8,196)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	219	54
Loss on disposal of property and equipment	1	-
Stock-based compensation expense for options and stock issued to employees and directors	413	2,135
Stock-based compensation expense for options and stock issued to non-employees	18	250
Stock option modification expense	77	243
Non-cash (gain) loss on change in fair value of warrant liability	(971)	501
Changes in operating assets and liabilities:		
Decrease (Increase) in Accounts receivable	1,546	(109)
Decrease in Inventory	89	273
Decrease in Prepaid expenses and other assets	379	943
Decrease (Increase) in Other assets long-term	48	(86)
(Decrease) Increase in Accounts payable and accrued liabilities	(56)	602
(Decrease) Increase in Deferred rent	(48)	40
(Decrease) Increase in Deferred revenue	(13)	6
Net cash used in operating activities	(3,575)	(3,344)
Investing activities:		
Purchases of property and equipment	(13)	(228)
Net cash used in investing activities	(13)	(228)
Financing activities:		
Proceeds from common stock issuances, net	5,585	-
Proceeds from exercise of options, net	11	129
Proceeds from stock options & restricted stock units (“RSUs”) for taxes	1	17
Settlement of restricted stock for tax withholding	-	(48)
Exercise of warrants, net	-	38
Net cash provided by financing activities	5,597	136
Net increase (decrease) in cash and cash equivalents and restricted cash	**2,009**	**(3,436)**
Cash, cash equivalents and restricted cash, beginning of period	3,673	9,986

Cash, cash equivalents and restricted cash, end of period	**$5,682**	**$6,550**

	Nine Months Ended September 30,	
	2018	**2017**
Supplemental disclosure of non-cash information		
Cumulative effect of adoption of new accounting standard	$2,638	$-
Stock issued to consultants for services, included in accounts payable and accrued liabilities	$-	$1
Fixed asset purchases, included in accounts payable and accrued liabilities	$7	$(52)
Severance paid in RSUs to non-employees	$-	$69
Equity transferred to warrant liability	$-	$58
Proceeds from stock options and restricted stock for taxes, in accounts payable and accrued liabilities	$1	$17

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018,* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. is a biopharmaceutical company focusing on commercializing and developing its non-antibiotic anti-infective products to address the unmet therapeutic needs of the global, topical anti-infective market with its two distinct product categories: the NEUTROX® family of products and the AGANOCIDE® compounds. The Neutrox family of products includes AVENOVA® for the eye care market, NEUTROPHASE® for wound care market, and CELLERX® for the aesthetic dermatology market. The Aganocide compounds, still under development, have target applications in the dermatology and urology markets.

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. It had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, it changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In June 2010, the Company changed the state in which it is incorporated (the "Reincorporation") and is now incorporated under the laws of the State of Delaware. All references to "the Company" herein refer to the California corporation prior to the date of the Reincorporation and to the Delaware corporation on and after the date of the Reincorporation. The Company has minimized research and development and is now focused primarily on commercializing prescription Avenova for the domestic eyecare market.

Effective December 18, 2015, the Company effected a 1-for-25 reverse split of its outstanding common stock (the "Reverse Stock Split") (See Note 11). The accompanying financial statements and related notes give retroactive effect to the Reverse Stock Split.

Liquidity

Based primarily on the funds available at September 30, 2018, the Company believes these resources will be sufficient to fund its operations into July 2019. The Company has sustained operating losses for the majority of its corporate history and expects that its 2018 expenses will exceed its 2018 revenues, as the Company continues to re-invest in its Avenova commercialization efforts. The Company expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, the Company's planned operations raise substantial doubt about its ability to continue as a going concern. The Company's liquidity needs will be largely determined by the success of operations in regard to the commercialization of Avenova. The Company also may consider other plans to fund operations including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones or an upfront fee; (2) raising additional capital through debt and equity financings or from other sources; (3) reducing spending on one or more of its sales and marketing programs; and/or (4) restructuring operations to change its overhead structure. The Company may issue securities, including common stock and warrants through private placement transactions or registered

public offerings, which would require the filing of a Form S-1 or Form S-3 registration statement with the Securities and Exchange Commission ("SEC"). In the absence of the Company's completion of one or more of such transactions, there will be substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are issued, and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to its ability to continue as a going concern.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars.

Reclassifications

Prior period amounts in the accompanying consolidated balance sheets have been reclassified to conform to current period presentation. Prior period amounts in the accompanying consolidated statements of operations and comprehensive loss have also been reclassified to conform to current period presentation. The reclassifications did not change the net loss or loss per share.

Additionally, prior period amounts in the accompanying consolidated statements of cash flow have also been reclassified to conform to current period presentation. The reclassifications did not change net cash used in operating activities, net cash used in investing activities, or net cash provided by financing activities.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as they relate to revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ from those estimates.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented.

The year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly-liquid instruments with a stated maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value. As of September 30, 2018, and December 31, 2017, the Company’s cash and cash equivalents were held in two highly-rated, major financial institutions in the United States.

Beginning fiscal 2018, the Company adopted Accounting Standards Update ("ASU") No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires the statement of cash flows to explain the change during the period relating to total cash, cash equivalents, and restricted cash. The Company adopted this standard using the retrospective transition method by restating its consolidated statements of cash flows to include restricted cash of $474 thousand in beginning and ending cash, cash equivalents, and restricted cash for the period ended December 31, 2017, and $475 thousand in the beginning and ending cash, cash equivalents, and restricted cash balances for the period ended September 30, 2018. Net cash flows for the nine months ended September 30, 2018 and 2017, did not change as a result of including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts presented on the statements of cash flows.

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash reported in the consolidated balance sheet that sum to the total of the same reported in the consolidated statement of cash flows:

	September 30, 2018	**December 31, 2017**
Cash and cash equivalents	$ 5,207	$ 3,199
Restricted cash included in Other assets	475	474
Total cash, cash equivalents, and restricted cash in the statement of cash flows	$ 5,682	$ 3,673

The restricted cash amount included in Other assets on the consolidated balance sheet represents amounts held as certificate of deposit for long-term financing and lease arrangements as contractually required by our financial institution and landlord.

Concentrations of Credit Risk and Major Partners

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits of cash and cash equivalents with two highly-rated, major financial institutions in the United States.

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held.

During the nine months ended September 30, 2018 and 2017, revenues were derived primarily from sales of Avenova directly to doctors through the Company's webstore and to three major distribution partners.

During the nine months ended September 30, 2018 and 2017, revenues from our major distribution partners greater than 10% were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Major distribution or collaboration partner	**2018**	**2017**	**2018**	**2017**
Distributor A	25 %	25 %	22 %	24 %
Distributor B	25 %	24 %	25 %	24 %
Distributor C	24 %	23 %	25 %	21 %

As of September 30, 2018 and December 31, 2017, accounts receivable from our major distribution or collaboration partners greater than 10% were as follows:

Major distribution or collaboration partner	**September 30, 2018**	**December 31, 2017**
Distributor A	20 %	25 %
Distributor B	28 %	23 %
Distributor C	36 %	22 %
Collaborator D	*	20 %

***Not greater than 10%**

The Company relies on two contract sole source manufacturers to produce its finished goods. The Company does not have any manufacturing facilities and intends to continue to rely on third parties for the supply of finished goods. Third party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality.

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash, cash equivalents and restricted cash, accounts receivable, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. Our warrant liability is carried at fair value.

The Company measures the fair value of financial assets and liabilities based on U.S. GAAP guidance, which defines fair value, establishes a framework for measuring fair value, and requires disclosures about fair value measurements.

Under U.S. GAAP, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is also established, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities;

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable; and

Level 3 – inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

Allowance for Doubtful Accounts

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identifies amounts due that are in dispute and it believes are unlikely to be collected. As of September 30, 2018 and December 31, 2017, management reserved $9 thousand and $13 thousand, respectively, primarily based on specific amounts that were in dispute or were over 120 days past due.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes, and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At September 30, 2018 and December 31, 2017, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $124 thousand and $140 thousand, respectively.

Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets of five to seven years for office and laboratory equipment, three years for computer equipment and software and seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of seven years or the lease term.

The costs of normal maintenance, repairs, and minor replacements are charged to operations when incurred.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets. There were no impairment charges during the nine months ended September 30, 2018 and September 30, 2017. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

Comprehensive Income (Loss)

Accounting Standards Codification (“ASC”) 220, *Comprehensive Income* requires that an entity’s change in equity or net assets during a period from transactions and other events from non-owner sources be reported. The Company reports unrealized gains and losses on its available-for-sale securities as other comprehensive income (loss).

Revenue Recognition

Beginning January 1, 2018, the Company has followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

The Company generates product revenue through product sales to its major distribution partners, a limited number of other distributors and via its webstore. Product supply is the only performance obligation contained in these arrangements, and the Company recognizes product revenue upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to, generally upon shipment to the distributor on a “sell-in” basis.

Other revenue is primarily generated through commercial partner agreements with strategic partners for the development and commercialization of the Company’s product candidates. The terms of the agreements typically include more than one performance obligation and generally contain non-refundable upfront fees, payments based upon achievement of certain milestones and royalties on net product sales.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. The Company's performance obligations include:

- Product supply
- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply
- Incremental discounts and product supply prepayments considered material rights to the customer

The Company has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or the Company's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations.

Transaction Price

The Company has both fixed and variable consideration. Under the Company's license arrangements, non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Product supply selling prices are identified as variable consideration subject to the constraint on variable consideration for estimated discounts, rebates, chargebacks and product returns. Funding of research and development activities are considered variable payments until such costs are reimbursed, at which point they are considered fixed. The Company allocates the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

For product supply under the Company's distribution arrangements, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because the Company does not have sufficient historical data to compute its own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. The Company updates the return rate assumption quarterly and applies it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the customer. At any point in time there is generally one month of inventory in the sales

channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved one month from when control is transferred.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur and achievement is in the control of the Company (such as a regulatory submission by the Company), the value of the associated milestone is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for arrangements that contain multiple performance obligations, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. When a contract contains more than one performance obligation, the Company uses key assumptions to determine the stand-alone selling price of each performance obligation. The estimated stand-alone selling prices for distribution rights and material rights for incremental discounts on product supply are calculated using an income approach discounted cash flow model and can include the following key assumptions: forecasted commercial partner sales, product life cycle estimates, costs of product sales, commercialization expenses, annual growth rates and margins, discount rates and probabilities of technical and regulatory success. For all other performance obligations, the Company uses a cost-plus margin approach. The Company allocates the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or services underlying each performance obligation.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the cost-to-cost input method.

The Company's intellectual property in the form of distribution rights are determined to be distinct from the other performance obligations identified in the arrangements and considered "right to use" licenses which the customer can benefit from at a point in time. The Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license.

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping costs, and other costs of goods sold. Cost of goods sold also includes any necessary allowance for excess and obsolete inventory along with lower of cost and estimated net realizable value.

Research and Development Costs

The Company charges research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. Research and development costs may vary depending on the type of item or service incurred, location of performance or production, level of availability of the item or service, and specificity required in production for certain compounds. The Company uses external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services. The Company's research, clinical and development activities are often performed under agreements it enters into with external service providers. The Company estimates and accrues the costs incurred under these agreements based on factors such as milestones achieved, patient enrollment, estimates of work performed, and historical data for similar arrangements. As actual costs are incurred, the Company adjusts its accruals. Historically, the Company's accruals have been consistent with

management's estimates and no material adjustments to research and development expenses have been recognized. Subsequent changes in estimates may result in a material change in the Company's expenses, which could also materially affect its results of operations.

Patent Costs

Patent costs, including legal expenses, are expensed in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASU No. 2014-12, *Compensation-Stock Compensation (Topic 718)*. Under the fair value recognition provisions, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model. See Note 12 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. The Company accounts for restricted stock unit awards issued to employees and non-employees (consultants and advisory board members) based on the fair market value of the Company's common stock as of the date of issuance.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized.

Common Stock Warrant Liability

For warrants that are newly issued or modified and there is a deemed possibility that the Company may have to settle them in cash, or for warrants it issues or modifies that contain an exercise price adjustment feature, the Company records the fair value of the issued or modified warrants as a liability at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model. The Lattice model provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of our judgment.

Net Loss per Share

The Company computes net loss per share by presenting both basic and diluted loss per share ("EPS").

Basic EPS is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method and using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods since their effect would be anti-dilutive.

During the three and nine months ended September 30, 2018, the basic EPS was a net loss of $0.09 and $0.31, respectively, per share and the diluted EPS was a net loss of $0.11 and $0.37, respectively, per share due to the gain on changes in fair value of warrant liability. During the three and nine months ended September 30, 2017, there was no difference between basic and diluted EPS due to the Company's net losses.

The following table sets forth the calculation of basic EPS and diluted EPS:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator				

Net loss	$(1,538)	$(2,447)	$(5,277)	$(8,196)
Less gain on changes in fair value of warrant liability	(267)	-	(971)	-
Net loss, diluted	$(1,805)	$(2,447)	$(6,248)	$(8,196)
Denominator				
Weighted average shares outstanding, basic	17,089	15,324	16,864	15,306
Net loss per share, basic	$(0.09)	$(0.16)	$(0.31)	$(0.54)
Weighted average shares outstanding, basic	17,089	15,324	16,864	15,306
Effect of dilutive warrants	59	-	192	-
Weighted average shares outstanding, diluted	17,148	15,324	17,056	15,306
Net loss per share, diluted	$(0.11)	$(0.16)	$(0.37)	$(0.54)

The following outstanding stock options and stock warrants were excluded from the diluted net loss per share computation, as their effect would have been anti-dilutive:

	As of	
	September 30,	
(in thousands)	2018	2017
Period end stock options to purchase common stock	3,180	2,893
Period end common stock warrants	-	544
	3,180	3,437

Recent Accounting Pronouncements

In 2014, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("Topic 606"). In 2015 and 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. Collectively, these are referred to as Topic 606, which replaces all legacy U.S. GAAP guidance on revenue recognition and eliminates all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying Topic 606, companies need to use more judgment and make more estimates than under the legacy guidance. This includes identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, allocating the transaction price to each distinct performance obligation, the level of effort required to satisfy performance obligations, and the period over which we expect to complete our performance obligations under the arrangement. As a result, the timing of recognition of revenue has more variability under the new revenue standard due to significant estimates involved in the new accounting. Topic 606, as amended, is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted one year earlier.

