

NovaBay Pharmaceuticals, Inc.  
Form 10-Q  
May 12, 2016

**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 March 31, 2016

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**  
**(State or other jurisdiction of incorporation or**  
**organization)**

**68-0454536**  
**(I.R.S. Employer Identification No.)**

**5980 Horton Street, Suite 550, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer  
Non-accelerated filer Smaller reporting company  
(Do not check if a smaller reporting company)

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

As of May10, 2016, there were 9,154,121 shares of the registrant's common stock outstanding.

**NOVABAY PHARMACEUTICALS, INC.**

**TABLE OF CONTENTS**

**PART I  
FINANCIAL INFORMATION**

Item 1.	Financial Statements	
	1. Consolidated Balance Sheets: March 31, 2016 (Unaudited) and December 31, 2015	3
	2. Consolidated Statements of Operations and Comprehensive Loss (Unaudited): Three months ended March 31, 2016 and 2015	4
	3. Consolidated Statements of Cash Flows (Unaudited): Three months ended March 31, 2016 and 2015	5
	4. Notes to Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4.	Controls and Procedures	33

**PART II  
OTHER INFORMATION**

Item 1A.	Risk Factors	34
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	45
Item 6.	Exhibits	45

<b>SIGNATURES</b>	46
-------------------	----

<b>EXHIBIT INDEX</b>	47
----------------------	----

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

NovaBay<sup>®</sup>, NovaBay Pharma<sup>®</sup>, Avenova<sup>™</sup>, NeutroPhase<sup>®</sup>, CelleRx<sup>®</sup>, AgaNase<sup>®</sup>, Aganocide<sup>®</sup>, AgaDerm<sup>®</sup>, Neutrox<sup>™</sup> and Going Beyond Antibiotics<sup>™</sup> 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 shares and per share data)**

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
	(unaudited)	Footnote 2
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,430	\$ 2,385
Accounts receivable, net of allowance for doubtful accounts (\$71 and \$40 at March 31, 2016 and December 31, 2015, respectively)	1,497	536
Inventory	1,201	1,345
Prepaid expenses and other current assets	433	261
Total current assets	4,561	4,527
Property and equipment, net	370	395
Other assets	-	155
<b>TOTAL ASSETS</b>	<b>\$ 4,931</b>	<b>\$ 5,077</b>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT)</b>		
Liabilities:		
Current liabilities:		
Accounts payable	\$ 1,820	\$ 2,483
Accrued liabilities	2,019	1,980
Deferred revenue	189	170
Total current liabilities	4,028	4,633
Deferred revenues - non-current	3,115	2,248
Deferred rent	189	189
Notes payable, related party	3,063	1,655
Warrant liability	1,835	1,450
Total liabilities	12,230	10,175

Stockholders' (deficit):

Common stock, \$0.01 par value; 240,000 shares authorized; 5,075 and 3,486 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	51	35
Additional paid-in capital	88,248	85,387
Accumulated deficit	(95,598 )	(90,520 )
Total stockholders' (deficit)	(7,299 )	(5,098 )
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT)	\$ 4,931	\$ 5,077

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 shares and per share data)

	Three Months Ended March 31,	
	2016	2015
Sales:		
Product revenue	\$1,655	\$492
Other revenue	64	46
Total net sales	1,719	538
Product cost of goods sold	611	148
Gross profit	1,108	390
Research and development	933	1,583
Sales and marketing	3,144	1,914
General and administrative	1,655	1,554
Total operating expenses	5,732	5,051
Operating Loss	(4,624)	(4,661)
Non cash (loss) gain on changes in fair value of warrant liability	(385 )	34
Other expense, net	(68 )	(11 )
Loss before provision for income taxes	(5,077)	(4,638)
Provision for income tax	-	(2 )
Net loss and comprehensive loss	\$(5,077)	\$(4,640)
Loss per share attributable to common stockholders (basic and diluted)	\$(1.24 )	\$(2.13 )
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic and diluted)	4,086	2,175

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

**NOVABAY PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)**

(in thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(5,077)	\$(4,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	40	41
Gain on disposal of property and equipment	—	(1 )
Stock-based compensation expense for options and stock issued to employees and directors	74	265
Stock-based compensation expense for options and stock issued to non-employees	19	20
Stock-based compensation expense for issuance of restricted stock units to employees	133	—
Stock-based compensation expense for issuance of restricted stock units to non-employees	21	—
Allowance for doubtful accounts	31	70
Note receivable impairment	91	—
Non-cash loss (gain) on change in fair value of warrants	385	(34 )
Changes in operating assets and liabilities:		
Accounts receivable	(992 )	(117 )
Inventory	144	29
Prepaid expenses and other assets	(107 )	(491 )
Accounts payable and accrued liabilities	(580 )	357
Deferred revenue	886	(6 )
Net cash used in operating activities	(4,932)	(4,507)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(16 )	(14 )
Proceeds from disposal of property and equipment	—	37
Net cash provided (used) by investing activities	(16 )	23
<b>Cash flows from financing activities:</b>		
Proceeds from common stock issuances, net	2,628	—
Proceeds from borrowings	1,365	—
Proceeds from shelf offering, net	—	4,653
Net cash provided by financing activities	3,993	4,653
Net increase (decrease) in cash and cash equivalents	(955 )	169
Cash and cash equivalents, beginning of period	2,385	5,429
Cash and cash equivalents, end of period	\$1,430	\$5,598



**Supplemental disclosure of non cash information**

Stock issued to consultants for services included in accounts payable and accrued liabilities	\$1	\$—
---	-----	-----

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

## **NOTE 1. ORGANIZATION**

NovaBay Pharmaceuticals, Inc. (the “Company”) is a biopharmaceutical company focused on commercializing prescription Avenova® daily lid and lash hygiene in the domestic eye care market.

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 August 2007, it formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which was formed to conduct research and development in Canada and was dissolved in July 2012, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. 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. Historically, the Company operated as four business segments. At the direction of its Board of Directors, the Company is focused primarily on commercializing prescription Avenova for managing hygiene of the eyelids and lashes in the United States and is now managed as a single business and not four segments.

Effective December 18, 2015, we effected a 1-for-25 reverse split of our outstanding common stock (the “Reverse Stock Split”) (See Note 10). The accompanying financial statements and related notes give retroactive effect to this reversal stock split.

### ***Need to Raise Additional Capital***

The Company has incurred significant losses from operations since inception and expects losses to continue for the foreseeable future. As of March 31, 2016, the Company had cash and cash equivalents of \$1.4 million. The Company’s operating plans call for cash expenditures to exceed \$18.0 million over the next twelve months. The Company plans to raise additional capital to fund its operations. The Company plans to finance its operations through the sale of equity securities, debt arrangements or partnership or licensing collaborations. Such funding may not be available or may be on terms that are not favorable to the Company. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to continue as a going concern. If the Company becomes unable to continue as a going concern, it may have to liquidate its assets and might realize significantly less than the values at which such assets are carried on its financial statements, and stockholders may lose all or part of their investment in Company common stock.

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 the Company's ability to continue as a going concern.

## **NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### ***Basis of Presentation***

The accompanying interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("GAAP") and with the instructions for Form 10-Q and Regulation S-X. Accordingly, they do not include all of the information and notes required for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 26, 2015. The unaudited condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

### ***Reclassifications***

Prior period amounts in the accompanying consolidated balance sheets have been reclassified to conform to current period presentation. The reclassifications did not change total assets, total liabilities, or total stockholders' equity.

### ***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, DermaBay, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

### ***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 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 Short-Term Investments***

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of March 31, 2016, the Company's cash and cash equivalents were held in financial institutions in the United States.

The Company classifies all highly liquid investments with a stated maturity of greater than three months at the date of purchase as short-term investments. Short-term investments generally consist of municipal and corporate debt securities. The Company has classified its short-term investments as available-for-sale. The Company does not intend to hold securities with stated maturities greater than twelve months until maturity. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other-than-temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. The interest income and realized gains and losses are included in other (expense), net within the consolidated statements of operations and comprehensive loss. Interest income is recognized when earned.

***Concentrations of Credit Risk and Major Partners***

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits of cash, cash equivalents and short-term investments with three 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. Additionally, the Company has established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

During the three months ended March 31, 2016, revenues were derived primarily from sales of Avenova directly to doctors through the Company's webstore and to three distribution partners. During the three months ended March 31, 2015, revenues were derived from one collaboration partner, service revenues and sales of NeutroPhase.

