

NovaBay Pharmaceuticals, Inc.  
Form 10-Q  
May 14, 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 March 31, 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**  
**(State or other jurisdiction of incorporation or**  
**organization)**

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

**5980 Horton Street, Suite 550, Emeryville CA 94608**

**(Address of principal executive offices) (Zip Code)**

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

As of May 4, 2015, there were 61,198,437 shares of the registrant's common stock outstanding.



**NOVABAY PHARMACEUTICALS, INC.**

**TABLE OF CONTENTS**

**PART I  
FINANCIAL INFORMATION**

Item 1.	Financial Statements	
	1. Consolidated Balance Sheets: March 31, 2015 and December 31, 2014	3
	2. Consolidated Statements of Operations and Comprehensive Loss: Three months ended March 31, 2015 and 2014	4
	3. Consolidated Statements of Cash Flows: Three months ended March 31, 2015 and 2014	5
	4. Notes to Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	26
Item 4.	Controls and Procedures	27

**PART II  
OTHER INFORMATION**

Item 1A.	Risk Factors	28
Item 6.	Exhibits	47

<b>SIGNATURES</b>	48
<b>EXHIBIT INDEX</b>	49

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

NovaBay<sup>®</sup>, NovaBay Pharma<sup>®</sup>, Avenova<sup>™</sup>, NeutroPhase<sup>®</sup>, CellerRx<sup>®</sup>, AgaNase<sup>®</sup>, Aganocide<sup>®</sup>, AgaDerm<sup>®</sup>, Neutrox<sup>™</sup> and Going Beyond Antibiotics<sup>™</sup> are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

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

<u>(in thousands, except par value)</u>	<b>March 31, 2015</b> (unaudited)	<b>December 31, 2014</b> (Note 2)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,598	\$ 5,429
Accounts receivable	283	273
Inventory	492	521
Prepaid expenses and other current assets	1,223	729
Total current assets	7,596	6,952
Property and equipment, net	408	436
Other assets	151	149
<b>TOTAL ASSETS</b>	<b>\$ 8,155</b>	<b>\$ 7,537</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Current liabilities:		
Accounts payable	\$ 2,178	\$ 1,865
Accrued liabilities	1,095	1,055
Deferred revenue	425	425
Total current liabilities	3,698	3,345
Deferred revenues - non-current	1,993	2,000
Deferred rent	176	171
Warrant liability	139	173
Total liabilities	6,006	5,689
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000 shares authorized; none outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, \$0.01 par value; 120,000 shares authorized at March 31, 2015 and December 31, 2014; 61,113 and 51,650 issued and outstanding at March 31, 2015 and December 31, 2014, respectively	611	516
Additional paid-in capital	77,725	72,879

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

Accumulated deficit during development stage	(76,187 )	(71,547 )
Total stockholders' equity	2,149	1,848
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 8,155</b>	<b>\$ 7,537</b>

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

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

<u>(in thousands, except per share data)</u>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Sales:		
Product revenue	\$492	\$188
Cost of goods sold	148	130
Gross profit	344	58
Other revenue:		
License, collaboration and distribution revenue	6	38
Other revenues	40	62
Total other revenue	46	100
Operating expenses:		
Research and development	1,641	2,548
Sales, general and administrative	3,410	1,708
Total operating expenses	5,051	4,236
Operating loss	(4,661 )	(4,078 )
Non-cash gain on changes in fair value of warrants	34	520
Other income (expense), net	(11 )	(7 )
Loss before provision for income taxes	(4,638 )	(3,565 )
Provision for income taxes	(2 )	—
Net loss	(4,640 )	(3,565 )
Change in unrealized gains on available-for-sale securities	—	2
Comprehensive loss	\$(4,640 )	\$(3,563 )
Net loss per share:		
Basic and diluted	\$(0.09 )	\$(0.08 )
Shares used in per share calculations:		
Basic and diluted	54,371	45,338

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





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

	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>2014</b>
<u>(in thousands)</u>		
<b>Cash flows from operating activities:</b>		
Net loss	\$(4,640)	\$(3,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	41	70
Net realized loss on sales of short-term investments	—	9
Loss (gain) on disposal of property and equipment	(1 )	2
Stock-based compensation expense for options and stock issued	265	245
to employees and directors		
Stock-based compensation expense for options, warrants and stock issued to non-employees	20	32
Non-cash gain on changes in fair value of warrants	(34 )	(520 )
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(47 )	524
(Increase) decrease in inventory	29	76
(Increase) decrease in prepaid expenses and other assets	(491 )	(71 )
Increase (decrease) in accounts payable and accrued liabilities	357	(1,152)
Increase (decrease) in deferred revenue	(6 )	(66 )
Net cash used in operating activities	(4,507)	(4,416)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(14 )	(12 )
Proceeds from disposal of property and equipment	37	—
Purchases of short-term investments	—	(3,512)
Proceeds from maturities and sales of short-term investments	—	1,200
Net cash provided by (used in) investing activities	23	(2,324)
<b>Cash flows from financing activities:</b>		
Proceeds from common stock issuances	—	40
Proceeds from exercise of options and warrants	—	5
Proceeds from financing, net of costs	4,653	6,511
Net cash provided by financing activities	4,653	6,556
Change in cash and cash equivalents	169	(184 )