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts that were not completed as of January 1, 2018. In addition, the Company has accounted for all contract modifications retrospectively for contracts in transition at the date of adoption by electing the contract modification practical expedient. Contract consideration has not been adjusted for the effects of a significant financing component if the time between the transfer of the good or service and payment timing is one year or less. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under Topic 605. See Note 8 for further information.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, to address the diversity in the classification and presentation of changes in restricted cash in the statement of cash flows by requiring entities to combine the changes in cash and cash equivalents and restricted cash in one line. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. Additionally, if more than one-line item is recorded on the balance sheet for cash and cash equivalents and restricted cash, a reconciliation between the statement of cash flows and balance sheet is required. The Company adopted the standard effective January 1, 2018 using the retrospective transition method. The impact of the adoption was not material to the consolidated statement of cash flows.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the lease accounting requirements in *Leases (Topic 840)*. ASU 2016-02 requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in

the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. The guidance also requires qualitative and specific quantitative disclosures to supplement the amounts recorded in the financial statements so that users can understand more about the nature of an entity's leasing activities, including significant judgments and changes in judgments. This guidance is effective beginning in the first quarter of fiscal year 2019. While the Company is currently evaluating the impact of the adoption of this standard on its financial statements, the Company anticipates the recognition of additional assets and corresponding liabilities on its condensed consolidated balance sheet related to leases.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effects of the adoption of ASU 2017-11 to its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting (Topic 718),* that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain specified exemptions. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the effects of the adoption of ASU 2018-07 to its consolidated financial statements.

NOTE 3. FAIR VALUE MEASUREMENTS

The Company measures the fair value of financial assets and liabilities based on authoritative guidance that defines fair value, establishes a framework consisting of three levels for measuring fair value, and requires disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's warrant liability is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions in the valuation of this liability.

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2018:

(in thousands)	Balance at September 30, 2018	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents	$ 102	$102	$ —	$ —
Restricted cash held as a certificate of deposit	324	324	—	—
Deposit held as a certificate of deposit	151	151	—	—
Total assets	$ 577	$577	$ —	$ —
Liabilities				

Warrant liability	$ 518	$—	$ —	$ 518
Total liabilities	$ 518	$—	$ —	$ 518

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2017:

(in thousands)	Balance at December 31, 2017	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents	$ 101	$101	$ —	$ —
Restricted cash held as a certificate of deposit	324	324	—	—
Deposit held as a certificate of deposit	150	150	—	—
Total assets	$ 575	$575	$ —	$ —
Liabilities				
Warrant liability	$ 1,489	$—	$ —	$ 1,489
Total liabilities	$ 1,489	$—	$ —	$ 1,489

As a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash gain of $267 thousand for the three-month period ended September 30, 2018 on a decrease in the fair value of the warrants. See Note 10 for further discussion of the calculation of the fair value of the warrant liability.

(in thousands)	Warrant liability
Fair value of warrant liability at December 31, 2017	$ 1,489
Decrease in fair value at March 31, 2018	(214)
Fair value of warrant liability at March 31, 2018	1,275
Decrease in fair value at June 30, 2018	(490)
Fair value of warrant liability at June 30, 2018	785
Decrease in fair value at September 30, 2018	(267)
Fair value of warrant liability at September 30, 2018	$ 518

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

(in thousands)	September 30, 2018	December 31, 2017
Prepaid employees' benefits	$ 6	$ 112
Prepaid sales rebate	644	923
Prepaid rent	-	123
Rent receivable	137	86
Retainers	116	-
Prepaid insurance	57	27
Prepaid fleet leasing costs	61	61
Prepaid dues and subscriptions	64	117
Other	234	214
Total prepaid expenses and other current assets	$ 1,319	$ 1,663

NOTE 5. INVENTORY

Inventory consisted of the following:

(in thousands)	**September 30, 2018**	**December 31, 2017**
Raw materials and supplies	$ 205	$ 298
Finished goods	309	346
Less allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments	(124)	(140)
Total inventory, net	$ 390	$ 504

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	September 30, 2018	December 31, 2017
Office and laboratory equipment	$ 24	$ 24
Furniture and fixtures	157	157
Computer equipment and software	370	354
Production equipment	105	105
Leasehold improvements	77	74
Total property and equipment, at cost	733	714
Less: accumulated depreciation and amortization	(462)	(243)
Total property and equipment, net	$ 271	$ 471

Depreciation and amortization expense was $92 thousand and $18 thousand for the three months ended September 30, 2018 and 2017, respectively, and $219 thousand and $54 thousand for the nine months ended September 30, 2018 and 2017, respectively.

NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	September 30,	December 31,

	2018	2017
Employee payroll and benefits	$ 759	$ 761
Severance/retirement pay	90	347
Inventory	63	-
Distributor fees and discounts	-	185
Sales rebates	-	106
Avenova contract liabilities (see Note 8)	1,599	-
Deferred rent	93	69
Other	147	204
Total accrued liabilities	$ 2,751	$ 1,672

NOTE 8. ADOPTION OF TOPIC 606, "REVENUE FROM CONTRACTS WITH CUSTOMERS"

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts that were not completed as of January 1, 2018. In addition, the Company has accounted for all contract modifications retrospectively for contracts in transition at the date of adoption by electing the contract modification practical expedient. Contract consideration has not been adjusted for the effects of a significant financing component if the time between the transfer of the good or service and payment timing is one year or less. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under Topic 605.

Transactions under the Company's major distribution agreements, which under prior guidance, were recognized upon shipment from its distributors to the final customers, are now recognized upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to. As a result, the Company now records contract liabilities for the invoiced amounts that are estimated to be subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. The constraint on variable consideration for product returns is a new estimation resulting from the earlier recognition under the new guidance. Based on this change, the entire deferred revenue and deferred cost of goods sold balances related to its distribution agreements were allocated to either contract liabilities and other liabilities associated with invoicing in periods prior to adoption or included in the cumulative adjustment to retained earnings upon adoption.

Milestone payments, which under the prior milestone recognition methodology were not recognized until they were substantively achieved, are included in the estimated transaction price when they are considered probable of being achieved. This may result in earlier recognition of revenue for the portion of milestone payments deemed probable which are allocated to performance obligations that are satisfied before the milestones are achieved. For license and collaboration revenue for which contract deliverables were previously accounted for as a combined unit of accounting

because products or services were not separable, the Company has identified that under the new guidance the separate performance obligations are capable of being distinct. As a result, the transaction price under these arrangements, including upfront fees and milestone payments, are allocated differently to each performance obligation and may be recognized at earlier points in time or with a different pattern of performance over time.

The following table shows the reconciliation of assets and liabilities disclosed in the Form 10-K for the year ended December 31, 2017, as adjusted, due to the modified retrospective adoption of Topic 606 on January 1, 2018 (in thousands):

	As Reported Under Topic 605	Effect of Change	As Adjusted Under Topic 606
Accounts receivable	$3,629	$530	$4,159
Inventory	$504	$(25)	$479
Accrued liabilities	$1,672	$1,166	$2,838
Deferred revenue	$2,841	$(2,766)	$75
Deferred revenue, non-current	$534	$(534)	$-
Accumulated deficit	$(111,074)	$2,639	$(108,435)

As a result of adopting Topic 606 using the modified retrospective approach, the following table shows the financial statement line items for the nine months ended September 30, 2018, as if revenue from contracts with customers had been accounted for under Topic 605 (in thousands, except per share data): [

	As Reported Under Topic 606	Effect of Change	As Revised Under Topic 605
Consolidated Balance Sheet:			
Accounts receivable	$2,612	$(371)	$2,241
Inventory	$390	$28	$418
Accrued liabilities	$2,751	$(1,375)	$1,376
Deferred revenue	$62	$2,623	$2,685
Deferred revenue, non-current	$-	$579	$579
Accumulated deficit	$(113,713)	$(2,170)	$(115,883)
Total net sales	$8,883	$465	$9,348
Cost of product sales	$1,062	$(3)	$1,059

Loss from operations	$(6,260)	$468	$(5,792)
Net loss	$(5,277)	$468	$(4,809)
Basic net loss per share	$(0.31)	$0.02	$(0.29)
Diluted net loss per share	$(0.37)	$0.03	$(0.34)
Consolidated Statement of Cash Flows:			
Net loss	$(5,277)	$468	$(4,809)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable	$1,546	$(159)	$1,387
Inventory	$89	$(3)	$86
Accounts payable and accrued liabilities	$(56)	$(240)	$(296)
Deferred revenue	$(13)	$(67)	$(80)

At September 30, 2018, approximately $62 thousand of transaction prices were allocated to unsatisfied performance obligations that the Company expects to be recognized during 2018.

For additional detail on the Company’s accounting policy regarding revenue recognition, refer to Note 2 above.

The following table presents changes in the Company's contract assets and liabilities for the nine months ended September 30, 2018:

	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
	(in thousands)			
Contract Liabilities: Deferred Revenue	$75	$ -	$ (13)	$ 62
Contract Liabilities: Accrued Liabilities	$1,458	$ 9,907	$ (9,696)	$ 1,669
Total	$1,533	$ 9,907	$ (9,709)	$ 1,731

During the nine months ended September 30, 2018, the Company recognized the following revenue (in thousands):

Revenue recognized in the period from:	
Amounts included in contract liabilities at the beginning of the period:	
Performance obligations satisfied	$1,432
New activities in the period:	
Performance obligations satisfied	$7,451
Total revenue	$8,883

License Collaboration and Distribution Agreements

In January 2012, the Company entered into a distribution agreement with China Pioneer, a Shanghai-based company that markets high-end pharmaceutical products into China and an affiliate of Pioneer Pharma (Singapore) Pte. Ltd. ("Pioneer Singapore"), for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of $312,500. NovaBay also received $312,500 in January 2013 related to the submission of the first marketing approval for the product to the Chinese Food and Drug Administration ("CFDA"). The deferred revenue was recognized as the purchase discounts were earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received $625,000 upon receipt of a marketing approval of the product from the CFDA.

In September 2012, the Company entered into two agreements with China Pioneer: (1) an international distribution agreement (“Distribution Agreement”) and (2) a unit purchase agreement (“Purchase Agreement”). These agreements were combined and accounted for as one arrangement with one unit of accounting for revenue recognition purposes.

Pursuant to the terms of the Distribution Agreement, China Pioneer has the right to distribute NeutroPhase, upon a marketing approval from a Regulatory Authority (as defined in the Distribution Agreement) in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, the Company received an upfront payment, which was recorded as deferred revenue. China Pioneer is also obligated to make certain additional payments to the Company upon receipt of the marketing approval. The Distribution Agreement further provides that China Pioneer is entitled to a cumulative purchase discount not to exceed $500,000 upon the purchase of NeutroPhase products, payable in NovaBay unregistered restricted common stock.

Pursuant to the Purchase Agreement, the Company also received $2.5 million from China Pioneer for the purchase of restricted units (with each restricted unit comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012 and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per unit. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and the fair value of the warrants based on the Black-Scholes Merton option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1 million, we reallocated $600,000 from deferred revenue to stockholders’ equity as consideration for the purchase of the units.

In December 2013, the Company announced it had expanded its NeutroPhase commercial partnership agreement with China Pioneer. The expanded agreement includes licensing rights to Avenova and CelleRx, which were developed internally by NovaBay. The expanded partnership agreement covers the commercialization and distribution of these products in China and 11 countries in Southeast Asia.

On February 7, 2012, the Company entered into a distribution agreement with Integrated Healing Technologies, LLC (“IHT”) to distribute NeutroPhase. NovaBay received an upfront payment of $750,000.

In April 2013, the Company entered into a collaboration and license agreement with Virbac. Under this agreement, Virbac acquired exclusive worldwide rights to develop the Company's proprietary compound, auriclosene (NVC-422), for global veterinary markets for companion animals. The Company received an upfront payment of $250,000.

On June 1, 2013, the Company entered into a distribution agreement with Principal Business Enterprise Inc. ("PBE") to distribute NeutroPhase. NovaBay received an upfront payment of $200,000.

Revenue has been recognized under these agreements as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2018**	**2017**	**2018**	**2017**
Amortization of upfront technology and access fees	$ -	$ 11	$ 13	$ 46
Product revenue	-	222	121	583
Total revenue recognized	$ -	$ 233	$ 134	$ 629

The Company had a deferred revenue balance of $2.0 million at December 31, 2017 related to these agreements, which consisted of the unamortized balances from upfront technology and access fees. Upon the adoption of Topic 606, deferred revenue decreased by $1.96 million and was recorded as part of the cumulative adjustment to the accumulated deficit. The decrease in deferred revenue related primarily to the identification of the licenses as "right of use" licenses under the current guidance for which control transferred to the customer at the onset of each contract. At September 30, 2018, the Company had deferred revenue of $62 thousand that relates to unsatisfied performance obligations of sample supply due to Pioneer China and PBE and an incremental discount on future product sales due to Pioneer China.

Avenova Distribution Agreements

In November 2014, the Company signed a nationwide distribution agreement for its Avenova product with McKesson Corporation ("McKesson") as part of the Company's commercialization strategy. McKesson makes Avenova widely available in local pharmacies and major retail chains across the U.S., such as Wal-Mart, Costco, CVS and Target. In January 2015, the Company signed a nationwide distribution agreement with Cardinal Health. In April 2015, the Company also signed a distribution agreement with AmerisourceBergen to distribute Avenova nationwide.