As of March 31, 2016, 33%, 24% and 10% of accounts receivable were derived from the Company's three primary distribution partners. As of December 31, 2015, 41% and 18% of accounts receivable were derived from the Company's two primary distribution partners.

***Fair Value of Financial Assets and Liabilities***

Financial instruments, including cash and cash equivalents, 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;

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

### ***Allowance for Doubtful Accounts***

We charge bad debt expense and record an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identified amounts due that are in dispute and it believes are unlikely to be collected at the end of March 31, 2016. At March 31, 2016, management had reserved \$71 thousand, primarily based on specific amounts that are in dispute and are 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.

Inventory is stated at the lower of cost or market 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 software and seven years for furniture and fixtures. Leasehold improvements are depreciated 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. During the three months ended March 31, 2016, the Company impaired a note receivable which was deemed to no longer be collectable, as the originator of the loan is not in business and the collateral held against the loan did not possess value in an amount sufficient to satisfy the loan. As a result, a \$91 thousand impairment charge was recorded to research and development expense for the three months ended March 31, 2016. There were no impairments during the three months ended March 31, 2015. Determination of recoverability is based on the 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 (Loss)***

ASU No. 2011-05, *Comprehensive Income (Topic 220)*, 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 (loss).

### ***Revenue Recognition***

The Company sells products through a limited number of distributors and via its webstore. The Company generally records product sales upon shipment to the final customer for its webstore sales and upon shipment from its distributor to the final customers for its major distribution partners.

The Company recognizes product revenue when: (i) persuasive evidence that an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) the Company's price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid the Company, or the customer is obligated to pay the Company and the obligation is not contingent on resale of the product, (iii) the customer's obligation to the Company would not be changed in the event of theft or



physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by the Company, (v) the Company does not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

***Product Revenue Allowances***

Product revenue is recognized, net of cash consideration paid to our customers and wholesalers, for services rendered by wholesalers in accordance with such wholesaler's agreements and includes both a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other product revenue allowances include certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue or as a selling expense at the later of the date at which the related revenue is recognized or the date at which the allowance is offered.

### ***Other Revenue***

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, and payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, the Company analyzes its multiple element arrangements to determine whether the elements can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting, and revenue is recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured. If these factors were to vary, the resulting change could have a material effect on our revenue recognition and on the Company's results of operations.

### ***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 inventory that may expire and become unsalable. The Company recorded an allowance for obsolete inventory of \$45 thousand during 2015, but did not record an allowance for excess inventory as of December 31, 2015. During the three months ended March 31, 2016, the Company disposed of the obsolete inventory and eliminated the allowance for obsolete inventory of \$45 thousand.

### ***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 11 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 based on the fair market value of the Company's common stock at 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 Liabilities***

For warrants that are issued or modified and there is a deemed possibility that the Company may have to settle the warrants in cash, or for warrants the Company issues or modifies that contain an exercise price adjustment feature that reduces the exercise price of the Company's common stock eligible for purchase thereunder in the event that the Company subsequently issues equity instruments at a price lower than the exercise price of the warrants, 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 on the consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model, which 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 the Company's 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 applicable period, including stock options and warrants, using the treasury stock 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 months ended March 31, 2016 and March 31, 2015, there was no difference between basic and diluted net loss per share due to the Company's net losses. The following table sets forth the calculation of basic EPS and diluted EPS:

	Three Months Ended March 31,	
	2016	2015
Net loss	\$(5,077)	\$(4,640)
Basic Shares	4,086	2,175
Add: shares issued upon assumed exercise of stock options and warrants	—	—
Diluted shares	4,086	2,175
Basic and diluted net loss per share	\$(1.24 )	\$(2.13 )

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:

	Three Months Ended	
	March 31,	
	2016	2015
Stock options	300	337
Stock warrants	1,458	854
	1,758	1,191

### ***Recent Accounting Pronouncements***

#### *Recent Accounting Pronouncements Not Yet Adopted*

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU No. 2014-09 uses a five-step model to determine revenue recognition in contracts with customers. The Company is currently evaluating the potential impact of this standard on its financial statements. ASU No. 2014-09 is effective for the Company in the first quarter of fiscal year 2019 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU No. 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU No. 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU No. 2014-09. Early adoption in the first quarter of fiscal year 2018 is permitted. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU No. 2015-03 changes the presentation of debt issuance costs in financial statements. Under the new guidance, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability, rather than as an asset. Amortization of the costs is reported as interest expense. This guidance became effective beginning in the first quarter of 2016. The Company’s adoption of this guidance did not result in a material impact to our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. ASU No. 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new guidance must be

applied on a prospective basis and is effective for the Company in the first quarter of fiscal year 2017, with early adoption permitted. The Company does not believe the implementation of this guidance will result in a material impact to its consolidated financial statements.

In August 2014, FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. This new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosure if substantial doubt exists. The new standard is effective for annual periods ending after December 15, 2016 and for annual periods and interim periods thereafter. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial statements

In January 2016, the FASB issued ASU 2016-01, *Financial Instructions – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. This guidance will be effective for the Company beginning in the first quarter of fiscal year 2018. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

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. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance is effective beginning in the first quarter of fiscal year 2017 and early adoption is permitted in an interim period with any adjustments reflected as of the beginning of the fiscal year that includes that interim period. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

### NOTE 3. FAIR VALUE MEASUREMENTS

The Company measures the fair value of financial assets and liabilities based on authoritative guidance which 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 March 31, 2016:

(in thousands)	Balance at March 31, 2016	Quoted Prices in	Significant Other	Significant
		Active Markets for Identical Items (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Liabilities</b>				
Warrant liability	\$ 1,835	\$ —	\$ —	\$ 1,835
Total liabilities	\$ 1,835	\$ —	\$ —	\$ 1,835



For the three months ended March 31, 2016 the Company recorded a non-cash loss of \$385 thousand in its consolidated statement of operations and comprehensive loss, as a result of the fair value adjustment of its warrant liability. See Note 9 for further discussion on the calculation of the fair value of the Company's warrant liability.

<b>(in thousands)</b>	<b>Warrant liability</b>
Fair value of warrants at December 31, 2015	\$ 1,450
Increase in fair value at March 31, 2016	385
Total warrant liability at March 31, 2016	\$ 1,835

#### **NOTE 4. INVENTORY**

Inventory consisted of the following:

<b>(in thousands)</b>	<b>March 31, 2016</b>	<b>December 31, 2015</b>
Raw materials and supplies	\$824	\$ 660
Goods in process	114	248
Finished goods	263	482
Less Reserve for obsolete inventory	-	(45 )
Total inventory	\$1,201	\$ 1,345

**NOTE 5. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

<b>(in thousands)</b>	<b>March 31, 2016</b>	<b>December 31, 2015</b>
Office and laboratory equipment	\$1,639	\$ 1,633
Furniture and fixtures	257	254
Software	37	37
Leasehold improvements	179	173
Total property and equipment, at cost	2,112	2,097
Less: accumulated depreciation	(1,742)	(1,702 )
Net property and equipment	\$370	\$ 395

Depreciation and amortization expense was \$40 thousand and \$41 thousand for the three months ended March 31, 2016 and 2015, respectively.

**NOTE 6. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following:

<b>(in thousands)</b>	<b>March 31, 2016</b>	<b>December 31, 2015</b>
Research and development	\$451	\$ 394
Employee payroll and benefits	514	614
Severance pay	591	590
Sales rebate	64	150
Other	399	232
Total accrued liabilities	\$2,019	\$ 1,980

**NOTE 7. RELATED PARTY NOTES PAYABLE**

Beginning on December 30, 2015, the Company entered into a series of agreements pursuant to a loan (the “*Loan*”) facilitated by China Kington Asset Management Co. Ltd. (“*China Kington*”). In connection with the Loan, the Company issued five (5) promissory notes (the “*Notes*”) payable to Mr. Mark Sieczkarek, the Gail J. Maderis Revocable Trust, Dr. T. Alex McPherson, Mr. Jian Ping Fu, and Pioneer Pharma (Singapore) Pte. Ltd. (“*Pioneer Singapore*”) (collectively, the “*Lenders*”), loaning the Company an aggregate of \$3.0 million. Specifically, Mr. Sieczkarek, Chairman of the Board of the Company (the “*Board*”) and Interim President and Chief Executive Officer of the Company, loaned the Company \$199 thousand; the Gail J. Maderis Revocable Trust, on behalf of Ms. Maderis, a Director of the Company, loaned the Company \$71 thousand; Dr. McPherson, a Director of the Company, loaned the Company \$20 thousand; Pioneer Singapore loaned the Company \$1.4 million; and Mr. Fu loaned the Company \$1.4 million. All Notes were issued on December 30, 2015 except the Note payable to Mr. Fu, which was issued on January 12, 2016.