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

Cash and cash equivalents, beginning of period	5,429	10,500
Cash and cash equivalents, end of period	\$5,598	\$10,316

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

## **NOTE 1. ORGANIZATION**

NovaBay Pharmaceuticals, Inc. (“we,” “NovaBay” or the “Company”) is a biopharmaceutical company focused on the development and commercialization of its non-antibiotic anti-infective products.

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, we changed our name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, we formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which was formed to conduct research and development in Canada which was dissolved in July 2012, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. In June 2010, we changed the state in which we are incorporated (the Reincorporation), and are now incorporated under the laws of the State of Delaware. All references to “we,” “us,” “our,” or “the Company” herein refer to the California corporation prior to the date of the Reincorporation, and to the Delaware corporation on and after the date of the Reincorporation. We currently operate 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 financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization period for payments received from product development and license agreements as they relate to revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ from those estimates.

### ***Cash, Cash Equivalents and Short-Term Investments***

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of March 31, 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.

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

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

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

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, the Company has established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

During the three months ended March 31, 2015, revenues were derived from one collaboration partner, service revenues and sales of NeutroPhase. During the three months ended March 31, 2014, revenues were derived from one collaboration partner, two distribution partners, service revenues and sales of NeutroPhase.

As of March 31, 2015, 46% and 13% of accounts receivable were derived from two distribution partners. As of December 31, 2014, 41% and 18% of accounts receivable were derived from two distribution partners.

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

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

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

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

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

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

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

### ***Inventory***

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes, pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods.

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

### ***Property and Equipment***

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

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

### ***Impairment of Long-Lived Assets***

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets 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.

### ***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***

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

Assuming the elements meet the revenue recognition guidelines the revenue recognition methodology prescribed for each unit of accounting is summarized below:

*Upfront Fees*—The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology licensed has no utility to the licensee. If the Company has performance obligations through research and development services that are required because its know-how and expertise related to the technology is proprietary, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of the performance obligations. The Company bases the estimate of the period of performance on factors in the contract. Actual time frames could vary and could result in material changes to their results of operations.

*Funded Research and Development*— Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. This revenue approximates the cost incurred. Reimbursements from collaborative partners for agreed-upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

*Milestones*—Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; the amount of the milestone is

reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

*Royalties*—The Company recognizes royalty revenues from licensed products upon the sale of the related products.

*Product Sales*—The Company sells NeutroPhase, CelleRx and Avenova through a limited number of distributors. The Company generally records product sales upon shipment to distributors if title and risk of loss pass to the distributors at the time of shipment. Otherwise, the Company records product sales upon shipment to final customers.

### ***Cost of Goods Sold***

Cost of goods sold includes third party manufacturing costs, shipping costs, cost of samples 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 March 31, 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 March 31, 2015 and March 31, 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 March 31,	
	2015	2014
Net loss	\$(4,640 )	\$(3,565 )
Basic shares	54,371	45,338
Add: shares issued upon assumed exercise of stock options and warrants	—	—
Diluted shares	54,371	45,338
Basic and diluted net loss per share	\$(0.09 )	\$(0.08 )

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>Three Months Ended March 31,</b>	
<b>(In thousands)</b>	<b>2015</b>	<b>2014</b>
Stock options	8,429	7,547
Stock warrants	21,339	6,165
	29,768	13,712

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

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 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 deposits 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 March 31, 2015:

#### Fair Value Measurements Using

(in thousands)	Balance at March 31, 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	\$5,598	\$ 5,598	\$ —	\$ —
Total assets	\$5,598	\$ 5,598	\$ —	\$ —
<b>Liabilities</b>				
Warrant liability	\$ 139	\$ —	\$ —	\$ 139
Total liabilities	\$ 139	\$ —	\$ —	\$ 139

For the three month period ended March 31, 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 \$34,000, in its consolidated statement of operations and comprehensive loss. See Note 6 for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	Warrant liability
Fair value of warrants at December 31, 2014	\$ 173
Adjustment to fair value at March	(34 )

31, 2015

Total warrant

liability at March

\$ 139

31, 2015

10

---



**NOTE 4. INVENTORY**

Inventory consisted of the following:

