

NovaBay Pharmaceuticals, Inc.  
Form 10-Q  
November 16, 2015  
**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

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

Commission file number 001-33678

**NOVABAY PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware** **68-0454536**  
**(State or other jurisdiction of incorporation or (I.R.S. Employer Identification No.)**

**organization)**

**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 November 2, 2015, there were 87,087,243 shares of the registrant's common stock outstanding.

**NOVABAY PHARMACEUTICALS, INC.**

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**PART I****FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NOVABAY PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
(in thousands, except per share data)	(unaudited)	(Audited; see note 2)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,383	\$ 5,429
Accounts receivable	543	273
Inventory	1,583	521
Prepaid expenses and other current assets	668	729
Total current assets	6,177	6,952
Property and equipment, net	359	436
Other assets	154	149
<b>TOTAL ASSETS</b>	<b>\$ 6,690</b>	<b>\$ 7,537</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Current liabilities:		
Accounts payable	\$ 2,870	\$ 1,865
Accrued liabilities	1,006	1,055
Deferred revenue	378	425
Total current liabilities	4,254	3,345
Deferred revenues - non-current	2,022	2,000
Deferred rent	187	171
Warrant liability	—	173
Total liabilities	6,463	5,689
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000 shares authorized; none outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, \$0.01 par value; 240,000 shares authorized at September 30, 2015 and 120,000 shares at December 31, 2014; 74,618 and 51,640 issued and outstanding at September 30, 2015 and December 31, 2014, respectively	746	516

Additional paid-in capital	85,797	72,879
Accumulated deficit	(86,316 )	(71,547 )
Total stockholders' equity	227	1,848
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 6,690	\$ 7,537

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

**NOVABAY PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(unaudited)**

(in thousands, except per share data)	Three Months Ended		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Sales:				
Product Revenue	\$1,136	\$90	\$2,559	\$299
Other Revenue	64	62	187	264
Total Net Sales	1,200	152	2,746	563
Product Cost of Goods Sold	269	42	670	189
Gross Profit	931	110	2,076	374
Operating Expenses:				
Research & development	1,920	2,312	4,806	7,078
Sales, general & administrative	4,359	1,911	12,138	5,273
Total Operating Expenses	6,279	4,223	16,944	12,351
Operating Loss	(5,348 )	(4,113 )	(14,868 )	(11,977 )
Non-cash gain (loss) on changes in FMV of Warrants	139	(104 )	173	1,213
Other income (expense), net	(31 )	(2 )	(64 )	48
Loss before provision for income taxes	(5,240 )	(4,219 )	(14,759 )	(10,716 )
Provision for income tax	(2 )	—	(10 )	(10 )
Net loss	(5,242 )	(4,219 )	(14,769 )	(10,726 )
Change in Unrealized gains (losses) on available for sale securities	—	3	—	6
Comprehensive loss	\$(5,242 )	\$(4,216 )	\$(14,769 )	\$(10,720 )
Loss per share (basic and diluted)	\$(0.07 )	\$(0.08 )	\$(0.23 )	\$(0.22 )
Basic & Diluted Shares	74,643	50,821	64,951	48,995

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



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

(in thousands)	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(14,769)	\$(10,726)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	123	185
Net realized loss on sales of short-term investments	—	29
Loss on disposal of property and equipment	(1 )	(54 )
Stock-based compensation expense for options issued to employees and directors	869	654
Stock-based compensation expense for options and stock issued to non-employees	140	121
Non-cash gain on change in fair value of warrants	(173 )	(1,213 )
Changes in operating assets and liabilities:		
Accounts receivable	(307 )	583
Inventory	(1,001 )	(175 )
Prepaid expenses and other assets	1	195
Accounts payable and accrued liabilities	1,057	(1,115 )
Deferred rent	15	—
Deferred revenue	(24 )	601
Net cash used in operating activities	(14,070)	(10,915)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(46 )	(63 )
Proceeds from disposal of property and equipment	37	109
Purchases of short-term investments	—	(4,012 )
Proceeds from maturities and sales of short-term investments	—	5,299
Net cash provided by (used in) investing activities	(9 )	1,333
<b>Cash flows from financing activities:</b>		
Proceeds from common stock issuances	—	179
Proceeds from exercise of options and warrants	—	6
Proceeds from shelf offering, net of costs	12,033	6,781
Net cash provided by financing activities	12,033	6,966
Net decrease in cash and cash equivalents	(2,046 )	(2,616 )
Cash and cash equivalents, beginning of period	5,429	10,500
Cash and cash equivalents, end of period	\$3,383	\$7,884



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

## **NOTE 1. ORGANIZATION**

NovaBay Pharmaceuticals, Inc. (“we,” “our,” “us,” the “Company” and “NovaBay”) is a biopharmaceutical company focused on the development and commercialization of its non-antibiotic, anti-infective products. NovaBay®, NovaBay Pharma®, Avenova®, NeutroPhase®, CelleRx®, intelli-Case™, AgaNase®, Aganocide®, AgaDerm®, Neutrox™ and Going Beyond Antibiotics™ are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

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, The Company changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, it formed two subsidiaries: (i) 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 which was dissolved in July 2012; and (ii) 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 was incorporated (the “Reincorporation”), and it is now incorporated under the laws of the State of Delaware. The Company currently operates in four business segments; see Note 10 for further details.

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

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

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

### ***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 consolidated financial statements and accompanying notes. These estimates include: (i) useful lives for property and equipment and related depreciation calculations; (ii) estimated amortization periods for payments received from product development and license agreements as they relate to revenue recognition; (iii) assumptions for valuing options and warrants; and (iv) income taxes. Actual results could differ from those estimates.

#### ***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 September 30, 2015, the Company's cash and cash equivalents were held in financial institutions in the United States and include deposits in money market funds, which were unrestricted as to withdrawal or use.

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

Financial instruments which potentially subject it 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.

#### ***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. Warrant liability is carried at fair value.



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

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

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

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

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

### ***Inventory***

Inventory is comprised of: (i) raw materials and supplies, such as bottles, packaging materials, labels, boxes, pumps; (ii) goods in progress, which are normally unlabeled bottles; and (iii) finished goods.

Inventory is stated at the lower of standard 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 and has determined that there was no impairment as of all periods presented. 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 and comprehensive loss.

### ***Comprehensive Income (Loss)***

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

### ***Revenue Recognition***

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.

### ***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 did not record an allowance for excess inventory as of September 30, 2015.

### ***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. 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. Research and development expenses under the collaborative agreements approximate the revenue recognized, excluding milestone and upfront payments received under such arrangements.

### ***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 ASC 718, *Compensation-Stock Compensation*. 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 8 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

### ***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 where there is a deemed possibility that the Company may have to settle the warrants in cash, the Company records the fair value of the issued warrants as a liability at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statement of operations and comprehensive loss. The fair values of these warrants have been determined using the Binomial Lattice (“Lattice”) valuation model. The Lattice model provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of judgment on the part of the Company.



*Net Income (Loss) per Share*

The Company computes net income (loss) per share by presenting both basic and diluted earnings (loss) per share (“EPS”).