The proceeds from the Notes are being used for general corporate purposes. Minimum quarterly payments of principal and interest began on March 31, 2016 and will continue on the last day of each June, September, December and March thereafter. The entire principal sum and any and all accrued and unpaid interest is payable in full upon the Company’s next financing, but in no event shall the term of the Loan extend beyond December 30, 2018, except for the loan by Mr. Fu, the term of which shall extend three (3) years from the date of issuance of the Note payable to Mr. Fu. The Notes will pay interest at a rate of six percent (6%) per annum and may be prepaid in whole or in part at any time without premium or penalty.

In connection with the Notes, China Kington has agreed to act as collateral agent for the benefit of the Lenders, in accordance with the terms of a collateral agency and intercreditor agreement (the “*Collateral Agency Agreement*”), which was entered into on December 30, 2015 between China Kington and the Lenders. To secure the Notes, China Kington has a perfected security interest in all tangible and intangible assets of the Company, pursuant to a security agreement (the “*Security Agreement*”) between the Company and China Kington, which was entered into on December 30, 2015.

As consideration to China Kington for facilitating the Loan, the Company agreed to the following: (1) the grant of a first right of refusal for China Kington (or its designee that shall be acceptable to the Company in its reasonable discretion) to lead financings for the Company for a period that is the shorter of two (2) years or the day that the Company’s cash flow has been equal to or greater than \$0 in each month for three (3) consecutive months, subject to certain limitations; (2) the participation of Mr. Sieczkarek as a Lender in this financing; (3) the participation of the Company’s Board of Directors, management and investors that the Board of Directors and management provide, to contribute an aggregate nine percent (9%) of funds in the Company’s next financing; (4) the appointment of two new members to the Company’s Board by China Kington; and (5) the Company’s agreement to reasonably cooperate with reasonable requests made by an auditor engaged, and paid for, by China Kington, subject to certain limitations. Upon the recommendation of China Kington, and after reviewing their relevant experiences and background and discussing the same, on January 26, 2016 the Board of Directors unanimously appointed Mr. Mijia “Bob” Wu and Mr. Xiaoyan “Henry” Liu to serve as Class I and Class III members of the Company’s Board of Directors, respectively.

As of March 31, 2016, outstanding amounts under the Notes were \$3.1 million, including accrued interest.

See the *Neutrophase Distribution Agreements* section of Note 12 for a description of the Company’s relationship with Pioneer Pharma Co., Ltd.

## **NOTE 8. COMMITMENTS AND CONTINGENCIES**

### *Operating Leases*

The Company leases laboratory facilities and office space under an operating lease which will expire on October 31, 2020. Rent expense was approximately \$253 thousand and \$256 thousand for the three months ended March 31, 2016 and 2015, respectively.

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

*Directors and Officers Indemnity*

As permitted under Delaware law and in accordance with its bylaws, the Company shall indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving at its 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 or officer insurance policy that limits its exposure and may enable the Company to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liability has been recorded for these agreements as of March 31, 2016.

In the normal course of business, the Company provides indemnifications of varying scope under agreements with other companies, typically clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, the Company 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, the Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liabilities have been recorded for these agreements as of March 31, 2016.

### *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 at March 31, 2016, that, in the opinion of management, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

### **NOTE 9. 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-Merton 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. 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 "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 (expiring March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in its October 2015 offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both warrants issued with a 15-month term (the "Short-Term Warrants") and warrants issued with a 60-month term (the "Long-Term Warrants") pursuant to the Agreement (together, the "March 2015 Warrants") and the warrants issued pursuant to the placement agent agreement dated June 29, 2011 (the "2011 Warrants"). Specifically, the amendments decreased the exercise price for both the March 2015 Warrants and the 2011 Warrants to \$5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the 2011 Warrants to March 6, 2020. A price protection provision also was added to both the 2011 Warrants and the 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 with an exercise price of \$5.00 per share.

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 this 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 of the Company sold common stock to Mr. Jian Ping Fu at that price.

The Company evaluated the change in terms of the July 2011 warrants and noted that the change in terms resulted in a revaluation at the time of the change. The warrants were re-issued and valued as of October 27, 2015 at \$361 thousand with the new terms, and a modification expense was recorded for the difference between the fair value of the warrants at their new terms after modification on October 27, 2015 and the fair value of the warrants at 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.

The key assumptions used to value the warrants after the modification at October 27, 2015 were as follows:

**Assumption**

Expected price volatility	80.00%
Expected term (in years)	4.36
Risk-free interest rate	1.23 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	\$2.60

The key assumptions used to value the warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	Period Ended	
	March 31, 2016	December 31, 2015
Expected price volatility	86.00%	80.00 %
Expected term (in years)	3.93	4.18
Risk-free interest rate	1.03 %	1.58 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	\$1.44	\$ 1.10



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 Agreement noted above, 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 at 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.

The key assumptions used to value the warrants after the modification at October 27, 2015 were as follows:

**Assumption**

Expected price volatility	80.00%
Expected term (in years)	4.36
Risk-free interest rate	1.23 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	\$2.78

The key assumptions used to value the Short-Term warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	Period Ended		
	March 31, 2016	December 31, 2015	
Expected price volatility	86.00%	80.00	%
Expected term (in years)	3.93	4.18	
Risk-free interest rate	1.03 %	1.58	%
Dividend yield	0.00 %	0.00	%
Weighted-average fair value of warrants	\$1.43	\$ 1.16	

The key assumptions used to value the Long-Term warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	Period Ended		
	March 31, 2016	December 31, 2015	
Expected price volatility	86.00%	80.00	%
Expected term (in years)	3.93	4.18	
Risk-free interest rate	1.03 %	1.58	%
Dividend yield	0.00 %	0.00	%
Weighted-average fair value of warrants	\$1.40	\$ 1.16	

As noted above, in October 2015, the Company issued warrants in connection with an underwriting agreement. The Company evaluated the terms of the 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. The fair value of the warrants at issuance was \$1.3 million.

The key assumptions used to initially value the warrants at October 27, 2015 were as follows:

**Assumption**

Expected price volatility	75.50%
Expected term (in years)	5.00
Risk-free interest rate	1.38 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	\$2.82

The key assumptions used to value the warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

<b>Assumption</b>	<b>Period Ended</b>		
	<b>March 31, 2016</b>	<b>December 31, 2015</b>	
Expected price volatility	82.00%	77.50	%
Expected term (in years)	4.53	4.83	
Risk-free interest rate	1.14 %	1.72	%
Dividend yield	0.00 %	0.00	%
Weighted-average fair value of warrants	\$ 1.59	\$ 1.21	

The details of all outstanding warrant liability as of March 31, 2016, are as follows:

	Shares	Warrant Liability
July 2011 Warrants	138,621	\$ 199,537
Long-Term Warrants	285,619	400,428
Short-Term Warrants	370,934	529,232
October 2015 Warrants	442,802	705,794
	1,237,976	\$ 1,834,991

## NOTE 10. STOCKHOLDERS' EQUITY

### *Amendments to Articles of Incorporation – Reverse Stock Split*

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

### *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 December 31, 2015, there were no shares of preferred stock outstanding.

### *Common Stock*

In February 2016, we 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. We 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. We entered into the second purchase agreement with Pioneer Singapore (the “Pioneer Agreement”), pursuant to which we 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. We 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.

### *Stock Warrants*

In February 2016, the strike prices 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 details of all outstanding warrants as of March 31, 2016, are as follows:

(in thousands, except per share data )	Warrants	Weighted-Average
		Exercise Price
Outstanding at December 31, 2015	1,458	\$ 5.19
Warrants granted	-	-
Warrants exercised	-	-
Warrants expired	-	-
Outstanding at March 31, 2016	1,458	\$ 4.58

**NOTE 11. EQUITY-BASED COMPENSATION***Equity Compensation Plans*

Prior to its Initial Public Offering (the “IPO”), the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the “2007 Plan”) to provide for the granting of stock 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. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans, and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. As of March 31, 2016, there were 26,039 shares available for future grant under the 2007 Plan.

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, not less than 110%. 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. All of the options granted prior to October 2007 include early exercise provisions that allow for full exercise of the option prior to the option vesting, subject to certain repurchase provisions. The Company issues new shares to satisfy option exercises under the plans.