<b>(in thousands)</b>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Raw materials and supplies	\$ 260	\$ 260
Goods in process	184	184
Finished goods	48	77
Total inventory	\$ 492	\$ 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 \$256,000 and \$255,000 for the three months ended March 31, 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 or officer insurance policy that limits its exposure and may enable them to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liability has been recorded for these agreements as of March 31, 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 March 31, 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 March 31, 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. The warrants contain a provision where the warrant holder would have the option to receive cash, equal to the Black-Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, after January 5, 2012, and if the closing bid price per share of the common stock 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:

<u>Assumption</u>	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Expected price volatility	60 %	70 %
Expected term (in years)	1.26	2.26
Risk-free interest rate	0.34%	0.56%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	\$0.04	\$0.38

#### **NOTE 7. STOCKHOLDERS' EQUITY**

On July 5, 2011, the Company closed a registered direct offering for the sale of 4,650,675 units (The "July 2011 Registered Direct Financing"), each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.75 of a share of common stock (or a total of 3,488,005 shares), at a purchase price of \$1.11 per unit. The warrants will be exercisable 180 days after issuance for \$1.33 per share and will expire five years from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together in the July 2011 Registered Direct Offering. The Company raised a total of \$5.2 million from the July 2011 Registered Direct Financing, or approximately \$4.6 million in net proceeds after deducting underwriting commissions of \$288,000 and other offering costs of \$244,000.

On December 6, 2012, the Company closed a public offering for the sale of 5,900,000 shares of common stock and 5,900,000 warrants to purchase 0.75 of a share of common stock (or a total of 4,425,000 shares), at a purchase price of \$1.25 per share with associated warrant. The warrants were immediately exercisable for \$1.50 per share and will expire one year from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together. The Company raised a total of \$7.4 million from this offering, or approximately \$6.6 million in net proceeds after deducting underwriting commissions of \$479,000 and other offering costs of \$240,000.

On November 14, 2013, the Company entered into an At-The-Market Offering Agreement ("2013 ATM Agreement"), with Ascendant Capital Markets ("Ascendant"), as its agent, and filed a prospectus supplement to its shelf registration

statement, pursuant to which the Company may offer and sell shares of our common stock having an aggregate offering price of up to \$5.0 million from time to time.

On October 16, 2014, the Company entered into an At-The-Market Offering Agreement (the “2014 ATM Agreement”, the “Agreement”) with Ascendant under which we may offer and sell our common stock having aggregate sales proceeds of up to \$10.0 million from time to time through Ascendant as our sales agent. Sales of our common stock through Ascendant are made by means of ordinary brokers’ transactions on NYSE MKT or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and Ascendant. Ascendant uses commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We pay Ascendant a commission of 3.0% of the gross sales proceeds of any common stock sold through Ascendant under the Agreement. We have also provided Ascendant with customary indemnification rights. In connection with the Agreement we terminated the At-The-Market Offering Agreement with Ascendant dated November 13, 2013.

We are not obligated to make any sales of common stock under the Agreement. The offering of shares of the Company’s common stock pursuant to the Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Agreement, or (ii) termination of the Agreement in accordance with its terms.

The common stock is being offered and sold pursuant to the Company’s effective shelf registration statement on Form S-3 and an accompanying prospectus (Registration Statement No. 333-180460) declared effective by the SEC on May 1, 2012 (the “Registration Statement”) and a prospectus supplement filed with the SEC on October 16, 2014.

For the year ended December 31, 2013, the Company sold 289,492 shares for gross proceeds of \$378,000, or approximately \$352,000 in net proceeds after deducting offering costs and commissions of \$26,000. For the year ended December 31, 2014, the Company sold 1.3 million shares for gross proceeds of \$1.2 million, or approximately \$1.1 million in net proceeds after deducting offering costs and commissions of \$81,000. For the three months ended March 31, 2015, the Company sold 189,709 shares for gross proceeds of \$118,000, or approximately \$107,000 in net proceeds after deducting offering costs and commissions of \$11,000. Under the terms of the 2014 and 2013 ATM Agreement, the Company paid to Ascendant 3% of the gross proceeds of all sales made under these agreements.

On December 2, 2013 the Company entered into a stock purchase agreement with Pioneer to purchase five million shares of NovaBay stock at \$1.14 per share, resulting in cash proceeds to NovaBay of \$5.7 million. In April 2013, the Company also sold 300,000 shares to W&M Carpenter III Trust FBO F Feichter IV for net proceeds of \$375,000.