During the three months ended September 30, 2018 and 2017, the Company earned $2.8 million and $3.5 million, respectively, and $7.7 million and $9.3 million, respectively, for the nine months ended September 30, 2018 and 2017, in sales revenue for its Avenova product from its distribution agreements.

The Company had a deferred revenue balance of $1.3 million at December 31, 2017 related to these agreements, which consisted of product sales that our customers had not resold to end users (sell-through approach). Upon the adoption of Topic 606, deferred revenue decreased by $1.3 million, with a portion associated with the constraint on variable consideration related to service fees/chargebacks, prompt payment discounts, rebates and returns in the amount of $0.6 million being reclassified as a contract liability. The remaining $0.7 million, including the net effect of deferred cost of goods sold, was recorded as part of the cumulative adjustment to the accumulated deficit. With the adoption of Topic 606, we recognize product sales as revenue when our products are sold to our customers.

At September 30, 2018, under the Avenova product distribution arrangements, the Company had a contract liability balance of $1.7 million. The contract liability is included in accounts payable and accrued liabilities in the balance sheet (see Note 7).

NOTE 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

Facility Leases

On August 24, 2016, we entered into an Office Lease (the “Lease”), pursuant to which we leased approximately 7,799 rentable square feet of real property located on the eleventh floor (Suite 1150) at 2000 Powell Street, Emeryville, California 94608 from KBSIII Towers at Emeryville, LLC (the “Landlord”), for our new principal executive offices. The expiration date of the Lease is February 28, 2022, unless earlier terminated pursuant to any provision of the Lease. The Company has the option to extend the term of the Lease for one five (5)-year period upon written notice to the Landlord due no earlier than twelve (12) months and no later than nine (9) months prior to the expiration of the Lease.

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The Company still has a lease commitment for the laboratory facilities and office space at Suite 550, EmeryStation North Building, 5980 Horton Street, Emeryville, California ("EmeryStation") under an operating lease that will expire on October 31, 2020. On July 11, 2016, the Company entered into a Sublease Agreement to sublease all 16,465 rentable square feet of real property at EmeryStation (the "Sublease Agreement"). The commencement date under the Sublease Agreement was September 8, 2016. The expiration date of the Sublease Agreement is October 21, 2020, as amended (while the expiration date of the Company's master lease for the EmeryStation premises is October 31, 2020), unless earlier terminated pursuant to the Company terminating its master lease for EmeryStation or the Sublease Agreement.

Rent expense, net, for the above two facility leases was approximately $96 thousand and $97 thousand, net, for the three months ended September 30, 2018 and 2017, respectively, and $289 thousand and $293 thousand, net, for the nine months ended September 30, 2018 and 2017, respectively.

The Company's monthly rent payments fluctuate under its various lease and sublease agreements. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis. The Company records deferred rent and sublease future minimum payments receivable for the difference between the amounts paid and recorded as expense.

Vehicle Fleet Leases

During the nine months ended September 30, 2018, the Company leased 54 vehicles under a master fleet lease agreement. Each lease is for a period of 36 months, which commenced upon the delivery of the vehicle. As of September 30, 2018, the aggregate monthly lease payment for all 54 vehicles is $14 thousand, including a management fee of $15 per vehicle. In addition, the Company made an initial payment of $3 thousand per vehicle, which it is amortizing over the 36-month lease period.

Lease expense, net, for the vehicle fleet was approximately $29 thousand and $28 thousand for the three months ended September 30, 2018 and 2017, respectively, and $91 thousand and $66 thousand for the nine months ended September 30, 2018 and 2017, respectively.

Directors and Officers Indemnification

As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of

potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, it has not recorded any liabilities for these agreements as of September 30, 2018.

In the normal course of business, the Company provides indemnification of varying scope under its agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, it generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of its products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to its products. The term of these indemnification agreements is generally perpetual. The potential future payments the Company could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit its exposure. As a result, it believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2018.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters as of September 30, 2018 that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company’s financial position, results of operations or cash flows.

NOTE 10. WARRANT LIABILITY

In July 2011, the Company sold common stock and warrants in a registered direct financing. As part of this transaction, 139,520 warrants were issued with an exercise price of $33.25 and were exercisable from January 1, 2012 to July 5, 2016. The terms of the warrants require registered shares to be delivered upon each warrant's exercise and also require possible cash payments to the warrant holders (in lieu of the warrant's exercise) upon specified fundamental transactions involving the Company's common stock, such as in an acquisition of the Company. Under ASC 480, *Distinguishing Liabilities from Equity*, the Company's ability to deliver registered shares upon an exercise of the warrants and the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. The warrants contain a provision according to which the warrant holder would have the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, after January 5, 2012, and if the closing bid price per share of the common stock in the principal market equals or exceeds $66.50 for any ten trading days (which do not have to be consecutive) in a period of fifteen consecutive trading days, the Company has the right to require the exercise of one-third of the warrants then held by the warrant holders.

In October 2015, the holders of all warrants issued pursuant to the Company's securities purchase agreement dated March 3, 2015 (the "2015 Securities Purchase Agreement") agreed to reduce the length of notice required to such investors prior to the Company's issuance of new securities from twenty business days to two business days, for the remainder of such investors' pre-emptive right period (which expired March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in the October 2015 Offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both the warrants with a 15-month term (the "Short-Term Warrants") and warrants with a five-year term (the "Long-Term Warrants") issued pursuant to the 2015 Securities Purchase Agreement (together, the "March 2015 Warrants") and the warrants issued pursuant to the placement agent agreement dated June 29, 2011 (the "July 2011 Warrants"). Specifically, the amendments decreased the exercise price for both the March 2015 Warrants and the July 2011 Warrants to $5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the July 2011 Warrants to March 6, 2020. A price protection provision also was added to both the July 2011 Warrants and March 2015 Warrants, such that if the Company subsequently sells or otherwise disposes of Company common stock at a lower price per share than $5.00 or any securities exchangeable for common stock with a lower exercise price than $5.00, the exercise price of such warrants will be reduced to that lower price.

In October 2015, the Company also entered into an underwriting agreement with Roth Capital Partners, LLC, relating to the public offering and sale of up to (i) 492,000 shares of the Company's common stock; and (ii) warrants to purchase up to 442,802 shares of the Company's common stock (the "October 2015 Warrants") with an exercise price of

$5.00 per share (the "October 2015 Offering"). The shares of common stock and warrants were issued separately. Each warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in the October 2015 Offering was $5.00 per share of common stock and related warrant. The net proceeds to the Company were approximately $2.1 million after deducting underwriting discounts and commissions and offering expenses.

In February 2016, the strike price of the July 2011, March 2015 and October 2015 warrants was reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Mr. Jian Ping Fu at that price.

The key assumptions used to value the July 2011 Warrants as of September 30, 2018 and December 31, 2017 were as follows:

Assumption	As of September 30, 2018		December 31, 2017	
Expected price volatility	66.00	%	91.00	%
Expected term (in years)	1.43		2.18	
Risk-free interest rate	2.69	%	1.91	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	$0.91		$ 2.72	

In March 2015, the Company issued both the Short-Term Warrants ($15.00 per share exercise price) and the Long-Term Warrants ($16.25 per share exercise price). At that time, the Company determined that these warrants qualified for equity accounting and did not contain embedded derivatives that required bifurcation. After the Company's agreement to modify the terms of the March 2015 Warrants and July 2011 Warrants in October 2015, the Company evaluated the change in terms of the March 2015 Warrants and noted that the change in terms resulted in liability classification of both the Short-Term and Long-Term Warrants. The March 2015 Warrants were re-issued and valued as of October 27, 2015 at a total of $1.8 million with the new terms, and a modification expense was recorded as the difference between the fair value of the warrants on their new terms after modification as of October 27, 2015 and the fair value of the warrants on their original terms prior to modification as of October 27, 2015. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss.

The key assumptions used to value the Short-Term Warrants as of September 30, 2018 and December 31, 2017 were as follows:

Assumption	As of September 30, 2018		December 31, 2017	
Expected price volatility	66.00	%	91.00	%
Expected term (in years)	1.43		2.18	
Risk-free interest rate	2.69	%	1.91	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	$0.69		$ 2.42	

The key assumptions used to value the Long-Term Warrants as of September 30, 2018 and December 31, 2017 were as follows:

Assumption	As of September 30, 2018		December 31, 2017	
Expected price volatility	66.00	%	91.00	%
Expected term (in years)	1.43		2.18	
Risk-free interest rate	2.69	%	1.91	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	$0.91		$ 2.72	

As noted above, the Company issued warrants in connection with the October 2015 Offering. The Company evaluated the terms of the October 2015 Warrants and noted that under ASC 480, the Company’s potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company’s control. Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss. The fair value of the warrants at issuance on October 27, 2015 was $1.3 million.

The key assumptions used to value the October 2015 warrants as of September 30, 2018 and December 31, 2017 were as follows:

Assumption	As of September 30, 2018		December 31, 2017	
Expected price volatility	66.00	%	90.00	%
Expected term (in years)	2.08		2.83	
Risk-free interest rate	2.82	%	1.96	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	$1.08		$ 2.86	

During the third quarter of 2016, a total of 3,613,284 warrants to purchase 3,613,284 shares of common stock were exercised related to warrants issued during July 2011, March 2015 and October 2015, resulting in gross proceeds of $6.9 million. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $1.6 million, with any change in fair value recorded in the consolidated statement of operations and comprehensive loss. The $1.6 million fair value was subsequently transferred to equity as of the date of exercise.

During the fourth quarter of 2016, a total of 363,523 warrants to purchase 363,523 shares of common stock were exercised related to the October 2015, November 2015 and December 2015 warrants resulting in gross proceeds of $0.9 million. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $0.5 million, with any change in fair value recorded in the consolidated income statement and comprehensive loss. The $0.5 million fair value was subsequently transferred to equity as of the date of exercise.

During the second quarter of 2017, a total of 21,000 warrants to purchase 21,000 shares of common stock were exercised related to the March 2015 Short-Term and Long-Term warrants resulting in gross proceeds of $38 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $58 thousand, with any change in fair value recorded in the consolidated income statement and comprehensive loss. The $58 thousand fair value was subsequently transferred to equity as of the date of exercise.

The details of the outstanding warrant liability as of September 30, 2018, were as follows:

Shares and dollars in thousands	**Shares**	**Warrant Liability**
July 2011 Warrants	49	$ 45
Long-Term Warrants	96	87
Short-Term Warrants	115	79
October 2015 Warrants	284	307
	544	$ 518

NOTE 11. STOCKHOLDERS' EQUITY (DEFICIT)

Amendments to Articles of Incorporation—Reverse Stock Split

Effective December 18, 2015, the Company amended its Certificate of Incorporation to affect a 1-for-25 reverse split of its outstanding common stock (the "Reverse Stock Split"). The Reverse Stock Split was approved by the Company's stockholders on December 11, 2015. The accompanying financial statements and related notes give retroactive effect to this Reverse Stock Split.

After approval by the Company's stockholders, the Company decreased the number of authorized shares from 240 million to 50 million effective June 4, 2018.

Preferred Stock

Under the Company's amended articles of incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the Board of Directors. As of September 30, 2018 and December 31, 2017, there were no shares of Company preferred stock outstanding.

Common Stock

In February 2016, the Company entered into three securities purchase agreements (the "Purchase Agreements") for the sale of an aggregate of 1,518,567 shares of the Company's common stock (the "Common Stock") to accredited investors for a total of $2.8 million. The Company entered into the first purchase agreement with Mr. Jian Ping Fu (the "Fu Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Fu 696,590 shares of Common Stock, at a per share price of $1.81, which was a five percent (5%) discount to the closing price of the Common Stock on February 16, 2016, the date of the Fu Agreement. The Company entered into the second purchase agreement with Pioneer Singapore (the "Pioneer Agreement"), pursuant to which the Company agreed to issue and sell to Pioneer Singapore 696,590 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. The Company entered into a third purchase agreement with Mark M. Sieczkarek (the "Sieczkarek Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Sieczkarek 125,387 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. The Common Stock issued by the Company pursuant to the Purchase Agreements has not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

China Kington Asset Management Co. Ltd. served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds received by the Company upon closing pursuant to the purchases by Pioneer Singapore and Mr. Fu. The amount of such commission was approximately $155 thousand.

On April 4, 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") for the sale of an aggregate 6,173,299 shares of Common Stock, par value $0.01 per share and warrants (the "April 2016 Warrants") exercisable for 3,086,651 shares of Common Stock to accredited investors for an aggregate purchase price of $11.8 million (the "Private Placement"). The warrants have a 4-year term and an exercise price of $1.91, callable by the Company if the closing price of the Common Stock, as reported on the NYSE American, is $4.00 or greater for five sequential trading days. The Private Placement closed in two tranches, the first of which closed on May 5, 2016, resulting in proceeds to the Company of $7.8 million (the "Primary Closing"), and the second of which closed on August 1, 2016, resulting in proceeds of $4.0 million to the Company (the "Secondary Closing"). In the Primary Closing, the Company issued 4,079,058 shares of Common Stock and April 2016 Warrants exercisable for 2,039,530 shares of Common Stock. In the Secondary Closing, the Company issued 2,094,241 shares of Common Stock and April 2016 Warrants exercisable for 1,047,121 shares of Common Stock. Both the Primary Closing and the Secondary Closing were subject to the same terms, containing customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the purchasers and other obligations of the parties and termination provisions.

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China Kington Asset Management Co. Ltd. served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds received by the Company upon closing pursuant to the purchases by certain investors. The amount of such commission was approximately $618 thousand.