Basic EPS is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and warrants, using the treasury stock method, using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods since their effect would be anti-dilutive. During the three months ended September 30, 2015 and 2014, and the nine months ended September 30, 2015 and 2014, 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:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	\$(5,242 )	\$(4,216 )	\$(14,769 )	\$(10,726 )
Basic and diluted loss per share	\$(0.07 )	\$(0.08 )	\$(0.23 )	\$(0.22 )
Basic shares	74,643	50,821	64,951	48,995
Add: shares issued upon assumed exercise of stock options and warrants	—	—	—	—
Diluted shares	74,643	50,821	64,951	48,995

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:

	<b>Nine Months Ended September 30,</b>	
<b>(In thousands)</b>	<b>2015</b>	<b>2014</b>
Stock options	8,595	8,181
Stock warrants	25,386	4,925
	33,981	13,106

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

There have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended September 30, 2015, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2014, that are of significance or potential significance to the Company.

### **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 cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities, certificates of deposit and U.S. government securities.

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 our own assumptions in the valuation of this liability.

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2015:

**Fair Value Measurements Using**

(in thousands)	Balance at September 30, 2015	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets</b>				
Cash equivalents	\$3,383	\$ 3,383	\$ —	\$ —
Total assets	\$3,383	\$ 3,383	\$ —	\$ —
<b>Liabilities</b>				
Warrant liability	\$—	\$ —	\$ —	\$ —
Total liabilities	\$—	\$ —	\$ —	\$ —

For the three and nine month periods ended September 30, 2015, as a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash gain on a decrease in the fair value of the warrants of \$139 and \$173 thousand, respectively, in its consolidated statements of operations and comprehensive loss.

For the three and nine month periods ended September 30, 2014, as a result of the fair value adjustment of the warrant liability, the Company recorded a noncash loss on an increase in the fair value of the warrants of \$104 thousand and a \$1.2 million noncash gain on a decrease in the fair value of the warrants, respectively, in its consolidated statements of operations and comprehensive loss. See Note 6 for further discussion on the calculation of the fair value of the warrant liability.

<b>(in thousands)</b>	<b>Warrant liability</b>
Fair value of warrants at December 31, 2014	\$ 173
Adjustment to fair value at September 30, 2015	(173 )
Total warrant liability at September 30, 2015	\$ —

**NOTE 4. INVENTORY**

Inventory consisted of the following:

<b>(in thousands)</b>	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Raw materials and supplies	\$ 1,236	\$ 260
Goods in process	216	184
Finished goods	131	77
Total inventory	\$ 1,583	\$ 521

**NOTE 5. 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 \$257 thousand and \$255 thousand for the three months ended September 30, 2015 and 2014, respectively. Rent expense was approximately \$758 thousand and \$790 thousand for the nine months ended September 30, 2015 and 2014, 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 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 and 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 September 30, 2015.

In the normal course of business, the Company provides indemnifications of varying scope under agreements with other companies, typically its 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 their 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 September 30, 2015.

#### *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 September 30, 2015, 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 6. WARRANT LIABILITY**

In July 2011, the Company sold common stock and warrants in a registered direct financing. As part of this transaction, 3,488,005 warrants were issued with an exercise price of \$1.33 and were exercisable on January 1, 2012, and expire on 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* ("ASC 480"), 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. Due to the cash settle 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 statements of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, after January 5, 2012, and if the closing bid price per share of the common stock on the principal market equals or exceeds \$2.66 for any ten trading days (which do not need 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, which would result in gross proceeds to the Company of approximately \$1.5 million.

The key assumptions used to value the warrants were as follows:

Assumption	September 30,	
	2015	2014
Expected price volatility	85 %	70 %
Expected term (in years)	0.76	1.76
Risk-free interest rate	0.23 %	0.47 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	\$—	\$0.18

**NOTE 7. STOCKHOLDERS' EQUITY***2015 Stock Warrants*

For the nine months ended September 30, 2015, the Company sold 2,026,391 shares of common stock for gross proceeds of \$1,271 thousand, or approximately \$1,148 thousand in net proceeds after deducting offering costs and commissions of \$101 thousand, pursuant to the At-The-Market Offering Agreement (The "ATM Agreement"), with Ascendant Capital Markets.

On March 3, 2015, the Company entered into a securities purchase agreement for the sale of its common stock and warrants in a private placement for net proceeds of approximately \$4.4 million. Investors purchased 9,273,332 units consisting of one share of the Company's common stock and two warrants to purchase an additional share and three-quarters share of common stock, respectively. The first warrant, totaling rights to 9,273,332 shares, which is exercisable beginning on the date six months after the date of issuance, entitles the holder to purchase one share of common stock at a price of \$0.60 per share, and includes a provision for forced conversion if the common stock trades at or above \$1.10 for 10 out of 20 consecutive trading days. This warrant will expire, unless exercised, 36 months following the date of issuance. The second warrant, totaling rights to 6,954,998 shares, entitles the holder to purchase three-quarters of one share of common stock at a price of \$0.65 per share, and is exercisable beginning on the date six months after the date of issuance. This warrant expires five years from the date of issuance, unless exercised. In connection with the securities purchase agreement, the Company also issued a warrant to the placement agent, totaling rights to 185,466 shares, which entitles the holder to purchase one share of common stock at a price of \$0.65 per share, and is exercisable beginning on March 6, 2015. This warrant expires 60 months from issuance, unless exercised. The gross proceeds of this sale were \$4.7 million, or approximately \$4.4 million in net proceeds after deducting offering costs and commissions of \$0.3 million.

In April 2015, the registration statement on Form S-3 associated with the Company's March 2015 private placement was declared effective by the U.S. Securities and Exchange Commission ("SEC"). The registration of these shares causes them to be eligible for open trading in the stock market.

On May 18, 2015, the Company entered into a securities purchase agreement for the sale of \$6.9 million of its common stock and warrants to purchase common stock in a private placement. Investors purchased 10,893,647 units consisting of one share of the Company's common stock and a warrant to purchase an additional one-half share of common stock. The cost per unit was \$0.63. The warrants, totaling rights to purchase 5,446,824 shares, exercisable beginning on the date six months after the date of issuance, entitled the holders to purchase one share of common stock at a price of \$0.78 per share, and included a provision for forced conversion if the common stock traded at or above \$1.10 for 10 out of 20 consecutive trading days. These warrants will expire, unless exercised, 18 months following the date of issuance. If fully exercised, these warrants would bring approximately \$4.2 million of gross proceeds to the Company. China Kington Investment Co Ltd acted as the sole placement agent of the offering, with Maxim Group LLC acting as financial advisor to the Company. Any offering of the securities under the resale registration statement will only be by means of a prospectus. The gross proceeds of this sale were \$6.9 million, or approximately \$6.3 million in net proceeds after deducting offering costs and commissions of \$0.6 million.

In July 2015, the registration statement on Form S-3 associated with the Company's May 2015 private placement was declared effective by the SEC. The registration of these shares causes them to be eligible for open trading in the stock market.

### **2014 Stock Warrants**

In March 2014, 1,400,000 warrants were issued. These warrants were issued with an exercise price of \$1.56 per share and expired on September 25, 2015. These outstanding warrants were fully exercisable at September 30, 2014.