On March 25, 2014, the Company closed a public offering for the sale of 5,600,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.25 of a share of common stock (or a total of 1,400,000 shares), at a purchase price of \$1.20 per unit. The warrants were immediately exercisable for \$1.56 per share and will expire eighteen months from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together. The Company raised a total of \$6.7 million from this offering, or approximately \$6.0 million in net proceeds after deducting underwriting commissions of \$470,000 and other offering costs of \$211,000.

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 \$4.5 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, 15 months following the date of issuance. The second warrant, totaling rights to 6,955,000 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 and one half years from closing, 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.

In April 2015, the registration statement on Form S-3 associated with the Company's March 2015 private placement has been 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.

*Stock Warrants*

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

In March 2015, 16,413,798 warrants were issued in connection with 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 15 months following the issuance. The second warrant, totaling rights to 6,955,000 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 and one half years from closing. 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.

**NOVABAY PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(unaudited)**

The details of all outstanding warrants as of March 31, 2015, are as follows:

<b>(in thousands, except per share data)</b>	<b>Warrants</b>	<b>Weighted-Average Exercise Price</b>
Outstanding at December 31, 2014	4,925	\$ 1.42
Warrants issued	16,414	\$ 0.62
Outstanding at March 31, 2015	21,339	\$ 0.81

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

Prior to our Initial Public Offering (IPO), the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the “2007 Plan”) to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. As of March 31, 2015, there were 2,162,826 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 March 31, 2015, and activity during the three-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	637	\$ 0.64		
Restricted stock units granted	89	\$ —		
Options exercised	(7 )	\$ 0.56		
Restricted stock units vested	(91 )	\$ —		
Options forfeited/cancelled	(241 )	\$ 1.65		
Outstanding at March 31, 2015	8,429	\$ 1.46	6.5	\$ 55
Vested and expected to vest at March 31, 2015	8,172	\$ 1.47	6.4	\$ 50
Vested at March 31, 2015	6,032	\$ 1.65	5.5	\$ 8
Exercisable at March 31, 2015	6,032	\$ 1.65	5.5	\$ 8

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 March 31, 2015, for options that have a quoted market price in excess of the exercise price ("in-the-money options"). The Company received no cash payments for the exercise of stock options during the three months ended March 31, 2015. The aggregate intrinsic value of stock option awards exercised was \$4,000 for the three months ended March 31, 2015, as determined at the date of option exercise. No options were exercised during three months ended March 31, 2014.



**NOVABAY PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

As of March 31, 2015, total unrecognized compensation cost related to unvested stock options was \$1.7 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 2.34 years.

*Stock Options and Awards to Employees and Directors*

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

During the three months ended March 31, 2015 and 2014 the Company granted options to purchase an aggregate of 597,000 and 435,000 shares of common stock, respectively, to employees and directors.

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

<u>Assumption</u>	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Expected price volatility	73 %	72 %
Expected term (in years)	5.11	5.28
Risk-free interest rate	1.61 %	1.70 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	\$0.39	\$0.76

*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 three months ended March 31, 2015 and 2014, the Company issued 89,000 and 48,000 shares of common stock, respectively, to employees.

For the three months ended March 31, 2015 and 2014, the Company recognized stock-based compensation expense of \$265,000 and \$245,000, respectively, for stock based awards to employees and directors.

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

During the three months ended March 31, 2015 and 2014, the Company granted options to purchase an aggregate of 40,000 and 15,000 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:



## NOVABAY PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

<u>Assumption</u>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Expected price volatility	79 %	79 %
Expected term (in years)	9.60	8.56
Risk-free interest rate	0.00%	2.59%
Dividend yield	1.91%	0.00%
Weighted-average fair value of options granted during the period	\$0.54	\$1.06

The Company did not grant any restricted stock to non-employees in the three months ended March 31, 2015. The Company granted restricted stock to non-employees totaling 8,000 shares of common stock in the three months ended March 31, 2014 in exchange for advisory and consulting services.

For the three months ended March 31, 2015 and 2014, the Company recognized stock-based compensation expense of \$20,000 and \$32,000, 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:

<b>(in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>

Research and development	\$ 130	\$ 76
General and administrative	155	201
Total stock-based compensation expense	\$ 285	\$ 277

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 amended this agreement in December 2009 and again in December 2010. Based on the Impetigo Phase 2a clinical trial results, in December 2010, Galderma S.A., exercised the option to continue with the development of impetigo and initiated a Phase 2 study. In November 2013, the Company announced that the auriclosene Phase 2b clinical study of impetigo had been completed. While the study showed that auriclosene is safe and well tolerated, it did not meet its primary clinical endpoint. Knowledge gained from two previous impetigo studies is expected to lead to both improvements in the clinical study protocol and an optimized auriclosene formulation if the program moves forward.