Also on April 4, 2016, the Company entered into a separate registration rights agreement (the "Registration Rights Agreement") with Messrs. Andros and Geckler, Dr. Rider, and the Children's Brain Disease Foundation (the "Participating Purchasers"), pursuant to which the Company agreed to file as many registration statements with the SEC as may be necessary to cover the resale of the shares and the April 2016 Warrants held by the Participating Purchasers, to use its commercially reasonable efforts to have all such registration statements declared effective within the time frames set forth in the Securities Purchase Agreement and the Registration Rights Agreement, and to keep such registration statements effective for the terms defined therein. The Company filed such Registration Statement to cover the resale of the shares and April 2016 Warrants held by the Participating Purchasers with the SEC on June 9, 2016 and received effectiveness of such Registration Statement on June 20, 2016 (Registration Number 333-211943).

During the third quarter of 2016, the Company recorded $6.6 million in net proceeds upon the exercise of 3,613,284 of the Company's warrants for 3,613,284 shares of the Company's Common Stock, including all of the warrants issued in May 2016 and August 2016. As consideration for the facilitation of the exercise of certain of these warrants held by non-U.S. citizens domiciled outside of the United States, China Kington received a six percent (6%) commission on the aggregate proceeds to the Company pursuant to such exercises. The amount of such commission was approximately $338 thousand.

During the fourth quarter of 2016, the Company recorded $0.9 million in net proceeds upon the exercise of 363,523 of the Company's warrants for 363,523 shares of the Company's Common Stock. As consideration for the facilitation of the exercise of certain of these warrants held by non-U.S. citizens domiciled outside of the United States, China Kington received a six percent (6%) commission on the aggregate proceeds to the Company pursuant to such exercises. The amount of such commission was approximately $32 thousand.

During the first quarter of 2018, we entered into a share purchase agreement with OP Financial Investments Limited for the sale of an aggregate of 1,700,000 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $5.984 million (the "OP Private Placement"). The OP Private Placement closed on February 8, 2018. OP Financial Investments Limited is an investment firm based in Hong Kong focused on cross-border investment opportunities and listed on the Hong Kong Stock Exchange. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $359 thousand. The Company also paid $34 thousand to NYSE American for the listing of the additional shares.

Stock Warrants

In February 2016, the strike prices of the July 2011, March 2015 Short-Term Warrants and Long-Term Warrants, and October 2015 warrants were reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Mr. Jian Ping Fu at that price.

In May 2016, the Company issued 2,039,530 warrants at the Primary Closing pursuant to the Securities Purchase Agreement. Please see the preceding subsection, “Common Stock,” for further details.

In August 2016, the Company issued 1,047,121 warrants at the Secondary Closing pursuant to the Securities Purchase Agreement. Please see the preceding subsection, “Common Stock,” for further details.

Effective September 29, 2016, the Company modified the exercise price of all warrants issued pursuant to the securities purchase agreement, dated May 18, 2015, from $19.50 to $3.15 per share, which reflected a discount of approximately sixteen percent (16%) to the closing price of the Company’s Common Stock on September 27, 2016. The Company has estimated the value of warrant modification as of the date of the modification by applying the Black-Scholes-Merton option pricing model using the single-option valuation approach. As a result of this modification, the Company recorded a non-cash loss of $270 thousand in general and administrative expense in the consolidated statement of operation and comprehensive loss.

The details of all outstanding warrants as of September 30, 2018, were as follows:

(in thousands, except for exercise price)	Warrants	Weighted-Average Exercise Price
Warrants outstanding December 31, 2017	544	$ 1.81
Warrants granted	—	—
Warrants exercised	—	—
Warrants expired	—	—
Warrants outstanding September 30, 2018	544	$ 1.81

NOTE 12. EQUITY-BASED COMPENSATION

Equity Compensation Plans

In October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of equity awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants, as determined by the Board of Directors. At the inception of the 2007 Plan, 40,000 shares were reserved for awards under the 2007 Plan.

For the years from 2009 to 2012, the number of shares of common stock authorized for awards under the 2007 Plan increased annually in an amount equal to the lesser of (a) 40,000 shares; (b) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year; or (c) such lesser number as determined by the Board. Accordingly, an additional 40,000, 37,427, and 37,207 shares of common stock were authorized for awards under the 2007 Plan in January 2012, 2011 and 2010, respectively. Beginning in 2013, the shareholders voted to remove the 40,000 share cap and the 2007 Plan's shares authorized for awards increased annually by 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year. Accordingly, an

additional 32,646 and 59,157 shares of common stock were authorized for awards under the 2007 Plan in January 2014 and 2013, respectively. On March 30, 2015, the Company filed a registration statement to add an additional 82,461 shares to the 2007 Plan's shares authorized for awards. In January 2016, the Company added 139,449 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. On May 26, 2016, the stockholders of the Company approved an amendment to the 2007 Plan to increase the number of shares of Company common stock authorized for awards thereunder by 1,124,826 shares. In January 2017, the Company added 610,774 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. As a result of the foregoing, the aggregate number of shares authorized for awards under the 2007 Plan was 2,318,486 shares, prior to its expiration on March 15, 2017 (after taking into account prior awards under the 2007 Plan).

Upon expiration of the 2007 Plan, new awards cannot be issued pursuant to the 2007 Plan, but awards outstanding as of its March 15, 2017 plan expiration date will continue to be governed by its terms. Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and, if granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service.

In March 2017, the Company adopted the 2017 Omnibus Incentive Plan (the "2017 Plan"), which was approved by shareholders on June 2, 2017, to provide for the granting of equity awards, such as nonqualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock, performance shares, stock appreciation rights ("SARs"), RSUs and other share-based awards to employees, directors, and consultants, as determined by the Board of Directors. The 2017 Plan will not affect awards previously granted under the 2007 Plan. The 2017 Plan allows for awards of up to 2,318,486 shares of the Company's common stock, plus an automatic annual increase in the number of shares authorized for awards on the first day of each of the Company's fiscal years beginning January 1, 2018 through January 1, 2027 equal to (i) four percent of the number of shares of Common Stock outstanding on the last day of the immediately preceding fiscal year or (ii) such lesser number of shares of Common Stock than provided for in Section 4(a)(i) of the 2017 Plan as determined by the Board. Accordingly, in January 2018, the Company filed a registration statement to add 615,392 shares to the 2017 Plan's shares authorized for awards, per the 2017 Plan's evergreen provision. As of September 30, 2018, there were 1,384,152 shares available for future awards under the 2017 Plan.

Under the terms of the 2017 Plan, the exercise price of NQSOs, ISOs and SARs may not be less than 100% of the fair market value of the common stock on the date of grant and, if ISOs are granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. The term of awards will not be longer than ten years, or in the case of ISOs, not longer than five years with respect to holders of more than 10% of the Company's stock. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service. The Company issues new shares to satisfy option exercises under the 2007 and 2017 plans.

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding as of September 30, 2018, and activity during the nine-month period then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	2,960	$ 5.16	8.6	$ 2,586
Options granted	852	$ 2.21		
Restricted stock units granted	12	$ —		
Options exercised	(4)	$ 2.35		
Restricted stock units vested	-	$ —		
Options forfeited/cancelled	(630)	$ 5.41		
Restricted stock units cancelled	(10)	$ —		
Outstanding at September 30, 2018	3,180	$ 4.32	8.3	$ 23
Vested and expected to vest at September 30, 2018	2,713	$ 4.62	8.3	$ 22
Vested at September 30, 2018	1,596	$ 6.12	7.6	$ —
Exercisable at September 30, 2018	1,596	$ 6.12	7.6	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of the Company's common stock as quoted on the NYSE American as of September 30, 2018 for options that have a quoted market price in excess of the exercise price. There were no stock option awards exercised for the three months ended September 30, 2018. There were 4 thousand stock option awards exercised during the nine months ended September 30, 2018 for which the Company received cash payments of $11 thousand. There was no intrinsic value for stock option awards exercised for the nine months ended September 30, 2018. There were 51 thousand stock option awards exercised for the three and nine months ended September 30, 2017 for which the Company received cash payments of $129 thousand. The aggregate intrinsic value of stock option awards exercised was $108 thousand for the nine months ended September 30, 2017.

As of September 30, 2018, total unrecognized compensation cost related to unvested stock options and restricted stock was approximately $1.8 million. This amount is expected to be recognized as stock-based compensation expense in

the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 3 years.

Stock Option Awards to Employees and Directors

The Company grants options to purchase common stock to its employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. The Company has estimated the value of stock option awards as of the date of grant by applying the Black-Scholes-Merton option pricing model using the single-option valuation approach. The application of this valuation model involves assumptions that are judgmental and subjective in nature. See Note 2 for a description of the accounting policies that the Company applied to value its stock-based awards.

During the nine months ended September 30, 2018 and 2017, the Company granted options to purchase an aggregate of 819,000 and 1,407,000 shares of common stock, respectively, to employees and directors.

The weighted-average assumptions used in determining the value of options are as follows:

	Nine Months Ended September 30,	
Assumption	**2018**	**2017**
Expected price volatility	88.86%	87.76%
Expected term (in years)	5.97	6.90
Risk-free interest rate	2.71 %	2.11 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	$1.64	$2.30

Expected Price Volatility—This is a measure of the amount by which the common stock price has fluctuated or is expected to fluctuate. The computation of expected volatility is based on the historical volatility of the Company's common stock and the common stock of comparable companies from a representative peer group selected based on industry and market capitalization data.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. The expected life assumption is based on the Company's historical data.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option.

Dividend Yield—The Company has not made any dividend payments, nor does it have plans to pay dividends in the foreseeable future.

Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

During the nine months ended September 30, 2018, the Company issued 12 thousand shares of restricted stock to employees. Additionally, during the nine months ended September 30, 2017, the Company did not issue any shares of restricted stock to employees.

For the three months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense of $163 thousand and $779 thousand, respectively, for stock-based awards to employees and directors. For the nine months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense of $490 thousand and $2,379 thousand, respectively, for stock-based awards to employees and directors.

In July 2017, Mr. Paulson announced his retirement from his position as CFO of the Company, to be effective as of December 31, 2017. As part of his employment agreement, the Company modified his stock options, effective upon his retirement. All outstanding stock options held by Mr. Paulson fully vested upon his retirement, and the option exercise period was extended from three months to three years, calculated from the date of his retirement. Options with an expiration date prior to the end of the exercise period will maintain the same expiration date. As this agreement was entered into during the third quarter of 2017 and Mr. Paulson continued providing services to the Company through December 31, 2017, the Company recorded stock-based compensation expense in connection with the stock option modification in both the third and fourth quarters of 2017. In connection with the stock option modification, the Company recognized stock-based compensation expense of $243 thousand during the three months ended September 30, 2017.

In March 2018, the Company modified stock options held by Mr. Liu, who resigned as a director of the Company, effective March 21, 2018. The option exercise period for Mr. Liu was extended from three months to three years, calculated from his date of resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $26 thousand.

Stock-Based Awards to Non-Employee Consultants

During the nine months ended September 30, 2018 and 2017, the Company granted options to purchase an aggregate of 32 thousand and 86 thousand shares of common stock, respectively, to non-employee consultants in exchange for advisory and consulting services. The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

	Nine Months Ended September 30,	
Assumption	**2018**	**2017**
Expected price volatility	85.03%	87.41%
Expected term (in years)	10.0	10.00
Risk-free interest rate	2.93 %	2.27 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	$2.01	$2.40

The Company did not grant restricted stock to non-employees in the nine months ended September 30, 2018. The Company granted 31 thousand shares of fully vested registered stock to non-employee Dr. Ron Najafi in the nine months ended September 30, 2017, as part of his settlement agreement, as described below. In addition, the Company also granted restricted stock to a non-employee consultant totaling 8 thousand shares of common stock in the nine months ended September 30, 2017, in exchange for advisory and consulting services.

For the three months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense of $5 thousand and $161 thousand, respectively, related to non-employee consultant stock and option grants. For the nine months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense of $18 thousand and $250 thousand, respectively, related to non-employee consultant stock and option grants.

In November 2015, Dr. Ron Najafi resigned from his position as President and CEO of the Company. As part of his separation agreement, in December 2016, the Company paid him a portion of the amount due under the agreement via a combination of registered shares and cash during fiscal year 2016. The expense related to this separation agreement was accrued for and expensed in the year ended December 31, 2015, and the shares were issued to him via fully vested registered stock in December 2016. In January 2017, the remaining portion of the amount due under the agreement was paid via a combination of registered shares and cash.

Summary of Stock-Based Compensation Expense

A summary of the stock-based compensation expense included in results of operations for the option and stock awards discussed above is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2018**	**2017**	**2018**	**2017**
Research and development	$16	$51	$35	$100
Sales and Marketing	40	153	119	247
General and administrative	112	736	354	2,281
Total stock-based compensation expense	$168	$940	$508	$2,628

Since the Company continues to operate at a net loss, it does not expect to realize any current tax benefits related to stock options.

NOTE 13. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan covering all eligible employees. The Company is not required to contribute to the plan and made no contributions during the nine months ended September 30, 2018.

NOTE 14. RELATED PARTY TRANSACTIONS

Related Party Financing

See Note 11, “Stockholders’ Equity (Deficit)” – “Common Stock” for a description of the Purchase Agreements and the Securities Purchase Agreement in April 2016. The following related parties participated in both transactions: Mr. Sieczkarek, Chairman of the Board, and former President and Chief Executive Officer of the Company; and Pioneer Singapore and Mr. Fu, the Company’s two largest stockholders.

Related Party Revenue

The Company recognized related party revenues from product sales and license and collaboration fees of zero and $6 thousand for the three months ended September 30, 2018 and 2017, respectively, and $13 thousand and $21 thousand for the nine months ended September 30, 2018 and 2017, respectively. There were no related party accounts receivable as of September 30, 2018 and December 31, 2017. See Note 8, “Adoption of Topic 606, “*Revenue from contracts with customers*”, for additional information regarding the Company’s distribution agreements with Pioneer, which is an affiliate of Pioneer Singapore, the Company’s largest stockholder.