*Stock Option Summary*

The following table summarizes information about the Company’s stock options outstanding at March 31, 2016, and activity during the three-month period then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average	Aggregate
			Remaining Contractual Life (years)	Intrinsic Value
Outstanding at December 31, 2015	388	\$ 32.03	6.2	19
Options granted	108	\$ 2.20		
Restricted stock units granted	73	\$ —		

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form 10-Q

Restricted stock units vested	(72	)	\$	—		
Options forfeited/cancelled/expired	(36	)	\$	31.80		
Outstanding at March 31, 2016	461		\$	24.93	11.0	\$ 31
Vested and expected to vest at March 31, 2016	456		\$	25.04	11.0	\$ 31
Vested at March 31, 2016	300		\$	34.63	5.4	\$ —
Exercisable at March 31, 2016	300		\$	34.63	5.4	\$ —

For options that have a quoted market price in excess of the exercise price (“in-the-money options”), 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 MKT as of March 31, 2016. There were no stock option awards exercised for the three months ended March 31, 2016. The Company received no cash payments for the exercise of stock options during the three months ended March 31, 2016. The aggregate intrinsic value of stock option awards exercised was \$4 thousand for the three months ended March 31, 2015, as determined at the date of option exercise.

As of March 31, 2016, total unrecognized compensation cost related to unvested stock options and restricted stock units was \$882 thousand. 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 2.02 years.

### ***Stock Options and 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 three months ended March 31, 2016 and 2015, the Company granted options to purchase an aggregate of 91 thousand and 24 thousand shares of common stock, respectively, to employees and directors.

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

<b><u>Assumption</u></b>	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Expected price volatility	87%	73%
Expected term (in years)	7.76	5.11
Risk-free interest rate	2.09%	1.61%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	\$1.60	\$9.75

*Expected Price Volatility*—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. The computation of expected volatility was based on the historical volatility of our own stock and 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.

Additionally, during the three months ended March 31, 2016 and 2015, the Company issued 64 thousand and 4 thousand shares of common stock, respectively, to employees.

For the three months ended March 31, 2016 and 2015, the Company recognized stock-based compensation expense of \$207 thousand and \$265 thousand, respectively, for stock based awards to employees and directors.

***Stock-Based Awards to Non-Employees***

During the three months ended March 31, 2016 and 2015, the Company granted options to purchase an aggregate of 17 thousand and 2 thousand shares of common stock, respectively, to non-employees 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:

<b><u>Assumption</u></b>	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Expected price volatility	87%	79%
Expected term (in years)	9.99	9.6
Risk-free interest rate	2.04%	1.91%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	\$2.64	\$13.50

The Company granted restricted stock to non-employees totaling 10 thousand shares of common stock in the three months ended March 31, 2016 in exchange for advisory and consulting services. The Company did not grant any restricted stock to non-employees in the three months ended March 31, 2015.

For the three months ended March 31, 2016 and 2015, the Company recognized stock-based compensation expense of \$40 thousand and \$20 thousand, respectively, related to non-employee stock and option grants.

***Summary of Stock-Based Compensation Expense***

A summary of the stock-based compensation expense included in the consolidated statement of operations and comprehensive loss for the options and stock discussed above is as follows (the amounts that would have been charged to cost of goods sold are not material and have been included in general and administrative below.):

**Three  
Months  
Ended**

<b>(in thousands)</b>	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
Research and development	\$31	\$130
Sales and marketing	2	1
General and administrative	214	154
Total stock-based compensation expense	\$247	\$285

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 12. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS**

### *Virbac Agreement*

In April 2012, the Company entered into a feasibility and option agreement with Virbac, a global animal health company for the development and potential commercialization of Aganocides for a number of veterinary uses for companion animals. Under the terms of the agreement, the Company received an upfront payment and is entitled to additional support for research and development. Virbac conducted veterinary studies using the Company's Aganocide compounds to assess feasibility for treating several veterinary indications.

In April 2013, the option was exercised, and 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 option exercise fee and may receive future development and pre-commercial milestone payments as a result of the collaboration. The Company also expects to receive royalties on the sale of any commercial products in the companion animal field. Virbac's option exercise follows its extensive testing of auriclosene for veterinary uses during the 12-month option period. The Company is recognizing the option exercise fee over its expected performance period of 10 years based on actual sales during this period.

The Company did not recognize any revenue under the Virbac agreement during three months ended March 31, 2016 and 2015, respectively.

The Company had a deferred revenue balance of \$246 thousand at March 31, 2016 and December 31, 2015, respectively, related to this agreement, which consisted of the unamortized balances on the upfront technology access fee and option fee and the support for ongoing research and development.

#### *NeutroPhase Distribution Agreements*

In January 2012, the Company entered into a distribution agreement with Pioneer Pharma Co., Ltd. ("Pioneer"), a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, the Company received an upfront payment of \$313 thousand. NovaBay also received \$313 thousand in January 2013, related to the submission of the first marketing approval for the product to the China Food and Drug Administration ("CFDA") (formerly the SFDA, State Food and Drug Administration), which was submitted in December 2012. The distribution agreement provides that Pioneer is entitled to receive cumulative purchase discounts of up to \$500 thousand upon the purchase of NeutroPhase product. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received \$625 thousand upon receipt of a marketing approval of the product from the CFDA.

In September 2012, the Company entered into two agreements with 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, Pioneer has the right to distribute NeutroPhase, upon receiving marketing approval from a regulatory authority, 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. Pioneer

is also obligated to make certain additional payments to the Company upon receipt of marketing approval. The Distribution Agreement further provides that Pioneer is entitled to a cumulative purchase discount not to exceed \$500 thousand upon the purchase of NeutroPhase product, payable in the Company's unregistered restricted common stock.

Pursuant to the Purchase Agreement, the Company also received \$2.5 million from Pioneer for the purchase of restricted units (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) 32,000 units in September 2012; and (2) 48,000 units in October 2012, with both tranches at a purchase price of \$31.25 per share. 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 thousand from deferred revenue to stockholders' equity as consideration for the purchase of the units.

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

During the three months ended March 31, 2016, the Company had three other smaller agreements and continues to seek additional distribution agreements.

Revenue has been recognized under these agreements as follows:

<b>(in thousands)</b>	<b>Three Months Ended March 31, 2016 2015</b>	
Amortization of Upfront Technology Access Fee	\$51	\$ 6
Total	\$51	\$ 6

The Company had a deferred revenue balance of \$271 thousand at March 31, 2016 and December 31, 2015, respectively, related to these agreements, which consisted of the unamortized balances on the upfront technology access fee and the support for ongoing research and development.

#### *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 signed a nationwide distribution agreement with AmerisourceBergen to market Avenova.

During the three months ended March 31, 2016 and March 31, 2015, the Company earned \$553 thousand and \$39 thousand, respectively, in sales revenue for its Avenova product from its distribution agreements.

**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 has made no contributions through March 31, 2016.

**NOTE 14. SUBSEQUENT EVENTS**

On April 4, 2016, the Company entered into a securities purchase agreement for the sale of an aggregate of 6,173,299 shares of the Company's common stock, par value \$0.01 per share (the "Shares"), and warrants exercisable for 3,086,651 Shares to accredited investors for an aggregate purchase price of \$11,791,000 (the "Private Placement"). For every one (1) Share purchased at \$1.91 per share, each purchaser will receive a warrant to purchase one-half a Share, with such warrants having a four (4)-year term and an exercise price of \$1.91, callable by the Company if the closing price of the Company's common stock, as reported on the NYSE MKT, is \$4.00 or greater for five (5) sequential trading days.

The Private Placement was designed to close in two tranches, the first of which occurred on May 6, 2016 (the "Primary Closing"), and the second of which is scheduled to occur on July 31, 2016 (the "Secondary Closing"). Both the Primary Closing of \$7.8 million of Company securities and the Secondary Closing of \$4.0 million of Company securities are subject to the same terms. Upon the Primary Closing, the Company used \$2.5 million in proceeds to repay principal on the Notes issued to the Lenders. See Note 7 for additional information regarding the Notes.

## **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, 2015, which was filed with the Securities and Exchange Commission (the "SEC") on March 4, 2016. 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 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 biopharmaceutical company developing products for the eye care market. We are currently focused primarily on commercializing prescription Avenova<sup>®</sup> for managing hygiene of the eyelids and lashes in the United States.

Avenova is the only eye care product formulated with a proprietary, stable and pure form of hypochlorous acid called Neutrox. By replicating the anti-microbial chemicals used by white blood cells to fight infection, Neutrox has proven in laboratory testing to have broad antimicrobial properties. Avenova with Neutrox removes debris from the skin on the eyelids and lashes without burning or stinging.