Galderma paid to NovaBay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. If products are commercialized under the agreement, NovaBay's royalties will escalate as sales increase. The Company received a \$1.0 million upfront technology access fee payment in the first quarter of 2009 and a \$3.25 million continuation fee and a \$500,000 fee to expand the license to include the Asia-Pacific Territory in December 2010. These fees were recorded as deferred revenues and recognized as earned on a straight-line basis over the Company's expected performance period. The initial upfront technology access fee was recognized over the initial 20 month funding term of the agreement through October 2010, and the continuation and license fees were recognized over the additional three year funding term of the agreement through November 2013.

**NOVABAY PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Revenue has been recognized under the Galderma agreement as follows:

<b>(in thousands)</b>	<b>Three Months Ended March 31, 2015</b>	<b>2014</b>
Amortization of Upfront Technology Access Fee	\$ —	\$ 1
On-going Research and Development (FTE)	—	—
Materials, Equipment, and Contract Study Costs	—	—
Total	\$ —	\$ 1

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

*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. The Company will conduct veterinary studies using NovaBay's Aganocide compounds to assess feasibility for treating several veterinary indications.



In April 2013, the option was exercised and the Company entered into a collaboration and license agreement with Virbac. Under this agreement, Virbac acquired exclusive worldwide rights to develop the Company's proprietary compound, auriclosene (NVC-422), for global veterinary markets for companion animals. The Company received an option exercise fee and may receive future development and pre-commercial milestone payments as a result of the collaboration. The Company also expects to receive royalties on the sale of any commercial products in the companion animal field. Virbac's option exercise follows its extensive testing of auriclosene for veterinary uses during the 12-month option period. The Company is recognizing the option exercise fee over its expected performance period of 10 years based on actual sales during this period.

The Company did not recognize any revenue under the Virbac agreement during three months ended March 31, 2015 and 2014, respectively.

The Company had a deferred revenue balance of \$246,000 at March 31, 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 that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of \$312,500. NovaBay also received \$312,500 in January 2013, related to the submission of the first marketing approval for the product to the CFDA (formerly the SFDA, State Food and Drug Administration), which was submitted in December 2012. The distribution agreement provides that Pioneer Pharma Co., Ltd is entitled to receive cumulative purchase discounts of up to \$500,000 upon the purchase of NeutroPhase product. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received \$625,000 upon receipt of a marketing approval of the product from the CFDA.

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

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

purchase of NeutroPhase product, payable in NovaBay unregistered restricted common stock.

**NOVABAY PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

In December 2013, the Company announced it had expanded its NeutroPhase commercial partnership agreement with Pioneer. The expanded 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 countries in Southeast Asia.

During the three months ended March 31, 2015, the Company had three other smaller agreements and continues to seek additional distribution agreements.

Revenue has been recognized under these agreements as follows:

<b>(in thousands)</b>	<b>Three Months Ended March 31, 20152014</b>	
Amortization of Upfront Technology Access Fee	\$6	\$ 15
On-going Research and Development (FTE)	—	22
Total	\$6	\$ 37

The Company had a deferred revenue balance of \$2.2 million at March 31, 2015 and December 31, 2014, respectively, related to these agreements, which consisted of the unamortized balances on the upfront technology access fee and the support for ongoing research and development.

#### *Avenova Distribution Agreements*

In November 2014, the Company signed a nationwide distribution agreement for its Avenova product with McKesson Corporation (“McKesson”). The agreement is part of the Company’s commercialization strategy. McKesson makes Avenova widely available in local pharmacies and major retail chains across the U.S., such as Wal-Mart, Costco, CVS and Target.

In November 2014, the Company entered into a new agreement with Alpha Pharma LLC to market NeutroPhase in the Ukraine.

In December 2014, the Company signed an exclusive distribution agreement for our NeutroPhase Skin and Wound Cleanser with the Biopharm Group, a leading pharmaceutical company in the Middle East, headquartered in Cairo, Egypt. Under the terms of the agreement, Biopharm will market *NeutroPhase* in Egypt, Saudi Arabia, Algeria, Sudan and Libya.

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 Avenova product.

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

During the three months ended March 31, 2015, the Company earned \$39,000 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 around the dermatology arena including the collaboration with Galderma and their impetigo clinical trial. The ophthalmology segment includes Avenova and its clinical trial on ophthalmology which it was conducting on its own. This segment also includes the i-Case product which is currently in development phases. The urology segment covers its urinary catheter encrustation and blockage (UCBE) trials. The wound care segment encompasses the business around its NeutroPhase product, which went on the market in December 2012. Its remaining activities are immaterial and are shown as an aggregate.