Related Party Expenses

The Company recognized no related party commission fees for the three months ended September 30, 2018 and 2017, and recognized related party commission fees of $359 thousand and zero for the nine months ended September 30, 2018 and 2017, respectively. These fees were paid to China Kington representing the commission on its sale of the Company’s common stock. See Note 11, “Stockholders’ Equity (Deficit)” – “Common Stock” for additional information regarding such commissions.

NOTE 15. SUBSEQUENT EVENTS

On September 28, 2018, Mark M. Sieczkarek was replaced as the President and Chief Executive Officer of the Company upon the appointment of John J. McGovern, the Company's Chief Financial Officer and Treasurer, to serve as the Company's Interim President and Chief Executive Officer. Mr. Sieczkarek remains the Chairman of the Company's Board of Directors. In connection with such change: (i) Mr. McGovern's base salary was increased from $298,000 to $370,000, effective October 1, 2018; (ii) Mr. McGovern was granted 250,000 non-qualified stock options under the 2017 Plan, effective October 9, 2018; and (iii) the Board of Directors approved cash compensation for a non-employee Chairman of the Board in the amount of $52,000 per annum, in addition to the base cash compensation for a non-employee director in the amount of $30,000 per annum.

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

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part I, Item 1 of this report, and with our consolidated financial statements and related notes, 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, which was filed with the Securities and Exchange Commission (the "SEC") on March 21, 2018. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," "goals," "plans," "believes," "estimates," variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Readers are cautioned that these forward-looking statements are only predictions based upon assumptions made that we believed to be reasonable at the time, and are subject to risks and uncertainties. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.

Overview

We are a medical device company predominantly focused on eye care. We are currently focused primarily on commercializing Avenova®, a prescription product sold in the United States for cleansing and removing foreign material including microorganisms and debris from skin around the eye, including the eyelid.

Avenova is an eye care product formulated with our proprietary, stable and pure form of hypochlorous acid. Avenova has proven in laboratory testing to have broad antimicrobial properties as a preservative in solution as it removes foreign material including microorganisms and debris from the skin on the eyelids and lashes without burning or

stinging. Our business strategy remains the same since November 2015, when we restructured our business to focus our resources on growing sales of Avenova in the United States. Our current three-part business strategy is comprised of: (1) focusing our resources on growing the U.S. commercial sales of Avenova, including implementation of a sales and marketing strategy intended to increase product margin and profitability; (2) maintaining low expenses and continuing to optimize sales force efficiency, including expansion of geographical reach and efforts directed to maintain and increase insurance reimbursement for Avenova; and (3) seeking additional sources of revenue through partnering, divesting and/or other means of monetizing non-core assets in urology, dermatology, and wound care.

Pursuant to our business strategy, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® for the wound care market and CelleRx® for the dermatology market. Since the launch of NeutroPhase in 2013, we have established a U.S. distribution partner and an international distribution partner in China. We currently do not sell or distribute CelleRx.

Avenova, NeutroPhase, and CelleRx are medical devices cleared by the FDA under the Food and Drug Administration Act Section 510(k). The products are intended for use under the supervision of healthcare professionals for the cleansing and removal of foreign material, including microorganisms and debris. For wound treatment, NeutroPhase® is also intended for use under the supervision of healthcare professionals for moistening absorbent wound dressings and cleansing minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts, giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, research and development costs, patent costs, stock-based compensation, income taxes and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements (Summary of Significant Accounting Policies), included in Part I, Item 1 of this report, we believe that the following accounting policies are most critical to fully understanding and evaluating our reported financial results.

Allowance for Doubtful Accounts

We charge “Bad Debt” expense and set up an “Allowance for Doubtful Accounts” when management identifies amounts due that are in dispute and believes it unlikely a specific invoice will be collected. At September 30, 2018 and December 31, 2017, management had reserved $9 thousand and $13 thousand, respectively, primarily based on specific amounts that were in dispute or were over 120 days past due as of those dates.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At September 30, 2018 and December 31, 2017, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $124 thousand and $140 thousand, respectively.

Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method.

Revenue Recognition

Beginning January 1, 2018, we have followed the provisions of Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

We generate product revenue through product sales to our major distribution partners, a limited number of distributors and via our webstore. Product supply is the only performance obligation contained in these arrangements and we recognize product revenue upon transfer of control to our major distribution partners at the amount of consideration that we expect to be entitled to, generally upon shipment to the distributor on a “sell-in” basis.

Other revenue is primarily generated through commercial partner agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include more than one performance obligation and generally contain non-refundable upfront fees, payments based upon achievement of certain milestones and royalties on net product sales.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under these agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Topic 606. Our performance obligations include:

- Product supply
- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply
- Incremental discounts and product supply prepayments considered material rights to the customer

We have optional additional items in our contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or our discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations.

Transaction Price

We have both fixed and variable consideration. Under our license arrangements, non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Product supply selling prices are identified as variable consideration subject to the constraint on variable consideration for estimated discounts, rebates, chargebacks and product returns. Funding of research and development activities are considered variable payments until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

For product supply under our distribution arrangements, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because we do not have sufficient historical data to compute our own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. We update the return rate assumption quarterly and apply it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the customer. At any point in time there is generally one month of inventory in the sales channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved after one month from when control is transferred.

The following table summarizes the activity in the accounts related to product revenue allowances (in thousands):

	Wholesaler/ Pharmacy fees	**Cash discounts**	**Rebate**	**Returns**	**Total**
Balance at December 31, 2017	$ (530)	$ (31)	$818	$ -	$257
Effect of Topic 606 Adoption	$ (27)	$ 35	$(573)	$ (42)	$(607)
Current provision related to sales made during current period	(1,853)	(333)	(7,253)	(468)	(9,907)
Payments	1,860	284	6,925	162	9,231
Balance at September 30, 2018	$ (550)	$ (45)	$(83)	$ (348)	$(1,026)

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, and achievement is in our control (such as a regulatory submission by us), the value of the associated milestone is included in the transaction price. Milestone payments that are not within our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for arrangements that contain multiple performance obligations, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. When a contract contains more than one performance obligation, we use key assumptions to determine the stand-alone selling price of each performance obligation. The estimated stand-alone selling prices for distribution rights and material rights for incremental discounts on product supply are calculated using an income approach discounted cash flow model and can include the following key assumptions: forecasted commercial partner sales, product life cycle estimates, costs of product sales, commercialization expenses, annual growth rates and margins, discount rates and probabilities of technical and regulatory success. For all other performance obligations, we use a cost-plus margin approach. We allocate the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under each arrangement. If we cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that we have incurred to perform the services using the cost-to-cost input method.

Our intellectual property in the form of distribution rights is determined to be distinct from the other performance obligations identified in the arrangements and considered “right to use” licenses which the customer can benefit from at a point in time. We recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license.

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping costs, and other costs of goods sold. Cost of goods sold also includes any necessary allowances for excess and obsolete inventory, along with lower of cost or estimated net realizable value.

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. Research and development costs may vary depending on the type of item or service incurred, location of performance or production, or lack of availability of the item or service, and specificity required in production for certain compounds. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services. Our research, clinical and development activities are often performed under agreements we enter into with external service providers. We estimate and accrue the costs incurred under these agreements based on factors such as milestones achieved, patient enrollment, estimates of work performed, and historical data for similar arrangements. As actual costs are incurred, we adjust our accruals. Historically, our accruals have been consistent with management's estimates, and no material adjustments to research and development expenses have been recognized. Subsequent changes in estimates may result in a material change in our expenses, which could also materially affect our results of operations.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures (Equity-Based Compensation) differ, or are expected to differ, from the previous estimate. See Note 12 of the Notes to Consolidated Financial Statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. For stock options granted to employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

Stock-based compensation arrangements with non-employees are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized.

Common Stock Warrant Liabilities

For warrants that are issued or modified and there is a deemed possibility that we may have to settle them in cash, or for warrants we issue or modify that contain an exercise price adjustment feature that reduces the exercise price and increases the number of shares of our common stock eligible for purchase thereunder in the event we subsequently issue equity instruments at a price lower than the exercise price of the warrants, we record the fair value of the issued or modified warrants as a liability at each balance sheet date and record changes in the estimated fair value as a non-cash gain or loss on the consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Lattice valuation model, and the change in the fair value is recorded in the consolidated statements of operations and comprehensive gain or loss. The Lattice model provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of our judgment. For additional information regarding the Company’s outstanding warrants, see Note 10 of the Notes to Consolidated Financial Statements (Warrant Liability).

Recent Accounting Pronouncements

See Note 2 of the Notes to Consolidated Financial Statements (Summary of Significant Accounting Policies) included in Part I, Item 1 of this report for information on recent accounting pronouncements.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,		Dollar Change	Percent Change
	2018	2017		
	(in thousands)			
Statement of Operations				
Sales:				
Product revenue, net	$3,142	$4,080	$(938)	(23)%
Other revenue	-	11	(11)	(100)%
Total sales, net	3,142	4,091	(949)	(23)%
Product cost of goods sold	332	521	(189)	(36)%
Gross profit	2,810	3,570	(760)	(21)%
Research and development	45	132	(87)	(66)%
Sales and marketing	3,230	3,296	(66)	(2)%
General and administrative	1,344	2,311	(967)	(42)%
Total operating expenses	4,619	5,739	(1,120)	(20)%
Operating loss	(1,809)	(2,169)	360	(17)%
Non-cash gain (loss) on changes in fair value of warrant liability	267	(281)	548	(195)%
Other income, net	4	3	1	33 %
Loss before provision for income taxes	(1,538)	(2,447)	909	(37)%
Provision for income tax	-	-	-	- %
Net loss and comprehensive loss	$(1,538)	$(2,447)	$909	(37)%

Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, decreased by $1.0 million, or 23%, to $3.1 million for the three months ended September 30, 2018 from $4.1 million for the three months ended September 30, 2017. The decrease in product revenue, net, is primarily the result of a decrease in the net selling price of Avenova products, along with $0.2 million decrease in non-Avenova product sales.

Other revenue decreased by $11 thousand for the three months ended September 30, 2018, to $0 from $11 thousand for the three months ended September 30, 2017.

Product cost of goods sold decreased by $0.2 million, or 36%, to $0.3 million for the three months ended September 30, 2018, from $0.5 million for the three months ended September 30, 2017. The decrease in product cost of goods sold was primarily the result of a decrease in product revenue, along with product mix.

Gross profit decreased by $0.8 million, or 21%, to $2.8 million for the three months ended September 30, 2018 from $3.6 million for the three months ended September 30, 2017. The decrease in gross profit was primarily the result of decreased product revenue, net.

Research and Development

Research and development expenses decreased by $87 thousand, or 66%, to $45 thousand for the three months ended September 30, 2018, down from $132 thousand for the three months ended September 30, 2017.

Sales and marketing

Sales and marketing expenses decreased by $0.1 million, or 2%, to $3.2 million for the three months ended September 30, 2018, down from $3.3 million for the three months ended September 30, 2017. The decrease is primarily due to the decrease in sales headcount and employee related costs, partly offset by an increase in sampling.

General and administrative

General and administrative expenses decreased by $1.0 million or 42%, to $1.3 million for the three months ended September 30, 2018, down from $2.3 million for the three months ended September 30, 2017. The decrease is primarily a result of lower stock-based compensation, including the CFO retirement package recorded in 2017, and other employee related costs, along with a decrease in professional services and consulting fees.

Non-cash gain (loss) on changes in fair value of warrant liability

The adjustments to the fair value of warrants resulted in a gain of $267 thousand for the three months ended September 30, 2018, compared to a loss of $281 thousand for the three months ended September 30, 2017.

In October 2015, we issued warrants and modified the terms of warrants originally issued in July 2011 and March 2015, resulting in the creation of warrant liabilities. For additional information regarding these warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report. During the three months ended September 30, 2018, the Company incurred a non-cash gain resulting from the reduction in the price of the Company’s common stock price during that period. During the three months ended September 30, 2017, the Company incurred a non-cash loss resulting from an increase in the price of the Company’s common stock during that period.

Other income, net

Other income, net, increased by $1 thousand for the three months ended September 30, 2018, to $4 thousand compared to $3 thousand for the three months ended September 30, 2017.

Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended September 30,		Dollar Change	Percent Change
	2018	2017		
	(in thousands)			
Statement of Operations:				
Sales:				
Product revenue, net	$8,870	$11,868	$(2,998)	(25)%
Other revenue	13	46	(33)	(72)%
Total net sales	8,883	11,914	(3,031)	(25)%
Product cost of goods sold	1,062	1,807	(745)	(41)%
Gross profit	7,821	10,107	(2,286)	(23)%
Research and development	152	264	(112)	(42)%
Sales and marketing	9,603	10,412	(809)	(8)%
General and administrative	4,326	7,134	(2,808)	(39)%
Total operating expenses	14,081	17,810	(3,729)	(21)%
Operating loss	(6,260)	(7,703)	1,443	(19)%
Non-cash gain (loss) on changes in fair value of warrant liability	971	(501)	1,472	(294)%
Other income, net	13	9	4	44%
Loss before provision for income taxes	(5,276)	(8,195)	2,919	(36)%
Provision for income tax	(1)	(1)	-	-%
Net loss and comprehensive loss	$(5,277)	$(8,196)	$2,919	(36)%

Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, decreased by $3.0 million, or 25%, to $8.9 million from $11.9 million for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017. The decrease in product revenue, net, is primarily the result of a 19% decrease in the number of Avenova units sold as well as a decrease in the net selling price of Avenova products. Also contributing to the decrease is a $0.5 million decrease in non-Avenova product sales.

Other revenue decreased by $33 thousand, or 72%, to $13 thousand from $46 thousand for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017, primarily due to lower non-Avenova sales.