In March 2015, 16,413,796 warrants were issued in connection with the March 2015 financing. The first warrant, totaling rights to 9,273,332 shares, is exercisable beginning on the date six months after the date of issuance with an exercise price of \$0.60 per share and expires 36 months following the issuance. The second warrant, totaling rights to 6,954,998 shares, is exercisable beginning on the date six months after the date of issuance with an exercise price of \$0.65 per share and expires five years from the date of issuance. The third warrant, totaling rights to 185,466 shares, is exercisable beginning on March 6, 2015 with an exercise price of \$0.65 per share and expires 60 months from issuance.

In May 2015, 5,446,824 warrants were issued in connection with the May 2015 financing. The warrants, exercisable on the date six months after the date of issuance, entitled the holders to purchase one share of common stock at a price of \$0.78 per share, and included a provision for forced conversion if the common stock traded at or above \$1.10 for 10 out of 20 consecutive trading days. These warrants will expire, unless exercised, 18 months following the date of issuance.

The details of all outstanding warrants as of September 30, 2015, are as follows:

<b>(in thousands, except per share data)</b>	<b>Warrants</b>	<b>Weighted-Average</b>	
		<b>Exercise Price</b>	
Outstanding at December 31, 2014	4,925	\$	1.42
Warrants issued	21,861	\$	0.66
Warrants expired	(1,400)	) \$	1.56
Outstanding at September 30, 2015	25,386	\$	0.76





**NOTE 8. EQUITY-BASED COMPENSATION*****Equity Compensation Plans***

Prior to its Initial Public Offering (“IPO”), the Company had two equity plans in place: the 2002 Stock Option Plan (the “2002 Plan”) and the 2005 Stock Option Plan (the “2005 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 Plan or 2005 Plan and any option cancellations or expirations from the 2002 Plan or 2005 Plan may not be reissued. As of September 30, 2015, there were 1,994,404 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, then 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 September 30, 2015, and activity during the nine-month period then ended:

<b>(in thousands, except years and per share data)</b>	<b>Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contractual Life (years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2014	8,042	\$ 1.53	6.3	23
Options granted	953	\$ 0.69		

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Restricted stock units granted	156	\$	—		
Options exercised	(7 )	\$	0.56		
Restricted stock units vested	(148 )	\$	—		
Options forfeited/cancelled	(396 )	\$	1.44		
Restricted stock forfeited/cancelled	(5 )	\$	—		
Outstanding at September 30, 2015	8,595	\$	1.44	5.9	\$ 8
Vested and expected to vest at September 30, 2015	8,390	\$	1.45	5.9	\$ 8
Vested at September 30, 2015	6,884	\$	1.55	5.3	\$ —
Exercisable at September 30, 2015	6,884	\$	1.55	5.3	\$ —

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 Market as of September 30, 2015, for options that have a quoted market price in excess of the exercise price. The Company received no cash payments for the exercise of stock options during the nine months ended September 30, 2015. There were no stock option awards exercised for the three months ended September 30, 2015 and 2014. The aggregate intrinsic values of stock option awards exercised were \$4 thousand and \$32 thousand for the nine months ended September 30, 2015 and 2014, respectively.

As of September 30, 2015, total unrecognized compensation cost related to unvested stock options was \$1.2 million. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.05 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.

During the nine months ended September 30, 2015 and 2014 the Company granted options to purchase an aggregate of 643,000 and 1.3 million 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>Nine months ended</b>	
	<b>September 30, 2015</b>	<b>2014</b>
Expected price volatility	74 %	77 %
Expected term (in years)	5.35	6.5
Risk-free interest rate	1.65 %	2.05 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	\$0.40	\$0.62

*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*—We have not made any dividend payments nor do we 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 nine months ended September 30, 2015 and 2014, the Company issued 143,000 and 48,000 shares of common stock, respectively, to employees.

For the three months ended September 30, 2015 and 2014, the Company recognized stock-based compensation expense of \$192 thousand and \$212 thousand, respectively, for stock based awards to employees and directors. For the nine months ended September 30, 2015 and 2014, the Company recognized stock-based compensation expense of \$869 thousand and \$654 thousand, respectively, for stock based awards to employees and directors.

In April 2015, the Company modified stock options of two of its directors, Mr. Cashion and Mr. Wicks, each of whom retired at the 2015 Annual Shareholder Meeting in June 2015. All outstanding stock options held by Mr. Cashion and Mr. Wicks fully vested upon retirement and the option exercise period was extended from 3 months to 4 years, calculated from the date of retirement. Options that have an expiration date prior to the end of the exercise period will maintain their same expiration date. In connection with the stock option modification, the Company recognized stock-based compensation expense of \$185 thousand.

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

During the nine months ended September 30, 2015 and 2014, the Company granted options to purchase an aggregate of 310,000 and 310,500 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>Assumption</b>	<b>Nine Months Ended</b>	
	<b>September 30, 2015</b>	<b>2014</b>
Expected price volatility	79 %	79 %
Expected term (in years)	9.38	8.56
Risk-free interest rate	2.07%	2.38%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	\$0.54	\$0.67

The Company granted restricted stock to non-employees totaling 13,000 and 23,000 shares of common stock in the nine months ended September 30, 2015 and 2014, respectively, in exchange for advisory and consulting services.

For the three months ended September 30, 2015 and 2014, the Company recognized stock-based compensation expense of \$29 thousand and \$40 thousand, respectively, related to non-employee stock and option grants. For the nine months ended September 30, 2015 and 2014, the Company recognized stock-based compensation expense of \$140 thousand and \$121 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 "Sales, general and administrative" below.):

<b>Three Months</b>	<b>Nine Months Ended</b>
---------------------	--------------------------

(in thousands)	Ended			
	September 30, 2015		September 30, 2014	
Research and development	\$86	\$96	\$266	\$220
Sales, general and administrative	135	156	743	555
Total stock-based compensation expense	\$221	\$252	\$1,009	\$775

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 9. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

##### *Galderma*

On March 25, 2009, the Company entered into a collaboration and license agreement with Galderma S.A. to develop and commercialize the Company's Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions.

The Company did not have any deferred revenue balances at September 30, 2015 and December 31, 2014, respectively, related to the Galderma agreement. As of September 30, 2015, the Company has earned \$4.25 million in milestone payments. As of September 30, 2015, the Company has not earned or received any royalty payments under the Galderma agreement, and does not expect to receive any milestone or royalty payments in the near future.

*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, NovaBay received an upfront payment and is entitled to additional support for research and development.

In April 2013, an 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 did not recognize any revenue under the Virbac agreement during the nine months ended September 30, 2015 and 2014, respectively.

The Company had a deferred revenue balance of \$246 thousand at September 30, 2015 and December 31, 2014, 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., a Shanghai-based company ("Pioneer") that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory.

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

The Company had a deferred revenue balance of \$2.4 million at September 30, 2015 and December 31, 2014, respectively, related to this distribution agreement, which consisted of the unamortized balances on the upfront technology access fee and the support for ongoing research and development.



*Distribution Agreements*

In November 2014, the Company signed an agreement with McKesson Corporation to distribute Avenova to the pharmacies in its network, including Wal-Mart, Costco, CVS and Target stores in the United States.