**NOVABAY PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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 we do 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 March 31,	
	2015	2014
Revenues:		
DermaBay (dermatology)	\$—	\$1
EyeBay (ophthalmology)	468	1
UroBay (urology)	—	—
MediBay (wound care)	30	224
Other	40	62
	\$538	\$288
Segment net income (loss):		
DermaBay (dermatology)	\$(236 )	\$(275 )
EyeBay (ophthalmology)	(2,351)	(1,779)
UroBay (urology)	(478 )	(497 )
MediBay (wound care)	(1,366)	(1,071)
Other	(230 )	(456 )
	\$(4,661)	\$(4,078)

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

(in thousands)	Three Months ended	
	March 31, 2015	March 31, 2014
Segment net loss	\$(4,661)	\$(4,078)
Non-cash gain on change in fair value of warrants	34	520
Other income (expense), net	(11 )	(7 )
Provision for income taxes	(2 )	—
Net loss	\$(4,640)	\$(3,565)

#### NOTE 11. SUBSEQUENT EVENTS

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

In April 2015, the registration statement on Form S-3 associated with the Company's March 2015 private placement for net proceeds of approximately \$4.5 million 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. See Note 7 for details of March 2015 private placement.

## 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. 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: (1) Neutrox,<sup>™</sup> our proprietary pure hypochlorous acid solution, and (2) our novel Aganocide<sup>®</sup> compounds. Using the Neutrox technology, we have developed three branded products, namely, Avenova<sup>™</sup> (previously known as i-Lid Cleanser) for the eye care market, NeutroPhase<sup>®</sup> for the wound-care market, and CelleRx<sup>®</sup> for the dermatology market. Our novel and patented Aganocide compounds are still in clinical development.

### 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, NeutroPhase, and CelleRx.

**Avenova (Ophthalmology).** Launched in the United States in 2014, Avenova (0.01% Neutrox) is the only 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 nationwide through distribution agreements with AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation. 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.

Avenova is well suited for daily use by the millions of Americans who suffer from chronic eye conditions like blepharitis and MGD. We estimate the U.S. market size for Avenova for the management of blepharitis and MGD at approximately \$500 million, and we believe that no other commercial products offer the unique advantages of Avenova. We are currently in process of seeking partners to distribute Avenova outside of the U.S.

Avenova is priced reasonably for consumers and is subject to private pay.

**NeuroPhase (Wound Care).** Since its U.S. launch in 2013, NeuroPhase has made a significant impact in wound care. Consisting of 0.03% Neutrox, NeuroPhase 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, NeuroPhase 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 NeuroPhase not only kills the microorganisms implicated in NF, but also neutralizes the toxins secreted by the microorganisms. Success using NeuroPhase as an irrigation solution has established it as an effective part of the adjunct treatment for this deadly disease.

We believe that NeuroPhase 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, NeuroPhase was named the official wound cleanser by the National Necrotizing Fasciitis Foundation. In the U.S. and internationally, NeuroPhase is distributed through commercial partners. In January 2012, we entered into an exclusive distribution agreement with Pioneer Pharma Holdings Limited (HK: 1345), or “Pioneer,” a Shanghai-based company, for the distribution of NeuroPhase throughout Southeast Asia and mainland China. We recently expanded the agreement with Pioneer so that it includes the licensing rights to CelleRx and Avenova in the same markets. In the U.S., NeuroPhase is distributed through our partner, Principle Business Enterprise (“PBE”). We also have international distribution agreements for NeuroPhase with (1) Biopharm for Egypt, United Arab Emirates, Algeria, Libya and Sudan, (2) Alpha Pharma LLC for Ukraine, and (3) Shin-Poong Pharma for South Korea. We are in the process of securing other partnerships for distribution of NeuroPhase 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, erythema, and exudate 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. We are currently looking for partners to commercialize CelleRx 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. We are seeking development partners for our auriclosene products.

### **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.

### **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 three months ended March 31, 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 Months Ended March 31, 2015 and 2014***

*License, Collaboration, Distribution and Product Revenue*

Total license, collaboration, distribution and product revenue was \$538,000 for the three months ended March 31, 2015, compared to \$288,000 for the three months ended March 31, 2014. The increase was related to sales of our Avenova product, for which we started commercialization in August 2014, partially offset by a decrease in our collaboration revenue.

License, collaboration, distribution and product revenue is due to several different agreements entered into by NovaBay. Those agreements are:

- various distribution agreements entered into for the distribution of NeutroPhase;
- a license and collaboration agreement entered into with Galderma in 2009;
- a distribution agreement covering China entered into with Pioneer Pharma in January 2012;
- a second distribution agreement with Pioneer Pharma covering South East Asia along with a stock purchase agreement; and
- a feasibility and option agreement with Virbac, a global animal health company, expanded to a collaboration in 2013.