Product cost of goods sold decreased by $0.7 million, or 41%, to $1.1 million for the nine months ended September 30, 2018, from $1.8 million for the nine months ended September 30, 2017. The decrease in product cost of goods sold was primarily the result of a decrease in product revenue, along with product mix.

Gross profit decreased by $2.3 million, or 23%, to $7.8 million for the nine months ended September 30, 2018 from $10.1 million for the nine months ended September 30, 2017. The decrease in gross profit was primarily the result of decreased product revenue, net.

Research and Development

Research and development expenses decreased by $112 thousand, or 42%, to $152 thousand for the nine months ended September 30, 2018, down from $264 thousand for the nine months ended September 30, 2017.

Sales and marketing

Sales and marketing expenses decreased by $0.8 million, or 8%, to $9.6 million for the nine months ended September 30, 2018, down from $10.4 million for the nine months ended September 30, 2017. The decrease was primarily due to a decrease in sales representative headcount, along with a decrease in consultants and marketing programs. This was partly off-set by an increase in sampling.

General and administrative

General and administrative expenses decreased by $2.8 million, or 39%, to $4.3 million for the nine months ended September 30, 2018, down from $7.1 million for the nine months ended September 30, 2017. The decrease is primarily a result of lower stock-based compensation and other employee related costs along with a decrease in professional services and consulting fees. Also contributing to the decrease were one-time expenses in 2017 that included the CFO retirement package and establishment of a Kozma litigation reserve.

Non-cash gain (loss) on changes in fair value of warrant liability

The adjustments to the fair value of warrant liability resulted in a gain of $1.0 million for the nine months ended September 30, 2018, compared to a loss of $0.5 million for the nine months ended September 30, 2017.

In October 2015, we issued warrants and modified the terms of warrants originally issued in July 2011 and March 2015, resulting in the creation of warrant liability. For additional information regarding these warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report. The Company incurred a non-cash gain in the nine months ended September 30, 2018 related to a change in the fair value of warrant liability that was caused by a decrease in the price of the Company's common stock. During the nine months ended September 30, 2017, non-cash loss on changes in fair value of warrant liability was caused by an increase in the price of the Company's common stock above the warrants' exercise prices.

Other income, net

Other income, net, increased to $13 thousand for the nine months ended September 30, 2018, as compared to $9 thousand for the nine months ended September 30, 2017.

Financial Condition, Liquidity and Capital Resources

As of September 30, 2018, our cash and cash equivalents were $5.2 million, compared to $3.2 million as of December 31, 2017. The Company has sustained operating losses for the majority of its corporate history and expects that its 2018 expenses will exceed its 2018 revenues, as the Company continues to re-invest in its Avenova commercialization efforts. The Company expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, the Company's planned operations raise substantial doubt about its ability to continue as a going concern. The Company's liquidity needs will be largely determined by the success of operations in regard to the commercialization of Avenova. The Company also may consider other plans to fund operations including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones or an upfront fee; (2) raising additional capital through debt and equity financings or from other sources; (3) reducing spending on one or more of its sales and marketing programs; and/or (4) restructuring operations to change its overhead structure. The Company may issue securities, including common stock and warrants through private placement transactions or registered public offerings, which would require the filing of a Form S-1 or Form S-3 registration statement with the SEC. In the absence of the Company's completion of one or more of such transactions, there will be substantial doubt about the Company's ability

to continue as a going concern within one year after the date these financial statements are issued, and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to its ability to continue as a going concern.

Net Cash Used In Operating Activities

For the nine months ended September 30, 2018, net cash used in operating activities was $3.5 million compared to $3.3 million for the nine months ended September 30, 2017. The increase was primarily due to the decrease of net loss by $2.9 million, a decrease in stock-based comp expense of $2.1 million, an increase in depreciation of $0.2 million, favorable changes in working capital of $0.3 million and gain on change of the warrant liability fair value by $1.5 million.

Net Cash Used In Investing Activities

For the nine months ended September 30, 2018, net cash used in investing activities for the purchase of property and equipment was $13 thousand, compared to $228 thousand for the nine months ended September 30, 2017.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $5.6 million for the nine months ended September 30, 2018, which was mainly attributable to the net proceeds from issuance of common stock related to the OP Private Placement. Net cash provided by financing activities was $136 thousand for the nine months ended September 30, 2017, with $48 thousand attributable to the settlement of restricted stock for tax withholding, offset by $38 thousand in exercise of warrants.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2017, we had net operating loss carryforwards for federal and state income tax purposes of $94.8 million and $78.5 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2024 and 2037. As of December 31, 2017, we also had tax credit carryforwards for federal income tax purposes of $1.3 million and $282 thousand for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2026. The state tax credits have an indefinite carryover period.

Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future, although there can be no assurances that our business will not be affected by inflation in the future.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2018.

Seasonality

Consistent with our peers in the United States pharmaceutical industry, our business experiences seasonality with the first quarter of each year typically being the lowest revenue quarter. This annual phenomenon is due to consumers facing the need to satisfy health insurance deductibles and changes to copays as each new insurance year begins.

Contractual Obligations

Our contractual cash commitments as of September 30, 2018 were as follows (in thousands):

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Facility leases	$2,928	$1,107	$1,636	$ 185	$ —
Vehicle leases	218	163	55	—	—
	$3,146	$1,270	$1,691	$ 185	$ —

Our commitments as of September 30, 2018 consist of two operating facility leases: the Lease and the lease for Emery Station, and 54 operating vehicle leases.

The total commitment for the Lease as of September 30, 2018 was $1.5 million due over the lease term, compared to $1.8 million as of December 31, 2017.

The total commitment of the Emery Station lease as of September 30, 2018 was $1.5 million due over such lease term, compared to $2.0 million as of December 31, 2017. On July 11, 2016, we entered into a Sublease Agreement to sublease our former corporate headquarters. Sublease rental reimbursement is not deducted from the above table. We anticipate collecting $685 thousand and $703 thousand in the years ending September 30, 2019 and 2020, respectively, under the Sublease for the lease of Emery Station.

Additionally, we have operating leases for a fleet of 54 vehicles, which commenced upon the delivery of the vehicles during the first quarter 2017. The total commitment for these leases as of September 30, 2018 was $218 thousand due over the lease terms, compared to $340 thousand as of December 31, 2017.

See Note 9 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report for further information regarding these leases.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk consists principally of interest rate risk on our cash and cash equivalents.

With most of our focus on Avenova in the domestic U.S. market, we do not have any material exposure to foreign currency rate fluctuations.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our interim Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Assessing the costs and benefits of such controls and procedures necessarily involves the exercise of judgment by management. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Based upon that evaluation, our interim Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

Our business is subject to a number of risks, the most important of which are discussed below. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC before deciding to buy, sell or hold our common stock. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations.

Risks Relating to Our Liquidity

There is uncertainty about our ability to continue as a going concern.

We have a limited number of commercial products, which are still in their early stage of commercialization, and we are focusing our commercialization efforts almost exclusively on Avenova. As a result, we have sustained operating losses for the majority of our corporate history and expect that our 2018 expenses will equal or exceed our 2018 revenues, as we continue to invest in our Avenova commercialization efforts. We expect to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Additional funding beyond the OP Private Placement may be needed in order to pursue our business plan, which includes increasing market penetration for our existing commercial products, research and development for additional product offerings, seeking regulatory approval for these product candidates, and pursuing their commercialization in the United States, Asia, and other markets. These circumstances raise doubt about our ability to continue as a going concern, which depends on our ability to raise capital to fund our current operations.

We have a history of losses and we may never achieve or maintain sustained profitability.

We have historically incurred net losses and we may never achieve or maintain sustained profitability. In addition, at this time:

- we expect to incur substantial marketing and sales expenses as we continue to attempt to increase sales of our Avenova product;
- our results of operations may fluctuate significantly
- we may be unable to develop and commercialize our product candidates and
- it may be difficult to forecast accurately our key operating and performance metrics because of our limited operating history.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully market and sell Avenova, either independently or with partners, we will not be able to generate sufficient revenues to achieve or maintain profitability in the future. Our failure to achieve and subsequently maintain profitability could have a material adverse impact on the market price of our common stock.

Risks Relating to Owning Our Common Stock

If our stockholders' equity does not meet the minimum standards of the NYSE American, we may be subject to delisting procedures.

On May 16, 2017, we received a letter from the NYSE American notifying us that our stockholders' equity as of March 31, 2017 was below the minimum requirements of Section 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide") (requiring stockholders' equity of $6.0 million or more if a company has reported losses from continuing operations and/or net losses in its five most recent fiscal years). In order to maintain our listing, we submitted a plan of compliance, addressing how we intended to regain compliance with the Company Guide within 12 months, or by May 16, 2018. On September 14, 2017, we were further notified by the NYSE American that our common stock no longer satisfied the requirements of Company Guide Section 1003(a)(ii) (requiring stockholders' equity of $4.0 million or more if a company has reported losses from continuing operations and/or net losses in three of the four most recent fiscal years).

On December 7, 2017, we were notified by the NYSE American that we regained compliance with all of the NYSE American continued listing standards by maintaining a market capitalization in excess of $50 million over the prior two quarters.

We are now subject to NYSE American's normal continued listing monitoring. However, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of December 7, 2017, NYSE American will examine the relationship between the above two incidents of noncompliance and re-evaluate our method of financial recovery. In addition, should our market capitalization fall below $50 million on a 30 trading day average, NYSE American can deem us to be incompliant and may truncate the compliance procedures described in Section 1009 of the Company Guide or immediately initiate delisting proceedings.

We cannot guarantee that our market capitalization will not fall below $50 million on a 30 trading day average or that we will be able to comply with the continued listing standards of NYSE American, and therefore our common stock may be subject to delisting. If our common stock is delisted, this could, among other things, substantially impair our ability to raise additional funds; result in a loss of institutional investor interest and fewer financing opportunities for us; and/or result in potential breaches of representations or covenants of our warrants, subscription agreements or other agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

If we conduct offerings in the future, the price at which we offer our securities may trigger a price protection provision included in warrants originally issued in July 2011, March 2015 and October 2015, reducing the probability and magnitude of any future share price appreciation.

As part of our October 2015 offering, we agreed to provide certain price protections affecting currently outstanding warrants exercisable for an aggregate of 544,695 shares of our common stock, of which the warrants exercisable for 260,093 shares will expire on March 6, 2020, and the warrants exercisable for 284,602 shares will expire on October 27, 2020 (the "Warrants"). Specifically, in the event that we undertake a third-party equity financing of either: (1) common stock at a sale price of less than $5.00 per share or (2) convertible securities with an exercise or conversion price of less than $5.00 per share, we have agreed to reduce the exercise price of all Warrants to such lower price. The exercise price of the Warrants is currently set at $1.81 as a result of our February 2016 private placement offering. The further reduction of the exercise price for the Warrants would limit the probability and magnitude of future share price appreciation, if any, by placing downward pressure on our stock price if it exceeds such offering sale price. All of the Warrants are currently exercisable and will remain so after any exercise price adjustment. In the past, we have extended the expiration dates or adjusted other terms of the Warrants as consideration for certain offering conditions, and we cannot assure you that we will not do so in the future. Any such modifications would reduce the probability and magnitude of any share price appreciation during the period of the extension. We cannot guarantee that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment. If you do receive a return on your investment, it may be lower than the return you would have realized in the absence of the price protection provisions discussed hereof.

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The price of our common stock may fluctuate substantially, which may result in losses to our stockholders.

The stock prices of many companies in the pharmaceutical and biotechnology industry have generally experienced wide fluctuations, which are often unrelated to the operating performance of those companies. The market price of our common stock is likely to be volatile and could fluctuate in response to, among other things:

- the announcement of new products by us or our competitors
- the announcement of partnering arrangements by us or our competitors
- quarterly variations in our or our competitors' results of operations
- announcements by us related to litigation
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates
- developments in our industry and
- general, economic and market conditions, including volatility in the financial markets, a decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors.

The volume of trading of our common stock may be low, leaving our common stock open to the risk of high volatility.

The number of shares of our common stock being actively traded may be very low and any stockholder wishing to sell his, her, or its stock may cause a significant fluctuation in the price of our stock. We have a number of large stockholders, including our principal stockholders China Pioneer, Pioneer Hong Kong as a wholly-owned subsidiary of China Pioneer and the recipient of all of the previous holdings of Pioneer Pharma (Singapore) Pte. Ltd. pursuant to an internal corporate reorganization of China Pioneer, Mr. Jian Ping Fu and OP Financial Investments Limited. As of September 30, 2018, each of China Pioneer, Mr. Fu and OP Financial Investments Limited own approximately 31%, 23% and 10% of our common stock, respectively. The sale of a substantial number of shares of common stock by such large stockholders within a short period of time could cause our stock price to decrease substantially. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that could discourage a third party from making a takeover offer that is beneficial to our stockholders.

Anti-takeover provisions of our amended and restated certificate of incorporation, bylaws and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

- a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without stockholder approval and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a Delaware corporation, we are subject to the Delaware General Corporation Law ("DGCL"), which includes provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our Company. Provisions of the DGCL could make it more difficult for a third party to acquire a majority of our outstanding voting stock by discouraging a hostile bid, or delaying, preventing or deterring a merger, acquisition or tender offer in which our stockholders could receive a premium for their shares, or effect a proxy contest for control of NovaBay or other changes in our management.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends, you will experience a return on your investment in our shares only if our stock price appreciates. We cannot assure you that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment.

China Pioneer, Pioneer Hong Kong, Mr. Jian Ping Fu, OP Financial Investments Limited and/or China Kington might influence our corporate matters in a manner that is not in the best interest of our general stockholders.