In January 2015, the Company signed a new agreement with Sarmedic Ltd to market Avenova in Israel.

In January 2015, the Company signed a nationwide distribution agreement with Cardinal Health, which delivers prescription drugs and many other products to retail pharmacies, hospitals, mail-order facilities, physician offices, surgery centers and other facilities across the U.S. Under the agreement, Cardinal Health will carry and distribute the Company's Avenova product.

In April 2015, the Company signed a U.S. distribution agreement for its Avenova product with AmerisourceBergen, one of the largest global pharmaceutical sourcing and distribution services companies.

During the three months ended September 30, 2015, the Company earned \$321 thousand in sales revenue for its Avenova product related to the distribution agreements. During the nine months ended September 30, 2015, the Company earned \$482 thousand in sales revenue for its Avenova product related to the distribution agreements.

**NOTE 10. SEGMENT INFORMATION**

The Company reports financial data for four reportable segments, coinciding with its four business units: dermatology, ophthalmology, urology and wound care. The dermatology segment includes all aspects of its business in the dermatology arena, including the collaboration with Galderma and their impetigo clinical trial pursuant to the collaboration and License Agreement described in Note 9. The ophthalmology segment includes Avenova and the Company's clinical trial on ophthalmology, which it was conducting on its own. This segment also includes the intelli-Case with hydrogen peroxide solutions. The urology segment covers the Company's urinary catheter blockage and encrustation (UCBE) trials. The wound care segment encompasses the business around its NeutroPhase product. The Company's remaining activities are immaterial and are shown as an aggregate.

The Company discloses information about its reportable segments based on the measures it uses in assessing the performance of each segment. The Company uses "segment net income (loss)" to measure the performance of its business units. Segment net income (loss) includes the allocation of certain corporate expense. These expenses have been allocated based on the FTE allocations to each individual segment or business unit.

The Company does not segregate specific assets to each business unit as it does not have a reasonable way to allocate the corporate assets to each unit and the Company does not use this as a measure of segment performance.

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
DermaBay (dermatology)	\$1	\$-	\$1	\$5
EyeBay (ophthalology)	1,119	90	2,393	110
UroBay (urology)	-	-	-	-
MediBay (wound care)	25	22	190	253
Other	55	40	162	195
	\$1,200	\$152	\$2,746	\$563
Segment net income (loss)				
DermaBay (dermatology)	\$(122 )	\$(468 )	\$(519 )	\$(1,073 )
EyeBay (ophthalology)	(2,662)	(1,911)	(7,553)	(5,113)
UroBay (urology)	(769)	(608)	(1,749)	(1,827)
MediBay (wound care)	(1,401)	(1,068)	(4,237)	(3,259)
Other	(394)	(58)	(810)	(705)
	\$(5,348)	\$(4,113)	\$(14,868)	\$(11,977)



A reconciliation of total segment net loss to consolidated net loss is as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Segment net loss	\$ (5,348 )	\$ (4,113 )	\$ (14,868 )	\$ (11,977 )
Non-cash gain on change in fair value of warrants	139	(104 )	173	1,213
Other income (expenses), net	(31 )	(2 )	(64 )	48
Provision for income taxes	(2 )	-	(10 )	(10 )
Net loss	\$ (5,242)	\$ (4,219)	\$ (14,769)	\$ (10,726)

#### NOTE 11. SUBSEQUENT EVENTS

The following subsequent events are not included in financial statements and are described in a Form 8-K filed by the Company on October 27, 2015:

##### *October 2015 Offering*

On October 22, 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 the Offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both the 15-month term (the "Short-Term Warrants") and 5-year term (the "Long-Term Warrants") warrants issued 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 all warrants to \$0.20 per share. Previously, the exercise price for the 2011 Warrants had been \$1.33 per share, while the exercise prices for the Short-Term Warrants and Long-Term Warrants had been \$0.60 and \$0.65 per share, respectively. 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 March 2015 Warrants, such that if the Company subsequently sells or otherwise disposes of Company common stock at a lower price per share than \$0.20 or any securities exchangeable for common stock with a lower exercise price than \$0.20, the exercise price of such warrants will be reduced to that lower price.

On October 23, 2015, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Roth Capital Partners, LLC, relating to the public offering and sale (the “Offering”) of up to (i) 12,300,000 shares of the Company’s common stock; and (ii) warrants to purchase up to 11,070,000 shares of the Company’s common stock with an exercise price of \$0.20 per share.

The shares of common stock and warrants were issued separately. There is not expected to be any trading market for the warrants issued in the Offering. Each warrant is exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in this offering was \$0.20 per share of common stock and related warrant. The net proceeds to the Company were approximately \$2.3 million after deducting underwriting discounts and commissions but not offering expenses. The sale of such shares and warrants closed on October 27, 2015.

## 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, 2014, which was filed with the Securities and Exchange Commission on March 26, 2015, and amended on April 14, 2015. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," "goals," "plans," "believes," "estimates," variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Readers are cautioned that these forward-looking statements are only predictions based upon assumptions made that we believed to be reasonable at the time, and are subject to risks and uncertainties. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on addressing the unmet therapeutic needs of the global, topical anti-infective market with two distinct technologies: (i) Neutrox™, our proprietary pure hypochlorous acid solution; and (ii) our novel Aganocide® compounds. Using the Neutrox technology, we have developed three branded products, namely, Avenova™ (previously known as i-Lid Cleanser) for the eye care market, NeutroPhase® for the wound-care market, and CelleRx® for the dermatology market. Our novel and patented Aganocide compounds are still in clinical development.

In April 2015, we also received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market our newly developed product, intelli-Case™, with hydrogen peroxide solutions for the eye care market.

Our business strategy is to focus on commercializing products in the eye care market to support revenue growth; introducing new, innovative eye care products that allow us to leverage our sales organization; developing and supporting distribution partnerships and agreements for our products in the U.S. and international markets; and seeking licensing, partnering, divestiture and/or other means of monetizing non-core assets in urology, dermatology, wound care and plastic surgery as an additional source of revenues and to reduce expenses.

***Products Containing Neutrox***

Neutrox is a pure, proprietary, stable formulation of hypochlorous acid (“HOCl”) in saline. HOCl is a naturally occurring compound that has been perfected over millions of years by the human immune system to be the “molecule of choice” to destroy pathogens. *In vitro* studies with HOCl have demonstrated broad-spectrum, anti-microbial, anti-inflammatory and anti-bacterial toxin activity. Three branded Neutrox-containing products are currently being commercialized as prescription medical devices: Avenova, NeuroPhase, and CelleRx.

***Avenova (Ophthalmology)***. Launched in the United States in 2014, Avenova (0.01% Neutrox) is a prescription product for daily eyelid and eyelash hygiene. Cleansing with Avenova removes microorganisms and debris from the skin on eyelids and lashes without burning or irritation.

A growing number of patients with blepharitis, meibomian gland dysfunction (“MGD”) and associated dry eye syndrome have found Avenova to be soothing and effective at removing microorganisms and debris, and many key opinion leaders in the field of eye care have embraced Avenova for the management of these eye conditions.