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 35% to \$1.6 million for the three months ended March 31, 2015, from \$2.5 million for the three months ended March 31, 2014. This decrease relates to the decrease in clinical activities as we completed our BAYnovation trial for viral conjunctivitis and our BACTOvation trial for bacterial conjunctivitis in 2014.

Starting fourth quarter of 2014, we are reducing research and development expenses for programs outside of eye care, unless these programs are funded through collaborations or partnerships.

#### *Sales, General and Administrative*

Sales, general and administrative expenses increased by 100% to \$3.4 million for the three months ended March 31, 2015, from \$1.7 million for three months ended March 31, 2014. The increase was due to 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 March 31, 2015, our cash and cash equivalents were \$5.6 million, compared to \$5.4 million at December 31, 2014. We have incurred cumulative net losses of \$76.2 million since inception through March 31, 2015. Since inception, we have funded our operations primarily through the sales of our stock and warrants and funds received under our collaboration agreements. Since December 31, 2013, we have raised net proceeds of \$1.6 million related to sales of our stock through the ATM Agreement set up in 2013. In March 2014, we closed a financing in which we raised a total of \$6.7 million, or approximately \$6.0 million in net cash proceeds after deducting underwriting commissions of \$0.5 million and other offering costs of \$0.2 million. In March 2015, we closed an additional financing in which we raised approximately \$4.5 million in net cash proceeds. This securities purchase agreement limits our ability to raise capital under our ATM agreement at prices below a set amount, which may prevent us from raising capital under our ATM agreement.

We believe our cash and cash equivalents are sufficient to fund our planned operations over the next twelve months through March 31, 2016. 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.

We do not anticipate that we will generate significant product revenue for the year ended December 31, 2015. 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, as well as through interest income earned on cash balances and short-term investments. 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 three months ended March 31, 2015, cash used in operating activities was \$4.5 million compared to \$4.4 million for the three months ended March 31, 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, which we started in August 2014, partially offset by a decrease in spending on clinical trials completed in 2014.

### ***Cash Provided By Investing Activities***

For the three months ended March 31, 2015, cash provided by investing activities of \$23,000 was attributed to proceeds received on disposal of equipment, net of cash spent on purchases of property and equipment. For the three months ended March 31, 2014, cash used by investing activities of \$2.3 million was attributable to purchases of short-term investments, net of sales and maturities.

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

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

Net cash provided by financing activities of \$6.6 million for the three months ended March 31, 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 our 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.

Our current business strategy is to focus on eye care. 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.

**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.

**Partnerships to Monetize Other Assets** – While we remain committed to the partnerships we currently have in wound care with (1) China’s Pioneer Pharma, 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; (2) in animal care with Virbac; and (3) 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 a 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, McKesson Corporation, Avenova is available under 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 the 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 conference 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, and 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, and 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 also have received FDA-clearance for a product that we believe could improve the care of contact lenses. We are currently seeking a partner to market this product.

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.

### ***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 our partner worldwide, PBE, China Pioneer Pharma, Shin-Poong Pharma, the Biopharm Group and Alpha Pharma LLC. 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 March 31, 2015.

### **Contractual Obligations**

Our commitments at March 31, 2015, consist of an operating lease. The operating lease consists of payments relating to the lease for various laboratory and office space in one office building in Emeryville, California. This lease expires on October 31, 2020, and the total commitment as of March 31, 2015, is \$3.8 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 March 31, 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 March 31, 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 not important 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 substantively 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.*

#### **Risks Relating to Our Business**

*Our future success is largely dependent on the successful commercialization of Avenova, CelleRx, and NeutroPhase.*

The future success of our business is largely dependent upon the successful commercialization of Avenova, CelleRx, and NeutroPhase. We are dedicating a substantial amount of our resources to advance Avenova and certain resources to advance CelleRx and NeutroPhase as aggressively as possible over the next twelve months. If we encounter difficulties in the commercialization of Avenova, CelleRx, and NeutroPhase, 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, CelleRx, and NeutroPhase. If this occurs, it will have an adverse impact on operations and ability to fund any future development or ongoing clinical trials.



*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.*

As of March 31, 2015, we had cash and cash equivalents and short-term investments of approximately \$5.6 million. While we have reduced our staff levels and reduced both our research and general expenditures, we expect our capital outlays and operating expenditures to increase over at least the next several years as we expand our clinical and regulatory activities as well as expand our sales activities with respect to Avenova. Conducting clinical trials 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 commercialization of auriclosene, our primary Aganocide compound, or any of any of our other Aganocide compounds. 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 ramp and amount of our sales of Avenova and other products;
- the extent to which we receive milestone payments or other funding from corporate partners, if any;
- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;

future clinical trial results;  
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, CelleRx, 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 on favorable terms, or at all. Our ability to obtain additional financing may 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.