In November 2015, we introduced a new business strategy to focus on growing sales of Avenova in the U.S. market and to restructure our business with the goal of achieving profitability from operations by the end of 2016. Our three-part business strategy is comprised of: (1) focusing our resources on growing the commercial sales of Avenova in the U.S. eye care market, including the implementation of an innovative sales and marketing strategy to increase product margin and profitability; (2) significantly reducing expenses through the restructuring of our operations and other cost reduction measures; 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.



We have developed additional commercial products containing Neutrox, including our NeutroPhase Skin and Wound Cleanser for wound care and CelleRx for the dermatology market. We have partnerships for NeutroPhase in the U.S. as well as select overseas markets, most notably China.

In addition to our Neutrox family of products, we have also synthesized and developed a second category of novel compounds aimed at harnessing the power of white blood cell chemistry to address the global, topical anti-infective market. This second product category includes auriclosene, our lead clinical-stage Aganocide compound, which is a patented, synthetic molecule with a broad spectrum of activity against bacteria, viruses and fungi.

### **Avenova**

Prescription Avenova (0.01% Neutrox) is well-suited for daily eyelid and eyelash hygiene by the approximately 30 million Americans who suffer from blepharitis and dry eye. Additionally, we estimate that an additional 11 million patients suffering from other conditions could potentially benefit from the use of Avenova, bringing the total potential market to approximately 41 million patients.

We are targeting a customer base of prescribers that includes the approximately 17,000 ophthalmologists and approximately 37,000 optometrists in the U.S. In August 2014, we launched a dedicated Avenova sales force of 10 direct medical sales representatives in 10 major metropolitan areas across the United States. This sales and marketing campaign initially targeted major urban areas where large numbers of individuals suffer from problems with their eyelids and lashes. These markets included New York, Los Angeles, Boston, Atlanta, and San Francisco.

Based on positive sales performance, we expanded our sales force to 35 direct medical sales representatives in February 2015 and to 43 direct medical sales representatives in August 2015. The sales representatives recruited for this effort have extensive experience with eye care products and medical devices—a skill set critical for rapid adoption of Avenova. Based on extensive market research, we have assigned our sales representatives to the markets across the U.S. representing the highest sales potential. These direct medical sales representatives are calling on targeted ophthalmologists and optometrists in those markets that treat large numbers of blepharitis and dry eye patients. Avenova is a natural addition to their existing lid hygiene regimens.

We have distribution agreements with McKesson Corporation, Cardinal Health and AmerisourceBergen Corporation that make Avenova accessible in 90% of the approximate 67,000 retail pharmacies across the U.S. Avenova also is marketed through the top ophthalmology and optometry networks. These include Vision Source Independent Optometry Network, the largest independent optometry network in the country representing 2,800 independent optometrist offices, and ALLDocs Optometry Group (also known as The Association of LensCrafters Leaseholding Doctors), the second largest independent optometry group in the U.S., which works closely with its LensCrafters partners. Through a partnership with ALPHAEON, Avenova is available to member ophthalmologists on the ShoutMD® Store, the first social commerce store for lifestyle healthcare products. Avenova is also available for order online with a prescription, and we provide an online pharmacy locator to assist patients with filling prescriptions.

We expect that our prescription business will be the main driver of long-term Avenova sales growth. Reimbursement under insurance coverage continues to grow with 68% of Avenova prescriptions covered by insurance plans at the end of 2015. Supported by the high percentage rate of insurance reimbursement, we are focusing our primary sales efforts on building our prescription business under a new value pricing model. We are working to improve insurance reimbursement coverage for Avenova and aligning our product pricing accordingly.

Although we are focusing on our prescription sales, we expect continued growth in the doctor to patient direct sales channel. We also expect to invest in systems that support prescribing physicians' efforts to educate their patients. We have made it easy for doctors to get Avenova into the hands of patients by providing availability through well-known national pharmacy chains, specialty pharmacies, or directly through the practitioners' office. Furthermore, in order to ensure consistent pricing, we have instituted rebate cards to ensure the best price for the patient at the pharmacy. This sales model combined with the prospect for further increases in reimbursement under insurance plans has the potential to provide us with additional revenue upside.

### **Partnerships to Monetize Other Assets**

We intend to seek additional sources of revenue and reduce expenses by licensing or selling select non-core assets, possibly including intelli-Case, NeutroPhase, CelleRx and our Aganocide compounds, including auriclosene.

Currently, the program with the most potential is our urology program. Statistically-significant and clinically-meaningful results from a Phase 2 clinical study of our Auriclosene Irrigation Solution (AIS) used to reduce urinary catheter blockage and encrustation (UCBE), were announced in September 2013. This study, comparing AIS to saline solution, achieved its primary endpoints and showed clear benefits for patients with long-term indwelling catheters. We initiated the next Phase 2 study in the fourth quarter of 2014 and in the fourth quarter of 2015 announced completion of that study. Patients with long-term indwelling urinary catheters were treated with AIS or its Vehicle. The results of this more demanding study showed that AIS was better than its Vehicle in preventing the reduction of flow through catheters due to encrustation, the primary efficacy measure, by a statistically-significant margin. Furthermore, there were no cases of clinical catheter blockage in the AIS arm of the study; all cases of clinical blockage requiring catheter removal occurred only in the Vehicle arm.

***NovaClear intelli-Case.*** In June 2015, we received FDA-clearance for the NovaClear intelli-Case, a highly innovative, easy-to-use device for use with hydrogen peroxide disinfection solutions for soft and rigid gas permeable contact lenses. The intelli-Case monitors the neutralization of hydrogen peroxide during the disinfection cycle with sophisticated microprocessor electronics embedded in the cap of what otherwise looks like a standard peroxide lens case. The LED indicators on the lid inform the user if the lenses are safe to insert into the eyes, resulting in a disinfection system that is safe yet simple to use. We are seeking potential partners with the resources to make this break-through device available to the largest number of contact lens wearers as soon as possible.

### ***Additional Neutrox-based Products***

In addition to Avenova, the Neutrox-branded products currently being commercialized as prescription medical devices are NeutroPhase and CelleRx.

***NeutroPhase (Wound Care).*** Since its launch in the U.S. in 2013, NeutroPhase has impacted how wound care is administered. Consisting of 0.03% Neutrox, NeutroPhase is used to cleanse and remove microorganisms from any type of acute or chronic wound and can be used with any type of wound care modality. Recently, NeutroPhase has been found to be an effective irrigation solution as part of the adjunct treatment for Necrotizing Fasciitis (“NF”). Also known as flesh-eating disease, NF typically has high mortality and amputation rates (30% and 70%, respectively), even with aggressive debridement and antibiotic treatment. We believe that NeutroPhase is also well-suited to treat the six million patients in the U.S. who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers.

In the U.S. and internationally, NeutroPhase is distributed through commercial partners. In January 2012, we entered into an exclusive distribution agreement with Pioneer Pharma Company Limited (“Pioneer”), a Shanghai-based company, for the distribution of NeutroPhase throughout Southeast Asia and mainland China. We subsequently expanded the agreement with Pioneer so that it includes the licensing rights to CelleRx and Avenova. In September 2014, China’s Food and Drug Administration cleared our NeutroPhase Skin and Wound Cleanser for sale throughout mainland China. In November 2014, Taiwan’s Food and Drug Administration cleared our NeutroPhase Skin and Wound Cleanser for sale in Taiwan. We began shipping NeutroPhase to China and Taiwan in the fourth quarter of 2014 to support our launch of NeutroPhase Skin and Wound Cleanser by Pioneer. In the U.S., NeutroPhase is distributed through our partner, Principle Business Enterprise (“PBE”).

***CelleRx (Dermatology).*** Created for cosmetic procedures, CelleRx (0.015% Neutrox) is a gentle cleansing solution that is effective for post-laser resurfacing, chemical peels and other cosmetic surgery procedures. Cosmetic surgeons and aesthetic dermatologists have found that CelleRx results in less pain, erythema, and exudate compared to Dakin solution, which contains bleach impurities. CelleRx is a non-alcohol formulation that doesn’t dry or stain the skin, and most importantly, has been shown to reduce the patient’s downtime post procedure.

### **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, 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 setup an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identified amounts due that are in dispute and it believes are unlikely to be collected at the end of 2015. At December 31, 2015, management had reserved \$40 thousand, primarily based on specific amounts that are in dispute and are over 120 days past due.

### ***Inventory***

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes, 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.

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

### ***Revenue Recognition***

We sell products through a limited number of distributors and via our webstore. We generally record product sales upon shipment to the final customer for our webstore sales and upon shipment from our distributor to the final customers for our major distribution partners.