In August 2014, we launched Avenova through a dedicated direct salesforce in the United States. Our medical sales representatives are targeting both optometrists and ophthalmologists, educating them on the attributes of Avenova as an advancement in the management of blepharitis, MGD and associated dry eye. Avenova is available under a prescription from approximately 90 percent of the retail pharmacies in the United States through distribution agreements with AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation. Avenova has been added to the Vision Source Independent Optometry Network, which is the largest independent optometry network in the country, representing 2,800 independent optometrist offices. Avenova is also marketed through ALLDocs Optometry Group, also known as The Association of LensCrafters Leaseholding Doctors and the second largest independent optometry group in the U.S. Avenova is also available for purchase by physicians on the ShoutMD® Store, a commercial website through an agreement with ALPHAEON Corporation.

Avenova is well suited for daily use by the approximately 30 million Americans who suffer from chronic eye conditions like blepharitis, MGD and associated dry eye syndrome. Avenova is also finding use as a pre-surgical treatment for Lasik and cataracts, for retinal injections and in managing and reducing contact lens intolerance. We estimate the U.S. market for Avenova at approximately 41 million patients and we believe that no other commercial products offer the unique advantages of Avenova with pure hypochlorous acid.

We have an agreement to market Avenova through Pioneer, for distribution throughout Southeast Asia and mainland China. We also have distribution agreements with (1) Sarmedic Ltd. in Israel and (2) Ophthalmic Instrument Company in New Zealand. We are currently in the process of seeking additional partners to distribute Avenova outside of the U.S.





**NeutroPhase (Wound Care).** Since its U.S. launch in 2013, NeutroPhase has made a significant impact in wound care. Consisting of 0.03% Neutrox, NeutroPhase may be 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 a high mortality and amputation rate (30% and 70%, respectively), even with aggressive debridement and antibiotic treatment. In vitro studies have shown that NeutroPhase both kills the microorganisms implicated in NF, and neutralizes the toxins secreted by the microorganisms. Success using NeutroPhase as an irrigation solution has established it as an effective part of the adjunct treatment for this deadly disease.

We believe that NeutroPhase is 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 March 2015, NeutroPhase was named the official wound cleanser by the National Necrotizing Fasciitis Foundation. In the U.S. and internationally, NeutroPhase is distributed through commercial partners. In Southeast Asia and mainland China, Pioneer distributes NeutroPhase and in the U.S., NeutroPhase is distributed through our partner, Principle Business Enterprise (“PBE”). We also have international distribution agreements for NeutroPhase with (i) Biopharm for MENA region (Middle East North Africa), (ii) Alpha Pharma LLC for Ukraine; and (iii) Shin-Poong Pharma for South Korea. We are in the process of securing other partnerships for distribution of NeutroPhase around the world.

**CelleRx (Dermatology).** Created for cosmetic procedures, CelleRx™ (0.015% Neutrox) is a gentle cleansing solution, which 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, less erythema, and less exudates compared to saline. CelleRx is a non-alcohol formulation that doesn’t dry or stain the skin, and most importantly, may reduce the patient’s down-time post procedure. Pioneer distributes CelleRx in Southeast Asia and mainland China and we are currently looking for partners to commercialize CelleRx in the U.S. and around the world.

#### ***Aganocide Compounds Still in the Development Stage***

Our first-in-class Aganocide compounds, led by auriclosene (NVC-422), are patented, synthetic molecules with a broad spectrum of activity against bacteria, viruses and fungi. In 2013, the World Health Organization (WHO) approved *auriclosene* as the new generic nomenclature for NVC-422, one of our Aganocide compounds. We have explored the use of our auriclosene in the indications of urology, dermatology, and ophthalmology.

In November 2015, we announced completion of a Phase 2b clinical trial to evaluate auriclosene to reduce UCBE in patients with long-term indwelling urinary catheters. We expect to announce results of the Phase 2b trial in early December 2015.

*Newly Developed Intelli-Case with Hydrogen Peroxide Solutions*

In April 2015, we received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market our newly developed product, intelli-case, with hydrogen peroxide for the eye care market.

Following the launch of Avenova, intelli-Case with hydrogen peroxide solutions is the second in a series of new products that we are developing in the eye care market. Hydrogen peroxide is an industry standard for disinfecting contact lenses, but can irritate the eye or fail to kill bacteria if not used correctly. intelli-Case is an innovative and easy-to-use device for the millions of Americans who wear contact lenses and want to use an effective disinfection system. The intelli-Case monitors the neutralization of hydrogen peroxide during the disinfection cycle with microprocessor electronics embedded in the cap of what otherwise looks like a standard peroxide lens case. The high-tech cap has three LED lights labeled UNSAFE, BUSY and READY. Lenses are placed into the case with hydrogen peroxide solution. The green light (READY) blinks when lenses are safe to insert into the eyes and continues to blink green until contact lenses are removed from the case.

The intelli-Case can be co-packaged with a hydrogen peroxide disinfection and cleaning solution and we are actively seeking a partnership with a hydrogen peroxide manufacturer. We believe that replacing the standard case that is typically boxed with hydrogen peroxide solutions with intelli-Case would make a differentiated product attractive to both eye care professionals and contact lens users.

We plan to test market intelli-Case together with hydrogen peroxide solution in a consumer-package product called NovaClear in select cities in California in late 2015 or early 2016. We are currently considering partners to commercialize intelli-Case on worldwide.

### **Recent Events**

In January 2015, we exhibited Avenova at Arab Health 2015. Held January 26-29, 2015, at the Dubai International Convention & Exhibition Centre in the United Arab Emirates, now in its 40th year, Arab Health 2015 is the largest healthcare conference in the world.

In January 2015, we signed a nationwide distribution agreement with Cardinal Health, which delivers prescription drugs and many other products to retail pharmacies, hospitals, mail-order facilities, physician offices, surgery centers and other facilities across the U.S. Under the agreement, Cardinal Health will carry and distribute our Avenova product.

In January 2015, we entered into a new agreement with Sarmedic Ltd to market Avenova in Israel.

In January 2015, we expanded our direct salesforce for Avenova from 15 medical representatives to 35 medical representatives. In February 2015, we deployed 35 dedicated medical representatives in major markets across the U.S.

In March 2015, we announced an exclusive distribution agreement with Alpha Pharma LLC to market NeutroPhase in the Ukraine.

In March 2015, we entered into a securities purchase agreement for the sale of our common stock and warrants in a private placement for net proceeds of approximately \$4.5 million.

In April 2015, we announced the appointment of Mark M. Sieczkarek as Chairman of the Board and LI Xinzhou (Paul Li) as a Director, effective April 10, 2015. NovaBay founder Dr. Ron Najafi remains on the Board and continues to serve as NovaBay's President and Chief Executive Officer. Mr. Sieczkarek has served as a director of NovaBay since January 2014.

In April 2015, we signed a U.S. distribution agreement for Avenova with AmerisourceBergen, one of the largest global pharmaceutical sourcing and distribution services companies.

In April 2015, we received 510(k) clearance from the U.S. Food and Drug Administration to market our newly developed product- intelli-Case with hydrogen peroxide solutions, for the eye care market.