After the OP Private Placement, China Pioneer beneficially owned approximately 31% of our outstanding common stock. Our director Mr. Xinzhou "Paul" Li is the chairman of China Pioneer. Pursuant to the arrangement of our Bridge Loan, facilitated by China Kington in January 2016, two (2) of our directors were nominated by China Kington, including Mr. Mijia "Bob" Wu, who is the Managing Director of China Kington and Non-Executive Director of Pioneer Hong Kong, and Mr. Xiaoyan "Henry" Liu, who has worked closely with China Kington on other financial transactions in the past. Subsequently, Mr. Henry Liu was replaced by Mr. Yanbin "Lawrence" Liu in connection with the closing of the OP Private Placement. Mr. Jian Ping Fu beneficially owns approximately 23% of our common stock, and OP Financial Investments Limited owns approximately 10%. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during 2016 and one purchase of Company securities by OP Financial Investments Limited in 2018.

As a result, China Pioneer, Pioneer Hong Kong as a wholly-owned subsidiary of China Pioneer and China Kington have input on all matters before our Board of Directors and may be able to exercise significant influence over all matters requiring board and stockholder approval. China Pioneer, Pioneer Hong Kong and China Kington may choose to exercise their influence in a manner that is not in the best interest of our general stockholders.

In addition, were China Pioneer, Pioneer Hong Kong, Mr. Fu and/or OP Financial Investments Limited to cooperate, they could eventually unilaterally elect all of their preferred director nominees at a Company Annual Meeting of Stockholders. Even with our classified board, China Pioneer, Pioneer Hong Kong, Mr. Fu and/or OP Financial Investments Limited could ensure that seven (7) of our eight (8) directors are either nominees of China Pioneer, Pioneer Hong Kong, OP Financial Investments Limited or China Kington after our 2020 annual meeting of stockholders. In the interim, China Pioneer, Pioneer Hong Kong, China Kington, Mr. Fu and/or OP Financial Investments Limited could exert significant indirect influence on us and our management.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in one or more changes of control, as defined by Section 382 of the Code. We have not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since our formation, due to the significant complexity and cost associated with such study. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. If we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Risks Relating to Our Business

Our future success is largely dependent on the successful commercialization of Avenova.

The future success of our business is largely dependent upon the successful commercialization of Avenova, which has a limited commercial history but constituted approximately 90% of our revenue for 2017. We are dedicating a substantial amount of our resources to advance Avenova as aggressively as possible. If we are unsuccessful in Avenova's broad commercialization, we may not have the resources necessary to continue our business in its current form. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to successfully commercialize our products. While we believe we are creating an efficient commercial organization, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of Avenova, which could cause our commercialization efforts to be unprofitable or less profitable than expected.

We expect to generate revenue from sales of Avenova, which is classified as a cleared medical device by the FDA, but we cannot guarantee that the FDA will continue to allow us to market and sell Avenova as a cleared medical device, which would halt our sales and marketing of Avenova and cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Our ability to generate product sales will depend on the commercial success of Avenova. Our ability to continue to commercialize Avenova and generate revenue depends upon, among other things:

FDA allowing us to continue marketing Avenova as an FDA clearance;
acceptance in the medical community;
the safety of Avenova's predicate devices;
the number of patients who use Avenova for the intended target;
sufficient coverage or reimbursement by third party payors;
our ability to successfully market Avenova; and
the amount and nature of competition from competing companies with similar products and procedures.

The sale of Avenova will be subject to, among other things, regulatory and commercial and market uncertainties that may be outside of our control. Products that are approved or cleared for marketing by the FDA may be materially adversely impacted by the emergence of new industry standards and practices or regulations that could render Avenova as well as our other cleared products less competitive or obsolete. We cannot guarantee that Avenova, our other cleared products, or products that may be approved or cleared for marketing in the future will not be materially adversely impacted by a change in industry standards or regulations. If changes to Avenova or our other cleared products that may market and sell in the future cause a delay in continued commercialization or if we cannot make a change to satisfy the industry standards and practices or regulations, we may not be able to meet market demand which may have a materially adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, the FDA may request that we submit another 510(k) premarket submission that compares to another predicate device. If we are unable to find an adequate predicate device that is substantially equivalent to Avenova for the treatment claims that we use to sell and market Avenova, we may not be able to obtain the necessary FDA clearance to continue to market and sell Avenova without performing comprehensive clinical trials. In such event, we would need to seek premarket approval from the FDA for the applicable product before we could continue to sell and market Avenova in the United States, which would be significantly more time consuming, expensive, and uncertain.

Our commercialized product Avenova, like our other cleared products, are not approved by the FDA as a drug, and we rely solely on the 510(k) clearance of our products as a medical device.

Our business and future growth depend on the development, use and sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA. As a medical device, we may only legally make very limited claims that pertain to our products' cleared intended use. Without claims of efficacy, market acceptance of our products may be slow.

There is significant risk that the FDA or other federal or state law enforcement authorities may determine that the nature and scope of our sales and marketing activities constitutes the promotion of our products for non-FDA-approved uses in violation of applicable law and as the sale of unapproved drugs, which is prohibited under applicable law. We face the risk that the FDA may take enforcement action against us for the way that we promote and sell our products. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of unapproved drug products, off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and be required to substantially limit and change our sales, promotion, grant and educational activities.

We have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory clearance or approvals, if such clearances or approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory clearances or approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only three employees. As a result, we may experience delays in connection with obtaining regulatory clearances or approvals for our products, if such clearances or approvals are obtained at all.

In addition, the products we currently have FDA clearance and/or approval or clearance in other countries as well as the products that we are developing and intend to market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. With respect to the products that we have FDA clearance, there can be no assurances that the FDA will continue to allow us to market those products without further clinical trials. With respect to products that we are currently developing but have no regulatory clearances or approvals, there can be no assurance that necessary regulatory clearances or approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees, and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us.

Developments after a product reaches the market may adversely affect sales of our products.

Even after obtaining regulatory clearances, certain developments may decrease demand for our products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of regulatory clearance of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of a product, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. In addition, some health authorities appear to have become more cautious when examining new products and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising, and promotion (in particular, direct to consumer advertising) and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products. If any of the above occurs to Avenova, our business, results of operations, financial condition and cash flows could be materially adversely affected.

We do not have our own manufacturing capacity, and we rely on partnering arrangements or third-party manufacturers for the manufacture of our products and potential products.

The FDA and other governmental authorities require that all of our products be manufactured in strict compliance with federal Quality Systems Regulations and other applicable government regulations and corresponding foreign standards. We do not currently operate manufacturing facilities for production of our products. As a result, we have partnered with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute our products and help us meet legal requirements. As we have limited control over our commercial partners, any performance failure on their part (including failure to deliver compliant, quality components or finished goods on a timely basis) could affect the commercialization of our products, producing additional losses and reducing or delaying product revenues. If any of our commercial partners or manufacturers have violated or is alleged to have violated any laws or regulations during the performance of their obligations to us, it is possible that we could suffer financial and reputation harm or other negative outcomes, including possible legal consequences.

Our products require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Accordingly, we and our third-party manufacturers are also subject to periodic unannounced inspections by the FDA to determine compliance with the FDA's requirements, including primarily current Good Manufacturing Practice (“cGMP”), the Quality Systems Regulations (“QSR”), medical device reporting regulations, and other applicable government regulations and corresponding foreign standards, including ISO 13485.

The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective, make additional therapeutic claims that are not commensurate to the accepted labeling claims, or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

Avenova’s FDA-clearance and our other products that have been cleared by the FDA or products that we may obtain FDA-clearance in the future, if at all, are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearance to one or all of our products that may be cleared in the future, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, FDA clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be materially adversely impacted.

We depend on skilled and experienced personnel and management leadership to operate our business effectively and maintain our investor relationships. If we are unable to retain, recruit and hire such key employees, our ability to manage our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers and other key employees. The efforts of our officers and other key employees are critical to us as we continue to focus on the commercialization of our Avenova product. The loss of any of our senior management team members could disrupt our business, affect key partnerships and impair our future revenue and profitability. Effective as of September 28, 2018, our Chief Executive Officer, Mark M. Sieczkarek, was replaced by John J. McGovern, our Chief Financial Officer and Treasurer, who was appointed to also serve as the Interim President and Chief Executive Officer of the Company until a successor is duly appointed. No assurance can be given that we will be able to timely locate a replacement or that such replacement will be effective in our growth.

We rely on a limited number of pharmaceutical wholesalers to distribute Avenova.

We intend to rely primarily upon a limited number of pharmaceutical wholesalers in connection with the distribution of Avenova. If we are unable to establish or maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability. We rely on our distribution agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation to fill Avenova prescriptions at most of the retail pharmacies in the United States. If they are not able to ensure consistent availability of our product at retail pharmacies, our revenues will suffer.

If we grow and fail to manage our growth effectively, we may be unable to execute our business plan.

Our future growth, if any, may cause a significant strain on our management and our operational, financial and other resources. Our ability to grow and manage our growth effectively will require us to implement and improve our operational, financial and management information systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management information systems could have a material adverse effect on our business, financial condition, and results of operations.

Government agencies may establish usage guidelines that directly apply to our products or proposed products or change legislation or regulations to which we are subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of our products and products that we may develop. In addition, there can be no assurance that government regulations applicable to our products or proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could modify, prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or in other countries.

We are subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we* may *also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which* may *limit our ability to commercialize our products.

The clearance that we have received from the FDA for our products is subject to strict limitations on the indicated uses for which the products may be marketed. The labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for are products are subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the products or the withdrawal of the products from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory clearance, product recalls, seizure of products, operating restrictions, injunctions, warning letters and other enforcement actions, and criminal prosecution. Any of these events could prevent us from marketing our products and our business may not be able to continue past such concerns.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are

required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If we experience unanticipated problems with the products, if or once approved or cleared for marketing, our products could be subject to restrictions or withdrawal from the market which may have a materially adverse impact on our business, financial condition, results of operations, and prospects.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for our cleared medical devices, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our current suppliers and suppliers that we may have relationships with in the future are required to comply with FDA's Quality Systems Regulations ("QSR") including for the manufacture, testing, control, quality assurance, labeling, shipping, storage, distribution and promotion of our products. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances that have already been granted; (9) refusal to grant export clearance for our products; or (10) criminal prosecution.

If any of these actions were to occur, it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements we may be unable to produce our products on a timely basis and in the required quantities, if at all.

If our product or products cause a reaction in a patient that causes serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that our device or a similar device has likely caused or would likely cause or contribute to death. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If our product or products cause an unexpected reaction to a patient or patients in certain ways that may have caused or contributed to serious injury, we will be subject to product liability claims.

We cannot make assurances that any liability insurance coverage that we qualify for, if at all, will fully satisfy any liabilities brought for any event or injury that is attributed to our product or products. Even if our liability insurance satisfies any and all products liabilities brought against us, any product liability claims may significantly harm our reputation and delay market acceptance of our product or products that may be cleared or approved in the future, if at all.

We expect to rely on third parties to conduct any future studies of our technologies that* may *be required by the FDA, and those third parties may not perform satisfactorily.

Though we do not anticipate conducting further clinical trials in the near future, should we decide otherwise, we may not have the ability to independently conduct the clinical or other studies that will be required to obtain FDA clearance for one or all of our products currently in development or products that we may develop in the future. Should we conduct clinical trials, those trials may be performed by third parties that may not perform satisfactorily, which may have a materially adverse impact on our business, financial condition, results of operations, and prospects.

Our past clinical trials may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.

Even though we have concluded or suspended all our clinical trials, an inherent risk remains. If a claim were to arise in the future based on our past clinical trial activity, we would most likely incur substantial expenses. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our products or product candidates. Our current clinical trial insurance covers individual and aggregate claims up to $5.0 million. This insurance may not cover all claims and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our cleared products and would be also competing with our products under development, if those products are cleared or approved. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we develop. If our technologies or products become obsolete or uncompetitive, our related product sales would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

Avenova faces substantial competition in the eye care markets in which we operate.

We face intense competition in the eye care market, which is focused on cost-effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation. Avenova faces substantial competition in the eye care market from companies of all sizes in the United States and abroad, including, among others, large companies such as Allergan plc and Shire plc, against products such as Restasis, Xiidra, eye wipes, baby shampoo and soap. These products are not saline with hydrochlorous acid as a preservative in solution and they are prescribed for eyelid and lash disease symptom management. There are also over-the-counter products that contain hypochlorous acid that compete with Avenova. Competition may increase further as existing competitors enhance their offerings or additional companies enter our markets or modify their existing products to compete directly with our products. The hypochlorous acid is used as only a preservative and Avenova relies on the 99.99% saline solution as its active ingredient. Many of our competitors have substantially more resources and a greater marketing scale than we do. We may not be able to sustain our current levels of growth as competitive pressures, including pricing pressure from competitors, increase. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements, our products may be rendered obsolete or non-competitive. In addition, if our competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization than we do, our operating results will materially suffer.

We may not be able to enhance the capabilities of our current and new products to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend significantly on our ability to keep pace with technological developments and evolving industry standards as well as respond to changes in customer needs. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we currently sell, Avenova in particular, and products that we plan to sell. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

Demands of third-party payors, cost reduction pressures among our customers, restrictive reimbursement practices, and cost-saving and other financial measures may adversely affect our business.

Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate that they will be reimbursed by such programs in the future. Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or group purchasing organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our

products, to negotiate reduced fees or other concessions or to delay payment. In addition, third-party payors may reduce or limit reimbursement for our products in the future, such as by withdrawing their coverage policies, canceling any future contracts with us, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers, lower pricing for our products to new customers, or limitations or reductions in reimbursement could have a material adverse effect on the financial position, cash flows and results of operations.