We recognize product revenue when: (i) persuasive evidence that an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) our price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid us, or the customer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the customer's obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by us, (v) we do not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

### ***Product Revenue Allowances***

Product revenue is recognized, net of cash consideration paid to our customers and wholesalers, for services rendered by wholesalers in accordance with such wholesaler's agreements and includes both a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other product revenue allowances include certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue or as a selling expense at the later of the date at which the related revenue is recognized or the date at which the allowance is offered.

### ***Other Revenue***

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, and payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and revenue is recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured. If these factors were to vary, the resulting change could have a material effect on our revenue recognition and on our results of operations.

### ***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 inventory that may expire and become unsalable. We did record an allowance for obsolete inventory of \$45 thousand during 2015, but did not record an allowance for excess inventory as of December 31, 2015.

### ***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, level 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***

We account 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 11 of the Notes to Consolidated Financial Statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. We account for restricted stock unit awards issued to employees and non-employees based on the fair market value of our common stock at the date of issuance.

### ***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 the warrants in cash, or for warrants we issue or modify that contain an exercise price adjustment feature that reduces the exercise price 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 Binomial Lattice (“Lattice”) valuation model, which 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.

### **Recent Accounting Pronouncements**

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

**Results of Operations***Comparison of the Three Months Ended March 31, 2016 and 2015*

	<b>Three Months Ended March 31,</b>		<b>Year-to-Year</b>	<b>Percent</b>
	<b>2016</b>	<b>2015</b>	<b>Change</b>	<b>Change</b>
	<b>(in thousands, except per share data)</b>			
<b>Statements of Operations Data:</b>				
Sales:				
Product revenue	\$1,655	\$492	\$ 1,163	236%
Other revenue	64	46	18	39%
Total net sales	1,719	538	1,181	220%
Product cost of goods sold	611	148	463	313%
Gross Profit	1,108	390	718	184%
Operating expenses:				
Research and development	933	1,583	(650 )	(41)%
Selling and marketing	3,144	1,914	1,230	64%
General and administrative	1,655	1,554	101	6%
Total operating expenses	5,732	5,051	681	13%
Operating loss	(4,624)	(4,661)	37	(1)%
Non-cash (loss) gain on change in fair value of warrants	(385 )	34	(419 )	(1232)%
Other expense, net	(68 )	(11 )	(57 )	518%
Loss before income taxes	(5,077)	(4,638)	(439 )	9%
Provision for income taxes	-	(2 )	2	(100)%
Net loss	\$(5,077)	\$(4,640)	\$ (437 )	9%

*Total Net Sales, Product Revenue and Gross Profit*

Total net sales were \$1.7 million for the three months ended March 31, 2016, compared to \$538 thousand for the three months ended March 31, 2015, which is primarily attributable to significantly increased sales of Avenova.

Product revenue increased by \$1.2 million, or 236%, to \$1.7 million from \$492 thousand, and other revenue increased by \$18 thousand, or 39%, to \$64 thousand from \$46 thousand for three months ended March 31, 2016, compared to the three months ended March 31, 2015. The change in product revenue was primarily the result of increased sales of Avenova in connection with the focus on product commercialization, partially offset by a reduction in other revenue because of our de-emphasis of technology and collaboration agreements.

Gross profit increased by \$718 thousand, or 184%, to \$1.1 million from \$390 thousand for the three months ended March 31, 2016, compared to the three months ended March 31, 2015. The increase in gross profit was primarily the result of increased sales of Avenova.

### *Research and Development*

Research and development expenses decreased by \$650 thousand, or 41%, to \$933 thousand for the three months ended March 31, 2016, down from \$1.6 million for the three months ended March 31, 2015. The reduction is primarily the result of reduced spending on clinical trials and the shift of capital resources from research and development to the commercialization of Avenova.

***Sales and marketing***

Sales and marketing expenses increased by \$1.2 million, or 64%, to \$3.1 million for the three months ended March 31, 2016, up from \$1.9 million for the three months ended March 31, 2015. The increase was primarily due to the increase in sales representative headcount and sales and marketing activities for the continued commercialization of Avenova.

***General and administrative***

General and administrative expenses increased by \$101 thousand, or 6%, to \$1.7 million for the three months ended March 31, 2016, up from \$1.5 million for the three months ended March 31, 2015. The increase was primarily due to the increase in professional fees related to our various equity and financial transactions.

***Non-cash (loss) gain on changes in fair value of warrants***

The adjustments to the fair value of warrants were a loss of \$385 thousand for the three months ended March 31, 2016, compared to a gain of \$34 thousand for the three months ended March 31, 2015.

The change in fair value of the warrant liability was attributable to the reduction in the strike price of the July 2011, March 2015 and October 2015 warrants to \$1.81, resulting from the sale of the Company's common stock to Mr. Jian Ping Fu at that price in February 2016.

***Other (expense), net***

Other (expense), net increased by \$57 thousand, or 518%, to \$68 thousand for the three months ended March 31, 2016, up from \$11 thousand for the three months ended March 31, 2015. The increase was due to the interest due on the notes entered into in December 2015 and February 2016 as part of the Company's \$3.0 million bridge loan (the "Bridge Loan"). For additional information regarding the notes and the Bridge Loan, please see Note 7 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report.

*Liquidity and Capital Resources*

As of March 31, 2016, our cash and cash equivalents were \$1.4 million, compared to \$2.4 million as of December 31, 2015. We have incurred cumulative net losses of \$95.6 million since inception through March 31, 2016. Since inception, we have funded our operations primarily through the sales of our stock and warrants and funds received under our collaboration agreements. In February 2015, we closed a financing in which we raised a total of \$2.8 million, or approximately \$2.6 million in net cash proceeds after deducting underwriting commissions and other offering costs of \$0.2 million. Additionally, we increased our borrowings by \$1.4 million as part of the Bridge Loan during the three months ended March 31, 2016.

Although we recently raised capital, our cash and our cash equivalents are not sufficient to fund our planned operations. To achieve this, we will continue with our historical financing strategy to raise additional capital in order to fund our operations and meet our ongoing obligations, with the goal of being cash flow positive by December 2016. There is no assurance that we will be able to raise capital, or if we are able to raise capital, that it will be on favorable terms. We incorporated additional information regarding risks related to our capital and liquidity in Item 1A. "Risk Factors" of this report, which should be read with this disclosure.

Until we can generate sufficient product revenue, we expect to finance future cash flow needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. In addition, we are seeking to monetize non-core assets such as our UCBE program. In two Phase 2 clinical studies, our AIS demonstrated clinically meaningful and statistically significant results in preventing encrustation and incidence of clinical blockage in the in-dwelling catheters of chronically catheterized patients. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience dilution. In addition, debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. We are currently seeking partners/purchasers who would pay an up-front fee for some of our "non-core assets," such as our urology and aesthetic dermatology programs.

***Net Cash (Used In) Operating Activities***

For the three months ended March 31, 2016, net cash used in operating activities was \$4.9 million compared to \$4.5 million for the three months ended March 31, 2015. The increase in 2016 of cash used in operating activities was due to spending on sales and marketing activities for the continued commercialization of Avenova.

***Net Cash (Used In) Provided by Investing Activities***

For the three months ended March 31, 2016, net cash used in investing activities of \$16 thousand was attributed to the purchases of property and equipment. For the three months ended March 31, 2015, cash provided by investing activities of \$23 thousand was attributed to proceeds received on disposal of equipment, net of cash spent on purchases of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities of \$4.0 million for the three months ended March 31, 2016 was primarily attributable to the sale of \$2.7 million of our common stock in our February 2016 financing. Additionally, the Company increased its borrowings by \$1.4 million as part of the Bridge Loan during the three months ended March 31, 2016.

Net cash provided by financing activities of \$4.7 million for the three months ended March 31, 2015 was primarily attributable to the sale of common stock and warrants in our March 2015 financing and the sale of our common stock under an at-the-market offering agreement.

***Net Operating Losses and Tax Credit Carryforwards***

As of December 31, 2015, we had net operating loss carryforwards for federal and state income tax purposes of \$80.6 million and \$77.1 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2016 and 2035. As of December 31, 2015, we also had tax credit carryforwards for federal income tax purposes of \$1,274 thousand and \$256 thousand for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2031. 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 have no off-balance sheet arrangements as of March 31, 2016.