In May 2015, we entered into a securities purchase agreement for the sale of \$6,863,000 of our common stock and warrants to purchase common stock in a private placement.

In September 2015, we entered into an exclusive distribution agreement with Ophthalmic Instrument Company to market Avenova™ in New Zealand.

In September 2015, we announced an agreement to market Avenova™ through ALLDocs Optometry Group, making Avenova™ available to this group's optometrists. ALLDocs is also known as The Association of LensCrafters Leaseholding Doctors and is the second largest independent optometry group in the U.S.

In September 2015, we formed a partnership with ALPHAEON Corporation, a social commerce company, to make Avenova™ available for purchase by physician members through the ShoutMD® Store website.

### **Critical Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim reporting. 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 included in the financial statements 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,

the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements (unaudited), included in Part I, Item 1 of this report, and are also described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014. We have not materially changed these policies from those reported in our Annual Report on Form 10-K for the year ended December 31, 2014.

## **Recent Accounting Pronouncements**

There have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended September 30, 2015, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2014, that are of significance or potential significance to the Company.

## **Results of Operations**

### *Comparison of the Three and Nine Months Ended September 30, 2015 and 2014*

#### *Revenue*

Total revenue was \$1.2 million for the three months ended September 30, 2015, compared to \$152 thousand for the three months ended September 30, 2014. Total revenue was \$2.7 million for the nine months ended September 30, 2015, compared to \$563 thousand for the three months ended September 30, 2014. The increases were related to sales of our Avenova product, for which we started commercialization in August 2014, partially offset by a decrease in collaboration revenue.

In November 2014, we signed a nationwide distribution agreement for Avenova™ with McKesson Corporation ("McKesson"). The agreement is part of our 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, we signed a nationwide distribution agreement with Cardinal Health, which delivers prescription drugs and many other products to retail pharmacies, hospitals, mail-order facilities, physician offices, surgery centers and other facilities across the U.S. Under the agreement, Cardinal Health will carry and distribute our Avenova™ product.

In April 2015, we signed a U.S. distribution agreement for Avenova™ with AmerisourceBergen, one of the largest global pharmaceutical sourcing and distribution services companies.

*Research and Development*

Total research and development expenses decreased by 17% to \$1.9 million for the three months ended September 30, 2015, from \$2.3 million for the three months ended September 30, 2014. Total research and development expenses decreased by 32% to \$4.8 million for the nine months ended September 30, 2015, from \$7.1 million for the nine months ended September 30, 2014. These decreases relate to the decrease in clinical activities as we completed our BAYnovation trial for viral conjunctivitis and our BACTOvation trial for bacterial conjunctivitis in 2014.

*Sales, General and Administrative*

Sales, general and administrative expenses increased by 132% to \$4.4 million for the three months ended September 30, 2015, from \$1.9 million for the three months ended September 30, 2014. Sales, general and administrative expenses increased by 128% to \$12.1 million for the nine months ended September 30, 2015, from \$5.3 million for the nine months ended September 30, 2014. The increases were due to increases in sales representative headcount and sales and marketing activities for the launch of Avenova™, which we started in August 2014.

We expect to incur increasing sales, general and administrative expenses throughout 2015 and in subsequent years as we support our launch of our Neutrox family of products.

*Non-Cash Gain (Loss) on Changes in Fair Value of Warrants*

The non-cash gain (loss) on changes in fair value of warrants relates to the fair value adjustment to the warrants issued with our July 2011 registered direct offering of common stock and warrants. This balance will fluctuate with the price of our stock.

*Other Income (Expense), Net*

Other income (expense), net changes were primarily attributable to the gains and losses on sales of our investments and losses on disposal of property.

We expect that other income (expense), net will fluctuate based on our cash balances and the fluctuation in the returns on our investments.

**Liquidity and Capital Resources**

As of September 30, 2015, our cash and cash equivalents were \$3.4 million, compared to \$5.4 million at December 31, 2014. Since December 31, 2014, we have raised net proceeds of \$1.1 million related to sales of our stock through our ATM Agreement set up in 2013. Since December 31, 2014, we closed two financings in which we raised a total of \$11.6 million, or approximately \$10.9 million in net cash proceeds.

Although the Company recently raised capital, our cash and cash equivalents are not sufficient to fund our planned operations through. To achieve this, the Company will continue with its historical financing strategy to raise this additional capital in order to fund its operations and meet its ongoing obligations with the goal of being cash flow positive by December 2016. There is no assurance that the Company will be able to raise capital or if it is able to raise capital, that it will be on favorable terms. The Company has incorporated additional risks related to its capital and liquidity in Item 1A of Part II of this Quarterly Report which should be read with this disclosure. Also, our capital requirements going forward will depend on numerous factors including:

- net income generated from sales of our Neutrox Family products;
- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of clinical trials;
- the time, cost and outcome involved in seeking regulatory approvals;
- our ability to establish and maintain strategic collaborations or partnerships for clinical trials, manufacturing and marketing of our product candidates; and
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop.

Until we can generate sufficient product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. 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. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations for some of our technologies or product candidates that we would otherwise seek to develop on our own. Such collaborations may not be on favorable terms or they may require us to relinquish rights to our technologies or product candidates.

### ***Cash Used in Operating Activities***

For the nine months ended September 30, 2015, cash used in operating activities was \$14.1 million compared to \$10.9 million for the nine months ended September 30, 2014. The increase in 2015 of cash used in operating activities was due to spending on sales and marketing activities for the launch of Avenova, and inventory to support our growth, partially offset by a decrease in spending on clinical trials completed in 2014.

### ***Cash Provided By (used in) Investing Activities***

For the nine months ended September 30, 2015, cash used in investing activities of \$9,000 was attributed to proceeds received on disposal of equipment, net of cash spent on purchases of property and equipment.

### ***Cash Provided by Financing Activities***

Net cash provided by financing activities of \$ 12.0 million for the nine months ended September 30, 2015, was primarily attributable to the sale of common stock and warrants in our financings completed in May 2015 and March 2015 and the sale of our common stock under the ATM Agreement.

Net cash provided by financing activities of \$7.0 million for the nine months ended September 30, 2014, was primarily attributable to the sale of common stock and warrants in our March 2014 financing and the sale of our common stock under the ATM Agreement.

## **Our Business Strategy- Focus on Ophthalmology Market**

Following a comprehensive review of our assets, competitive positions, and markets and market dynamics at the end of 2014, we determined that focusing on eye care, our largest business segment, affords us the best opportunity for near-term revenue growth and, ultimately, profitability and positive operating cash flow. We will continue to support the distribution agreements in place for our other products and in international markets, and are committed to monetizing other assets. We have significantly reduced expenses for the support of programs outside of eye care, with the exception of those programs that are funded through collaborations or partnerships.

We have three business priorities:

**Revenue Growth in Eye Care** – In January 2015, we increased our direct salesforce for the promotion of Avenova daily-use prescription eye care product to 35 medical representatives, most of whom have more than 10 years of experience promoting ophthalmic products. By February, all 35 medical sales representatives were deployed in major U.S. markets. To further bolster our presence in the market and capitalize on our market acceptance, we plan to expand the salesforce of medical representatives.