Federal and state healthcare reform legislation, including the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the "Affordable Care Act," may also adversely affect our business. The Affordable Care Act contains provisions aimed at improving quality and decreasing costs in the Medicare program, such as value-based payment programs and reduced hospital payments for avoidable readmissions and hospital acquired conditions. The Affordable Care Act has been, and continues to be, subject to judicial and legislative challenges seeking to modify, limit, replace, or repeal the legislation. While we cannot predict what additional healthcare programs and regulations will be implemented at the federal or state level, or the effect of any future legislation or regulation on our business, any changes that lower potential reimbursement for our products, impose additional costs, reduce the potential number of people eligible for reimbursement for the use of our products, or otherwise reduce demand for our products, could adversely affect our business, financial condition and results of operations.

The pharmaceutical and biopharmaceutical industries are characterized by patent litigation, and any litigation or claim against us may impose substantial costs on us, place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain six months of exclusivity as a generic product under the Hatch-Waxman Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position, and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may be issued to third parties which our technology may infringe. Because patent applications can take many years to issue and because patent applications are not published for a period of time, or in some cases at all, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, would divert management's attention from our business and could have a material negative effect on our business, operating results or financial condition. If a dispute involving our proprietary technology were resolved against us, it could mean the earlier entry of some or all third parties seeking to compete in the marketplace for a given product, and a consequent significant decrease in the price we could charge for our product. If such a dispute alleging that our technology or operations infringed third party patent rights were to be resolved against us, we might be required to pay substantial damages, including treble damages and attorney's fees if we were found to have willfully infringed a third party's patent, to the party claiming infringement, to develop non-infringing technology, to stop selling any products we develop, to cease using technology that contains the allegedly infringing intellectual property or to enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

If product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities.

Despite all reasonable efforts to ensure safety, it is possible that we or our collaborators will sell Avenova or NeutroPhase or products that we currently do not sell but may sell in the future such as CelleRx and intelli-Case, which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention, and could have a material adverse effect on our financial condition, business and results of operations.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources.

If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the U.S. and other

countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

There is no assurance that any patents issued to us, or in-licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted thereunder will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute, obtain or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know-how may become known or be independently discovered by competitors.

We operate in the State of California. The laws of the State prevent us from imposing a delay before an employee who may have access to trade secrets and proprietary know-how can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damage has been done to our company.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

Our current patent portfolio could leave us vulnerable to larger companies who have the resources to develop and market competing products.

We aggressively protect and enforce our patent rights worldwide. However, certain risks remain. There is no assurance that patents will issue from any of our applications or, for those patents we have or that do issue, that the claims will withstand an invalidity challenge or be sufficiently broad to protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the Neutrox composition. This relatively weak patent portfolio leaves us vulnerable to competitors who wish to compete in the same marketplace with similar products. If a potential competitor introduces a formulation similar to Avenova or NeutroPhase with a similar composition that does not fall within the scope of the method of treatment/manufacture claims, then we or a potential marketing partner would be unable to rely on the allowed claims to protect its market position for the method of using the Avenova or NeutroPhase composition, and any revenues arising from such protection would be adversely impacted.

If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA has cleared or approves products that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products
- published studies demonstrating the cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or commercial payers and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

Failure to comply with laws and regulations governing the sales and marketing of our products could materially impact our revenues.

We engage in various marketing, promotional and educational activities pertaining to, as well as the sale of, pharmaceutical products and/or medical devices in the United States and in certain other jurisdictions outside of the United States. The promotion, marketing and sale of pharmaceutical products and medical devices is highly regulated and the sales and marketing practices of market participants, such as us, have been subject to increasing supervision by governmental authorities, and we believe that this trend will continue.

In the United States, our sales and marketing activities are regulated by a number of regulatory authorities and law enforcement agencies, including the U.S. Department of Health and Human Services, the FDA, the Federal Trade Commission, the U.S. Department of Justice, the SEC, and state regulatory authorities. These authorities and agencies and their equivalents in countries outside the United States have broad authority to investigate market participants for potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products and medical devices, including the False Claims Act, the Anti-Kickback Statute, the UK Bribery Act of 2010 and the Foreign Corrupt Practices Act, and their state equivalents, among others, for alleged improper conduct, including corrupt payments to government officials, improper payments, inducements, and financial relationships with and to medical professionals, patients, and sales personnel, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies and providers may also be subject to enforcement actions or prosecution for such improper conduct. Any inquiries or investigations into our operations, or enforcement or other regulatory action against us, by such authorities could result in significant defense costs, fines, penalties and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or us, from government reimbursement programs or subject us to regulatory controls or government monitoring of our activities in the future.

Failure to obtain and/or maintain required licenses or registrations could reduce revenue.

Our business is subject to a variety of licensing or registration requirements by the FDA, certain states and foreign jurisdictions where our products are distributed. Failure to obtain or maintain required licenses could result in the termination of the sale of certain products in the application states or foreign jurisdictions, or the termination of such products. We may also be subject to fines and other penalties imposed by the relevant government authorities for non-compliance.

The process for obtaining licenses or registrations can be lengthy and expensive and the results sometimes are unpredictable. If we are unable to obtain licenses or registrations needed to produce, market and sell our products in a timely fashion, or at all, our revenues could be materially and adversely affected.

We are subject to U.S. healthcare fraud and abuse and health information privacy and security laws, and the failure to comply with such laws may adversely affect our business.

We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The U.S. laws that may affect our ability to operate include, but are not limited to: (i) the federal Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies, and relationships with healthcare providers or other persons and entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third party payers that are false or fraudulent, and from offering or transferring remuneration to a Medicare or state healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state healthcare program; (iii) the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, among other things, created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and places restrictions on the use of such information for marketing communications; (v) the Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to "payments or other transfers of value" made to physicians and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members; (vi) the government pricing rules and price reporting laws applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, and the TRICARE program; and (vii) state and foreign law equivalents of each of the above laws, such as state anti-kickback and false claims laws which may apply to items

or services reimbursed by any third party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, and state and foreign price and payment reporting and disclosure laws, many of which differ from each other in significant ways and often are not preempted by their federal counterparts, thus complicating compliance efforts. Violations of the health information privacy and fraud and abuse laws may result in severe penalties against us and/or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Defense of litigation claims and government investigations can be costly, time consuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. Certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with health information privacy or fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that may govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. Due to the breadth of these statutory provisions, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the U.S. Department of Justice, and other agencies have increased their enforcement activities and scrutiny with respect to sales, marketing, research, financial relationships with healthcare providers, rebate or copay arrangements, discounts, and similar activities and relationships of pharmaceutical and medical device companies in recent years, and many companies have been subject to government investigations related to these practices and relationships. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacture and/or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs, and other sanctions.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audit reports to stockholders causes our expenses to be higher than they would be if we were a privately-held company. The increased costs associated with operating as a public company may decrease our net income or increase our net loss, and may cause us to reduce costs in other areas of our business or increase the prices of our product to offset the effect of such increased costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations.

A failure of our internal control over financial reporting could materially impact our business or stock price.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. An internal control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all internal control systems, internal control over financial reporting may not prevent or detect misstatements. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud and could expose us to litigation or adversely affect the market price of our common stock.

Significant disruptions of information technology systems or breaches of information security could adversely affect our businesses.

We rely to a large extent upon information technology systems to operate our businesses. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious

third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

ITEM 6. EXHIBITS

The following exhibits are filed with or incorporated by reference into this report.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	10-K	001-33678	3.1	3/21/2018	
3.2	Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-33678	3.1	6/04/2018	
3.3	Bylaws	8-K	001-33678	3.2	6/29/2010	
4.1	Form of 2011 Warrant, as amended (issued pursuant to the placement agent agreement dated June 29, 2011, as amended)	10-K	001-33678	4.1	3/23/2017	
4.2	Form of Warrant issued in March 2015 Offering, as amended (issued with 15-month term)	10-K	001-33678	4.2	3/23/2017	
4.3	Form of Warrant issued in March 2015 Offering, as amended (issued with 5-year term)	10-K	001-33678	4.3	3/23/2017	
4.4	Form of Warrant issued in May 2015 offering	10-Q	001-33678	4.7	8/13/2015	
4.5	Form of Warrant issued in October 2015 offering, as amended	10-K	001-33678	4.5	3/23/2017	
4.6	Registration Rights Agreement (between the Company, Pioneer Pharma (Singapore) Pte. Ltd., and Anson Investments Master Fund LP, et al.)	8-K	001-33678	10.2	3/09/2015	
4.7	Registration Rights Agreement (between the Company, China Kington Investment Co. Ltd. and Dr. Dean Rider)	10-Q	001-33678	4.9	8/13/2015	
4.8	Registration Rights Agreement (among the Company and each of the purchasers named therein).	8-K	001-33678	4.2	4/05/2016	
10.1+	Indemnity Agreement (Form of Indemnity Agreement between the Company and its Directors and Officers)	10-Q	001-33678	10.1	8/12/2010	

10.2+	NovaCal Pharmaceuticals, Inc. 2005 Stock Option Plan as amended	S-1	333-140714	10.2	3/30/2007
10.3+	NovaBay Pharmaceuticals, Inc. 2007 Omnibus Incentive Plan (as amended and restated)	S-8	333-215680	99.1	1/24/2017
10.4+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan	S-8	333-218469	99.1	6/02/2017
10.5+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan (Form Agreements to the 2017 Omnibus Incentive Plan)	S-8	333-218469	99.2	6/02/2017
10.6+	Non-Employee Director Compensation Plan	8-K	001-33678	10.1	10/11/2018
10.7+	Separation Agreement (by and between the Company and Ramin “Ron” Najafi)	8-K	001-33678	10.1	11/19/2015
10.8+	Amendment to Separation Agreement, dated December 15, 2016 (by and between the Company and Ramin “Ron” Najafi)	8-K	001-33678	10.1	12/19/2016
10.9+	Mutual & General Release, dated February 29, 2016 (by and between the Company and Roy Wu)	8-K	001-33678	10.1	3/01/2016

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference	Filing Date	
10.10+	Executive Employment Agreement (Employment Agreement of Mark M. Sieczkarek expired June 1, 2017)	8-K	001-33678	10.1	5/27/2016	
10.11+	Executive Employment Agreement (Employment Agreement of Mark M. Sieczkarek expired June 1, 2018)	8-K	001-33678	10.1	6/06/2017	
10.12+	Executive Employment Agreement (Employment Agreement of John J. McGovern)	8-K	001-33678	10.1	7/10/2017	
10.13+	Executive Employment Agreement (Employment Agreement of Lewis Stuart)	8-K	001-33678	10.1	11/28/2017	
10.14+	Executive Employment Agreement (Employment Agreement of Justin M. Hall expired December 31, 2017)	8-K	001-33678	10.3	1/05/2016	
10.15+	Executive Employment Agreement (Employment Agreement of Justin M. Hall)	8-K	001-33678	10.1	12/20/2017	
10.16+	Executive Employment Agreement (Employment Agreement of Thomas J. Paulson ended December 31, 2017)	8-K	001-33678	10.2	1/05/2016	
10.17	Office Lease between EmeryStation Associates II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North	S-1, as amended	333-140714	10.10	3/30/2007	
10.18	Fifth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.20	3/14/2008	
10.19	Sixth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q, as amended	001-33678	10.1	11/14/2008	
10.20	Seventh Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q	001-33678	10.2	8/09/2012	
10.21	Eighth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.19	3/04/2016	

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Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference	Filing Date	
10.22	Office Lease (between the Company and KBSIII Towers at Emeryville, LLC)	8-K	001-33678	10.1	8/26/2016	
10.23	Sublease Agreement by and between NovaBay Pharmaceuticals, Inc. and Zymergen, Inc., dated July 11, 2016	8-K	001-33678	10.1	7/15/2016	
10.24†	Collaboration and License Agreement by and between NovaBay Pharmaceuticals, Inc. and Galderma S.A.	10-Q, as amended	001-33678	10.2	8/04/2009	
10.25†	Amendment No. 1 to the Collaboration and License Agreement	10-K	001-33678	10.18	3/30/2010	
10.26†	Amendment No. 2 to the Collaboration and License Agreement	10-K	001-33678	10.24	3/10/2011	
10.27†	International Distribution Agreement (by and between the Company and Pioneer Pharma Co. Ltd.)	10-K	001-33678	10.18	3/27/2012	
10.28	Securities Purchase Agreement (between the Company and Jian Ping Fu)	8-K	001-33678	10.1	2/17/2016	
10.29	Securities Purchase Agreement (between the Company and Pioneer Pharma (Singapore) Pte. Ltd.)	8-K	001-33678	10.2	2/17/2016	
10.30	Securities Purchase Agreement (between the Company and Mark M. Sieczkarek)	8-K	001-33678	10.3	2/17/2016	
10.31	Securities Purchase Agreement (among the Company and each of the purchasers named therein).	8-K	001-33678	10.1	4/05/2016	
10.32	Commission structure for warrant exercise	8-K	001-33678	Item 1.01	9/30/2016	
10.33	Share Purchase Agreement (by and between the Company and Ch-gemstone Capital (Beijing) Co., Ltd.) (terminated January 31, 2018)	10-Q	001-33678	10.1	11/14/2017	
10.34	Amended and Restated Share Purchase Agreement (by and between the Company and Ch-gemstone Capital (Beijing) Co., Ltd.) (terminated January 31, 2018)	8-K	001-33678	10.1	11/21/2017	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference	Filing Date	
10.35	Share Purchase Agreement (by and between the Company and OP Financial Investments Limited)	8-K	001-33678	10.1	2/06/2018	
31.1	Certification of the Principal Executive Officer and Principal Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)					X
32.1‡	Certification by the Chief Executive Officer and Chief Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

+Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

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 14, 2018 NOVABAY PHARMACEUTICALS, INC.

/s/ John J. McGovern
John J. McGovern
Interim President and Chief Executive Officer

(principal executive officer)

Date: November 14, 2018 /s/ John J. McGovern
John J. McGovern
Chief Financial Officer

(principal financial officer)