### ***Contractual Obligations***

Our commitments at March 31, 2016 consist of an operating lease. The operating lease consists of payments relating to the lease for various laboratory and office space in one office building in Emeryville, California. This lease expires on October 31, 2020, and the total commitment as of March 31, 2016 is \$3.1 million due over the lease term, compared to \$3.2 million as of December 31, 2015.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risk consists principally of interest rate risk on our cash, cash equivalents, and short-term investments. Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in interest rates, particularly because the majority of our investments are in short-term debt securities.

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital; assurance of liquidity needs; best available return on invested capital; and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. As of March 31, 2016, and December 31, 2015, we did not have any short-term marketable securities, as all our investment portfolio was held in cash and cash equivalents. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

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 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"). Based upon that evaluation, our 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.



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.

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

There was no change in our internal control over financial reporting during the quarter ended March 31, 2016, 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. 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. 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.*

#### **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, and these products are still in their early stage of commercialization and will require significant additional investment before we realize substantial revenue. As a result, we have incurred since our inception, and expect to continue to incur until at least the end of 2016, substantial net losses. Moreover, our cash position is inadequate to support our current business operations and substantial additional funding will 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 for the eye care market, seeking regulatory approval for these product candidates, and pursuing their commercialization in the U.S., Asia, and other markets. These circumstances raise substantial 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 expect that we will incur net losses in the future, and that we may never achieve or maintain sustained profitability.*

We expect to incur substantial marketing and sales expenses as we attempt to increase sales of our Avenova product. We expect to incur losses for the foreseeable future, and we may never achieve or maintain sustained profitability. In addition, at this time we are subject to the following risks:

our results of operations may fluctuate significantly, which may adversely affect the value of an investment in our common stock;

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.

***We may be unable to raise additional capital on acceptable terms in the future, which may in turn limit our ability to develop and commercialize products and technologies.***

While we have reduced our staff levels and reduced both our research and general expenditures, we believe our capital outlays and operating expenditures will outsize our expected near-term revenue. Commercializing a product is very expensive, and we expect that we will need to raise additional capital, through future private or public equity offerings, strategic alliances or debt financing, before we achieve a breakeven point between expenses and product sales. In addition, we may require even more significant capital outlays and operating expenditures if we do not continue to partner with third parties to develop and commercialize our products.

Our future capital requirements will depend on many factors, including:

the availability and willingness of capital markets to fund our planned operations;

economic conditions out of our control;

market acceptance and revenue growth of Avenova;

the extent to which we receive milestone payments or other funding from external partners, if any;

the scope, rate of progress, cost and results of our pre-clinical studies and clinical trials and other research and development activities, if any;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technological and market developments;

the costs associated with marketing and selling Avenova and NeutroPhase;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

Additional financing may not be available to us on favorable terms, or at all. The securities rules and regulations limit our sale of securities registered on a Form S-3 to one-third of the aggregate market value of our outstanding common equity held by non-affiliates (the "Aggregate Market Value") during a 12-month period as long as our Aggregate Market Value is below \$75 million. In our October 2015 public offering of common stock and accompanying warrants to purchase common stock, we utilized substantially all of our remaining capacity to sell securities on Form S-3 at the time and we currently have no capacity to sell additional securities on Form S-3. Until our Aggregate Market Value reaches \$75 million, our ability to raise capital on Form S-3 is limited, especially during the period through October 2016. As a result, we may have to raise capital on a Form S-1 registration statement, which requires more disclosure than the Form S-3, would cause additional legal and other expenses, and could delay the timing of any future offerings. Even after October 2016, we may not be able to raise the amount of capital we need on a Form S-3 if our low Aggregate Market Value persists.

In connection with the Bridge Loan, we granted China Kington Asset Management Co. Ltd. ("China Kington") a first right of refusal to lead our financings for a period that is the shorter of two years after the Bridge Loan or until our net cash flow has been no less than \$0 for three consecutive months. Such financings must be unanimously approved by our Board of Directors, which includes two members nominated by China Kington pursuant to the Bridge Loan, until the Bridge Loan is paid off. On April 4, 2016, we entered into a Securities Purchase Agreement for the sale of

\$11.8 million in our securities in two closings. In connection with the first such closing on May 9, 2016, we repaid \$2.5 million in principal on the Bridge Loan, and we have agreed with the lenders to repay the remaining \$500 thousand in principal upon the second closing, which is scheduled to occur on July 31, 2016. As a result of these restrictions, if the second tranche of the private placement does not close as scheduled, we might not be able to obtain the additional capital we need, or to do so on the most favorable terms.

Our ability to obtain additional financing may also be negatively affected by the recent volatility in the financial markets, as well as the general downturn in the economy and decreased consumer confidence. Even if we succeed in selling additional securities to raise funds, our existing stockholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing stockholders. In addition, if in the future we sell, or grant options or rights to purchase, our common stock at an effective price per share less than the subsequently adjusted exercise price of our warrants originally issued in July 2011, March 2015 and October 2015, the exercise price of these warrants will be reduced to equal such lower price, subject to certain exemptions as provided in the warrants. The exercise price of such warrants is currently set at \$1.81 as a result of the Company's February 2016 private placement offering. For additional information, please see the risk factor below entitled "*If we conduct offerings in the future, the price at which we offer our securities is likely to 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.*"

If we raise additional capital through strategic alliance and licensing arrangements, we may have to trade our rights to our technology, intellectual property or products to others on terms that may not be favorable to us. If we raise additional capital through debt financing, the financing may involve covenants that restrict our business activities.

### **Risks Relating to Owning Our Common Stock**

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

On April 28, 2015, we received a letter from the NYSE MKT notifying us that our stockholders' equity as of December 31, 2014 was below the minimum requirements of Sections 1003(a)(ii) and (iii) of the NYSE MKT Company Guide. In order to maintain our listing, we submitted a plan of compliance, addressing how we intend to regain compliance with the Company Guide within 18 months, or by October 28, 2016. On March 17, 2016, we were further notified by the NYSE MKT that our common stock no longer satisfied the requirements of Company Guide Section 1003(a)(i) of the NYSE MKT Company Guide. We continue our listing but will be subject to periodic reviews by the exchange. If we do not make progress consistent with the plan, the exchange will initiate delisting procedures, as appropriate.

We are pursuing options to address the stockholders' equity deficiency as indicated in our plan submitted to the NYSE MKT. However, we cannot guarantee that we will be able to comply with the listing requirements, 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 amend certain terms of the warrants we previously issued in July 2011 and March 2015 to certain investors. As a result, in four different sets of warrants issued in July 2011, March 2015 and October 2015, we agreed to provide certain price protections affecting warrants exercisable for an aggregate of 1,317,227 shares of our common stock, of which 874,425 shares must be issued, if at all, by March 6, 2020, and 442,802 shares must be issued, if at all, by October 27, 2020. 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 price of less than \$5.00 per share, we have agreed to reduce the exercise price of all warrants discussed hereof to such lower price. As a result, if any future offering is conducted at a common stock price or warrant exercise price under \$5.00 per share (as adjusted for any reverse stock split or similar transaction), these price protections will be triggered. The exercise price of such warrants is currently set at \$1.81 as a result of the Company's February 2016 private placement offering. The further reduction of the exercise price for the warrants discussed hereto 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 these 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 previously-issued 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.

***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:

- successful shifting in strategy to focus on the eye care market;
- 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 the recent volatility in the financial markets and 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 traded may be very low. Any stockholder wishing to sell his/her stock may cause a significant fluctuation in the price of our stock. We have a number of large stockholders, including our principal stockholders Pioneer and Mr. Jian Ping Fu. 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, amended and restated 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, 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 Delaware General Corporation Law 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.

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

As of March 6, 2016, Pioneer beneficially owns approximately 26% of our common stock. Our director Mr. Xinzhou “Paul” Li is the chief executive officer and chairman of Pioneer. Pursuant to the arrangement of our Bridge Loan, two 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, and Mr. Xiaoyan “Henry” Liu, who has worked closely with China Kington on other financial transactions in the past. Mr. Jian Ping Fu beneficially owns approximately 31% of our common stock. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during the last year.

As a result, 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. In particular, under our Bridge Loan, for a period that is the shorter of two years after the Bridge Loan or until our net cash flow has been no less than \$0 for three consecutive months, our financings must be unanimously approved by our Board of Directors, which provides Pioneer and China Kington a veto right over such financings until the Bridge Loan is repaid. Please see the risk factor entitled “*We may be unable to raise additional capital on acceptable terms in the future, which may in turn limit our ability to develop and commercialize products and technologies.*” Pioneer 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 Pioneer and Mr. Fu to cooperate, they could unilaterally elect all of their preferred director nominees at our 2017 Annual Meeting of Stockholders. Even with our classified board, Pioneer and Mr. Fu could ensure that five (5) of our eight (8) directors are either nominees of Pioneer or China Kington. In the interim, Pioneer, China Kington and/or Mr. Fu could exert significant indirect influence on us and our management in anticipation of a possible change in control of our Board of Directors.