**Product Line Expansion in Eye Care** – We continue to develop innovative products for the eye care market and plan to add new products currently in development in the next 12 to 18 months. In April 2015, we received 510(k) clearance from the U.S. Food and Drug Administration to market our newly developed product for the eye care market- intelli-Case. Following the launch of Avenova, intelli-Case is the second in a series of new products that we are developing in the eye care market.

**Partnerships to Monetize Other Assets** – We remain committed to the partnerships we currently have; (i) in wound care with Pioneer in mainland China and SE Asia, PBE in the U.S., Korea's Shin-Poong Pharma, the Middle East's Biopharm Group and Alpha Pharma LLC in the Ukraine to market NeutroPhase; (ii) in animal care with Virbac; and (iii) in dermatology with Galderma. Sarmedic Ltd has exclusive distribution rights for Avenova in Israel. China's Pioneer Pharma and its subsidiaries have distribution rights for Avenova and NeutroPhase in China, Hong Kong, Macau and Taiwan, Singapore, Malaysia, Indonesia, Myanmar, Philippines, Thailand, Vietnam, Brunei, Cambodia and Laos.

We intend to seek additional sources of revenue and reduce expenses by licensing or selling select assets in urology, dermatology, wound care, and cosmetic surgery/aesthetic dermatology.

***Revenue Growth in Eye Care***

The eye care market that we currently address through our direct salesforce is large. An estimated 30 million Americans suffer from eyelid conditions such as blepharitis, meibomian gland dysfunction (MGD) and associated dry eye syndrome. We estimate that the annual market for these conditions collectively represents an estimated \$500 million in the U.S. alone. In January 2015, we rebranded what was previously known as i-Lid Cleanser to Avenova, in order to more clearly differentiate this prescription product from over-the-counter (OTC) detergent-based lid wipes. Our prescription-only Avenova offers advantages as part of the regimen for managing these eyelid conditions compared with alternative regimens, such as antibiotics, steroids and detergent-based OTC cleansers.

In August 2014, we started commercialization of Avenova with a salesforce of 10 dedicated medical sales representatives led by Glenn Moro, our Vice President, Sales and Marketing Avenova. Mr. Moro is a proven marketing leader in the eye care industry, who served for 27 years in various leadership, marketing and sales roles at Alcon Laboratories, Inc., culminating in the position of Global Director of Marketing for the Contact Lens Care products. We expanded our direct salesforce to 35 medical representatives in January 2015 focusing promotion of Avenova to ophthalmologists and optometrists. Based on extensive market research, we have assigned our sales representatives to the markets across the U.S. representing the highest sale potential for Avenova. Through our distribution agreements with AmerisourceBergen Corporation, Cardinal Health, and McKesson Corporation, Avenova is available with a prescription through approximately 90 percent of the 67,000 retail pharmacies across the U.S. Avenova also has been added to the Vision Source Independent Optometry Network, which is the largest independent optometry network in the country, representing 2,800 independent optometrist offices.

With the active support of key opinion leaders in the field of eye care, some of whom have joined our Ophthalmic and Optometry Advisory Boards, we expect to continue our active educational and marketing programs for Avenova throughout 2015. We plan to have an active presence at major eye care conferences in the coming months. Industry conferences we have attended or are targeting in 2015 include the American Academy of Ophthalmology, the American Optometric Association, the American Society of Cataract and Refractive Surgery Conferences and the South Eastern Congress of Optometry, as well as numerous Vision Expo meetings held around the U.S.

At eye care industry conferences and meetings, and in professional publications and surveys, nationally prominent ophthalmologists and optometrists are reporting improvements in the management of eyelid conditions for patients using Avenova. We also have heard from patients that Avenova has brought long-sought relief after years of suffering from blepharitis, MGD and associated dry eye.

#### ***Product Line Expansion in Eye Care***

We plan to expand our product offering in eye care by developing or acquiring new products to be promoted by our direct salesforce of medical representatives.

We are developing new formulations in our Neutrox and Aganocide product categories that we believe will strengthen our position as an eye-care innovator. We intend to create proprietary products with novel formulations of Neutrox for the management of blepharitis, MGD and associated dry eye syndrome. We are currently developing an Aganocide-based topical product that may complement the action of Neutrox-based solutions.

We are actively evaluating a number of existing products to be synergistic with and complementary to Avenova. All products under consideration are intended to leverage our direct salesforce of medical representatives and bolster its productivity. Intelli-Case with hydrogen peroxide solutions is the second in a series of new products that we are developing in the eye care market. In April 2015, we received 510(k) clearance from the U.S. Food and Drug Administration to market Intelli-Case. The Intelli-Case can be co-packaged with a hydrogen peroxide disinfection and cleaning solution and we are actively seeking a partnership with a hydrogen peroxide solution manufacturer. We believe that replacing the standard case that is typically boxed with hydrogen peroxide solutions with the Intelli-Case would make a differentiated product attractive to both eye care professionals and contact lens users.

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

We intend to consider strategic alternatives for our assets and technology for programs not related to eye care. We plan to retain and support our partnerships to market NeutroPhase with PBE, Pioneer, Shin-Poong Pharma, the Biopharm Group and Alpha Pharma LLC, among others. The potential markets are significant, with an estimated 24 million people suffering from diabetic ulcers and other chronic wounds in China alone, and millions more in Middle Eastern countries.

We also see a value in the proven ability of our Auriclosene product to reduce the encrustation and blockage of in-dwelling urinary catheters. We are working with investment bankers to monetize that value by identifying a suitable partner.

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

As of December 31, 2014, we had net operating loss carryforwards for federal and state income tax purposes of \$61.9 million and \$61.8 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2015 and 2034. As of December 31, 2014, we also had tax credit carryforwards for federal income tax purposes of \$387,000.

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, though 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 September 30, 2015.

## **Contractual Obligations**

Our commitments at September 30, 2015, consist of an operating lease. The operating lease consists of payments relating to the lease for laboratory and office space in one office building in Emeryville, California. This lease expires on October 31, 2020, and the total commitment as of September 30, 2015 is \$3.3 million due over the lease term, compared to \$3.9 million as of December 31, 2014.

## **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 September 30, 2015, and December 31, 2014, 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.

To date, we have operated exclusively in the United States and have not had 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 September 30, 2015, 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. These risks have not changed materially from the risks described under Part I, Item 1A “Risk Factors” included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2015, except for those risk factors marked with an asterisk (\*).*

#### **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 any substantial revenue. As a result, we have incurred since our inception, and expect to continue to incur in the foreseeable future, 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 has included 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 have incurred net losses each year since our inception through September 30, 2015, with the exception of 2009 due to a milestone payment under our agreement with Galderma. 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. Launching a new 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 planned our 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
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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, which resulted in net proceeds to us of \$2.1 million, we utilized substantially all of our remaining shares on Form S-3 at the time. 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.

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. 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 or share price 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 is 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 November 28, 2016. 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.

In addition, pursuant to Section 1003(f)(v) of the NYSE MKT Company Guide, the NYSE MKT will consider delisting securities selling at a "low price per share" if the issuer fails to effect a reverse stock split. The current NYSE MKT internal precedent threshold of what it considers to be a "low price per share" is an average minimum closing stock price of under \$0.20 over any 30-day consecutive trading period. As of November 3, 2015, our 30-day average closing stock price was \$0.28 per share, which is above the \$0.20 "low price per share" minimum threshold. However, the Company's closing stock price has dipped below \$0.20 per share on several trading days, dipping to a \$0.16 per share closing price on October 23, 2015.

We are pursuing options to address the stockholders' equity deficiency as indicated in our plan submitted to the NYSE MKT. We are also seeking to effect a reverse stock split, although we have not been asked by the NYSE MKT to do so. 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.

***We are seeking shareholder approval of a charter amendment that would authorize the Board to effect a reverse stock split, which could lead to a decrease in our overall market capitalization.\****

Our Board has unanimously approved a proposal to effect a reverse split of all of our outstanding shares of common stock by a ratio in the range of 1-for-15 to 1-for-25. Such proposal is being placed before our stockholders for approval at a special meeting to be held on December 11, 2015. If this proposal is approved by our stockholders, our Board shall have sole discretion pursuant to Section 242(c) of the Delaware General Corporation Law to elect, as it determines to be in the Company's best interests and without further action by our stockholders, whether or not to effect the reverse stock split before January 31, 2016, or to abandon it. A reverse stock split may be viewed negatively by the market and, consequently, could lead to a decrease in our overall market capitalization. If the per share market price of our common stock does not increase in proportion to the reverse stock split ratio, then the value of our Company, as measured by our market capitalization, will be reduced. Additionally, any reduction in our market capitalization may be magnified as a result of the smaller number of total shares of common stock outstanding following the reverse stock split.

***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 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, which in the aggregate affect warrants exercisable for 30,786,338 shares of our common stock, 19,716,338 shares which must be issued, if at all, by March 6, 2020, and 11,070,000 shares which 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 \$0.20 per share; or (2) convertible securities with an exercise price of less than \$0.20 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 \$0.20 per share (as adjusted for any reverse stock split or similar transaction) these price protections will be triggered. The 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. 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.

### **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 and certain resources to advance NeuroPhase, and Intelli-Case as aggressively as possible over the next six months. 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 and NeuroPhase. If this occurs, it will have an adverse impact on operations and ability to fund any future development or ongoing clinical trials.

***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 would likely 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 may acquire other businesses or form joint ventures or in-license compounds that could disrupt our business, harm our operating results, dilute your ownership interest in us, or cause us to incur debt or significant expense.***

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, and enter into technology or pharmaceutical compound licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to enhance our ability to commercialize our product candidates and expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of commercial partnering agreements, strategic alliances, joint ventures or in-licensing of compounds. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we in-license any



additional compounds, we may fail to develop the product candidates, and spend significant resources before determining whether a compound we have in-licensed will produce revenues. Any future acquisitions or in-licensing by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture. To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions by incurring indebtedness. Additional funds may not be available on terms that are favorable to us, or at all.

***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. Creating a reliable revenue stream depends on our ability to manage an effective staff.\****

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. The loss of any of our senior management team members could disrupt our business and affect key partnerships.

***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 device 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 Phase IV post-approval studies, for which we would have to expend additional resources, which 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.

***Conducting clinical trials of our product candidates may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.***

The risk of clinical trial liability is inherent in the testing of pharmaceutical and medical device products. If we cannot successfully defend ourselves against any clinical trial claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our product candidates. 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.

***If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages. Compliance with environmental regulations can be expensive, and noncompliance with these regulations may result in adverse publicity and potentially significant monetary damages and fines.***

Our activities currently require the controlled use of potentially harmful biological materials and other hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability

could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject, on an ongoing basis, to U.S. federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In addition, if more stringent laws and regulations are adopted in the future, our costs to comply could be substantial, and we could be required to make significant changes to our testing and production process.

***The pharmaceutical and biopharmaceutical industries are characterized by patent litigation and any litigation or claim against us may cause us to incur substantial costs, and could 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 issue 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, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorney's fees if we were to be 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.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Some of our employees may have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could severely harm our business.

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

The product candidates we are developing or attempting to develop will, in most cases, undergo extensive clinical testing and will require approval from the applicable regulatory authorities prior to sale. However, despite all reasonable efforts to ensure safety, it is possible that we or our collaborators will sell products, including Avenova, NeuroPhase, 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.

***Failure to obtain sufficient quantities of products and substances necessary for research and development, pre-clinical studies, human clinical trials and product commercialization that are of acceptable quality at reasonable prices or at all could constrain our product development and have a material adverse effect on our business.***

We have relied and will continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization. It will be important to us that such products and substances can be manufactured at a cost and in quantities necessary to make them commercially viable. We have not attempted to identify, and do not know whether there will be, any third party manufacturers which will be able to meet our needs with respect to timing, quantity and quality for commercial production. In addition, if we are unable to contract for a sufficient supply or required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our research and development, pre-clinical and clinical testing would be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of products. Any such delay may have a material adverse effect on our business, financial condition and results of operations.

***Because our clinical development activities rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.***

As a result of our clinical development, we will have access to very sensitive data regarding the patients enrolled in our clinical trials. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, create national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies like NovaBay. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to reach or maintain profitably in the future.

***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.

***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 market place 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 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: November 16, 2015 NOVABAY PHARMACEUTICALS, INC.

/s/ Ramin Najafi  
Ramin (“Ron”) Najafi  
President and Chief Executive Officer

*(duly authorized officer)*

Date: November 16, 2015 /s/ Thomas J. Paulson  
Thomas J. Paulson  
Chief Financial Officer

*(principal financial officer)*

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference			Filing Date	Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference		
3.1	Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-33678	3.1	6/29/2010	
3.2	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-33678	3.1	6/04/2014	
3.3	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-33678	3.1	10/02/2015	
3.4	Bylaws of NovaBay Pharmaceuticals, Inc.	8-K	001-33678	3.2	6/29/2010	
4.1	Form of Warrant issued in August 2009 offering	8-K	001-33678	4.3	8/21/2009	
4.2	Form of Warrant issued in July 2011 offering (as amended).	8-K	001-33678	4.4	10/27/2015	
4.3	Form of Warrant issued in December 2012 offering	8-K	001-33678	4.1	12/6/2012	
4.4	Form of Warrant issued in March 2015 offering (issued with 15-month term, as amended).	8-K	001-33678	4.2	10/27/2015	
4.5	Form of Warrant issued in March 2015 offering (issued with 5-year term, as amended).	8-K	001-33678	4.3	10/27/2015	
4.6	Form of Warrant issued in May 2015 offering	10-Q	001-33678	4.7	8/13/2015	
4.7	Form of Warrant issued in October 2015 offering.	8-K	001-33678	4.1	10/27/2015	
10.1	Underwriting Agreement, dated October 23, 2015, between NovaBay Pharmaceuticals, Inc. and Roth Capital Partners, LLC.	8-K	001-33678	1.1	10/27/2015	
31.1	Certification of the Principal Executive Officer of					X

31.2	NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a). 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

Exhibit Description	Exhibit Description	Incorporation by Reference			Filing Date	Filed Herewith
		Form	File Number	Exhibit/ Form 8-K Item Reference		
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.