***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, 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 carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. Since the Company’s formation, the Company has 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. The Company has not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since the Company’s formation, due to the significant complexity and cost associated with the study. If the Company has experienced a change of control at any time since its formation, its 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 will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss 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. We are dedicating a substantial amount of our resources to advance Avenova as aggressively as possible. If we encounter difficulties in the commercialization of Avenova, we will 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. We believe we are creating an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures. However, 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.

***Our commercialized products are not approved by the FDA as a drug, so we rely solely on the 510(k) clearance of Neutrox 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, our claims regarding efficacy are limited. Without claims of efficacy, market acceptance of our products may be slow.

***We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.***

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. 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 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 change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

***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.***

We do not currently operate manufacturing facilities for production of our product and product candidates. We have no experience in product formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we have partnered and expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing or delaying product revenues.

Our products and product candidates will 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. These manufacturers and partners are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with Quality Systems Regulations, current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party compliance with these regulations and standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

In addition, if the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we will need to manufacture them in larger quantities. Significant scale-up of manufacturing will require validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product, the regulatory approval or commercial launch of any products may be delayed or there may be a shortage in supply and our business may be harmed as a result.

***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 with the goal of achieving positive cash flow from operations by the end of 2016. Any of our officers and other key employees may terminate their employment at any time, and the loss of any of our senior management team members could disrupt our business, affect key partnerships and impair our future revenue and profitability.

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

We intend to rely primarily upon 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.

***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 product candidates. 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 and our collaborators are and will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators 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 medical devices and drug products and candidates.***

Any regulatory approvals that we receive may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The FDA may require us to commit to perform lengthy post marketing studies, which would require us to expend additional resources and thus could have an adverse effect on our operating results and financial condition. In addition, if the FDA approves any of our drug product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drugs, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drugs or the withdrawal of the drugs from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing any products we may develop and our business could suffer.

***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 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 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.

***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, there may be applications now pending of which we are unaware that may later result in issued patents that our products may 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 such a dispute 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 products, including Avenova, NeutroPhase, 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 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 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.

***A default under the terms of our Bridge Loan could result in the loss of our intellectual property, including intellectual property related to Avenova.***

As partial collateral for the approximately \$3.0 million Bridge Loan, we granted China Kington, as collateral agent, a lien on all of our intellectual property. If we default on the Bridge Loan, including by failing to make any payment due pursuant to the loan, China Kington would have the right to foreclose on our intellectual property. We cannot successfully commercialize Avenova without control of the related intellectual property portfolio. A loss of such intellectual property would prevent us from executing our current business strategy, which is essential to our efforts to achieve profitability. For further information regarding the possible risks if we fail to commercialize Avenova, please see the risk factor entitled “*Our future success is largely dependent on the successful commercialization of Avenova.*”

***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 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 (hypochlorous acid) 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 product candidates 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 healthcare 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.

***If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.***

The market for our products and product candidates is characterized by intense competition and rapid technological advances. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We compete for market share against fully-integrated pharmaceutical and medical device companies or other companies that develop products independently or collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater capital resources, larger research and development staffs and facilities, and greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and devices;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing, distributing and selling products.

Our competitors may:

develop and patent processes or products earlier than we will;

develop and commercialize products that are less expensive or more efficient than any products that we may develop;

obtain regulatory approvals for competing products more rapidly than we will; and

improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

We cannot assure you that our competitors will not succeed in developing technologies and products that are more effective than any developed by us or that would render our technologies and any products we develop obsolete. If we are unable to compete successfully against current or future competitors, we may be unable to obtain market acceptance for any product candidates we create, which could prevent us from generating revenues or achieving profitability and could cause the market price of our common stock to decline.

*Our ability to generate revenues from our current products and any products we develop will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from healthcare payers.*

Significant uncertainty exists as to the cost and reimbursement status of newly-approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and/or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic data on any of our products. If customers and insurance companies are not willing to pay the set price for our products, our revenue will be limited.

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

The information required by this Item 2 was previously reported in Item 1.01 of our Current Report on Form 8-K filed with the SEC on February 17, 2016, and the information in such Item 1.01 is incorporated herein by reference.

## **ITEM 6. EXHIBITS**



See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated here by reference.

**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: May 12, 2016 NOVABAY PHARMACEUTICALS, INC.

/s/ Mark M. Sieczkarek  
Mark M. Sieczkarek  
**Interim Chief Executive Officer and President**

*(duly authorized officer)*

Date: May 12, 2016 /s/ Thomas J. Paulson

Thomas J. Paulson  
**Chief Financial Officer**

*(principal financial officer)*

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporation by Reference			Filed Herewith
		Form Number	File Number	Exhibit/ Form 8-K Item Filing Date	
3.1	Amended and Restated Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	6/29/2010	
3.2	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	6/04/2014	
3.3	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	10/02/2015	
3.4	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	12/21/2015	
3.5	Bylaws of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.2	6/29/2010	
4.1	Form of Warrant issued in August 2009 offering.	8-K	001-336784.3	8/21/2009	
4.2	Form of Warrant issued in July 2011 offering.	8-K	001-336784.4	10/27/2015	
4.3	Form of Warrant issued in December 2012 offering.	8-K	001-336784.1	12/6/2012	
4.4	Form of Warrant issued in March 2014 offering.	8-K	001-336784.1	3/20/2014	
4.5	Form of Warrant issued in March 2015 offering (issued with 15-month term).	8-K	001-336784.2	10/27/2015	
4.6	Form of Warrant issued in March 2015 offering (issued with 5-year term).	8-K	001-336784.3	10/27/2015	
4.7	Form of Warrant issued in May 2015 offering.	10-Q	001-336784.7	8/13/2015	
4.8	Form of Warrant issued in October 2015 offering.	8-K	001-336784.1	10/27/2015	
4.9	Form of Warrant issued in May 2016 offering.	8-K	001-336784.1	4/05/2016	
4.10	Promissory Note Payable to Mark M. Sieczkarek.	8-K	001-3367810.1	1/6/2016	
4.11	Promissory Note Payable to The Gail J. Maderis Revocable Trust.	8-K	001-3367810.2	1/6/2016	
4.12	Promissory Note Payable to T. Alex McPherson.	8-K	001-3367810.3	1/6/2016	
4.13	Promissory Note Payable to Pioneer Pharma (Singapore) Pte. Ltd.	8-K	001-3367810.4	1/6/2016	

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form 10-Q

4.14	Promissory Note Payable to Jian Ping Fu.	8-K001-33678 10.1 1/14/2016	
4.15	Collateral Agency and Intercreditor Agreement (among China Kington Asset Management Co. Ltd. and the lenders named therein).	8-K001-33678 10.5 1/06/2016	
4.16	Security Agreement (between the Company and China Kington Asset Management Co. Ltd.).	8-K001-33678 10.6 1/06/2016	
4.17	Registration Rights Agreement (among the Company and each of the purchasers named therein).	8-K001-33678 4.2 4/05/2016	
10.1	Executive Employment Agreement (Employment Agreement of Mark M. Sieczkarek).	8-K001-33678 10.1 1/05/2016	
10.2	Executive Employment Agreement (Employment Agreement of Thomas J. Paulson).	8-K001-33678 10.2 1/05/2016	
10.3	Executive Employment Agreement (Employment Agreement of Justin M. Hall).	8-K001-33678 10.3 1/05/2016	
10.4	Mutual & General Release (between the Company and Roy J. Wu).	8-K001-33678 10.13 01/2016	
10.5	Securities Purchase Agreement (between the Company and Jian Ping Fu).	8-K001-33678 10.1 2/17/2016	
10.6	Securities Purchase Agreement (between the Company and Pioneer Pharma (Singapore) Pte. Ltd.).	8-K001-33678 10.2 2/17/2016	
10.7	Securities Purchase Agreement (between the Company and Mark M. Sieczkarek).	8-K001-33678 10.3 2/17/2016	
10.8	Securities Purchase Agreement (among the Company and each of the purchasers named therein).	8-K001-33678 10.1 4/05/2016	
31.1	Certification of the Principal Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).		X
31.2	Certification of the 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 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
32.2‡	Certification by the 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

\* XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