In addition, it is often the case that the cost of pharmaceutical development can be significantly greater than initially anticipated. This may be due to any of a large number of possible reasons, some of which could have been anticipated, while others may be caused by unpredictable circumstances. A significant increase in our costs would cause the amount of financing that would be required to enable us to achieve our goals to be likewise increased.

If we determine that we need to raise additional funds and we are not successful in doing so, we may be unable to complete the clinical development of some or all of our product candidates or to seek or obtain FDA approval of our product candidates. Such events could force us to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts or forego attractive business opportunities.

***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 March 31, 2015, with the exception of 2009. For the years ended December 31, 2014, 2013 and 2012, we had net losses of approximately \$15.2 million, \$16.0 million and \$7.0 million, respectively. For the three ended March 31, 2015, we had net losses of approximately \$4.6 million. We were able to record a profit in 2009 due to our receipt of a \$3.75 million milestone payment under our agreement with Galderma; however, there is no assurance that we will receive any additional large milestone payments under this

or any other agreement and, as a result, may not be able to achieve or maintain profitability in the future. Through March 31, 2015, we had an accumulated deficit of approximately \$76.2 million. We have been, and expect to remain for the foreseeable future, engaged in research and development, in addition to our commercialization efforts. We have incurred substantial research and development expenses, which were approximately \$9.5 million, \$12.5 million and \$9.3 million for the years ended December 31, 2014, 2013 and 2012, respectively, and \$1.6 million for the three months ended March 31, 2015. We expect to continue to make, for at least the next several years, expenditures for the development of products that incorporate our Aganocide compounds, as well as continued research into the biological activities of our Aganocide compounds, which expenditures are accounted for as research and development expenses. We also expect to incur substantial marketing and sales expenses as we have just recently launched Avenova. We expect to incur losses for the foreseeable future, and we may never achieve or maintain sustained profitability. We anticipate that our expenses related to our clinical trials and regulatory activities will increase substantially in the foreseeable future as we:

incur commercialization expenditures for Avenova and other products;

conduct pre-clinical studies and clinical trials for our product candidates in different indications;

develop, formulate, manufacture and commercialize our product candidates either independently or with partners;

pursue, acquire or in-license additional compounds, products or technologies, or expand the use of our technology;

maintain, defend and expand the scope of our intellectual property; and

hire additional qualified personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully market and sell our products, or develop, obtain regulatory approval for and commercialize auriclosene, 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 have limited data on the use of some of our products in humans and will need to perform costly and time consuming clinical trials to bring our product candidates to market.***

Much of the data that we have on our auriclosene compound is from in-vitro (laboratory) studies, in-vivo animal studies, Phase 1 human safety studies, or some small-scale Phase 2a or other exploratory clinical studies. We will need to conduct additional Phase 2 and Phase 3 human clinical trials to confirm such results in larger patient populations to obtain approval from the FDA of our Aganocide drug product candidates. Often, positive in-vitro, in-vivo animal studies, or early human clinical trials are not followed by positive results in later clinical trials, and we may not be able to demonstrate that our Aganocide product candidates are safe and effective for indicated uses in humans or that they are active against antibiotic resistant microbes, do not allow pathogens to develop resistance or are active against bacteria in biofilm. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved Aganocide product for commercialization or achieve sales or profits.

***If we are unable to develop and obtain regulatory approval for our Aganocide compounds, we may never generate product revenues from our Aganocide compounds.***

To date, our revenues have been derived mainly from research and development collaboration and license agreements. We have not yet generated any substantial revenue from Avenova and CelleRx. We have generated only limited revenues from sales of NeutroPhase, and we cannot guarantee that we will ever be able to generate substantial revenue from Avenova, CelleRx or NeutroPhase. Our Aganocide compounds are still in development and we will not be able to generate commercial revenue from the sale of these product candidates until we have received regulatory approval for them. Satisfaction of all regulatory requirements applicable to our product candidates typically takes many years, is dependent upon the type, complexity, novelty and classification of the product candidates, and requires the expenditure of substantial resources for research and development and testing. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before we can submit for and gain approval from the FDA and regulatory authorities in other countries. In addition, to compete effectively, our products will need to be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We cannot be certain that the clinical development of any of our current product candidates or any other product that we may develop in the future will be successful, that they will receive the regulatory approvals required to commercialize them, or that any of our other in-licensing efforts or pre-clinical testing will yield a product suitable for entry into clinical trials. For example, in August 2014 we announced that our ophthalmic formulation of auriclosene did not meet the primary or secondary endpoints in a Phase 2 clinical study in patients with adenoviral conjunctivitis, and that we do not intend to initiate any new studies of auriclosene for this indication. Our commercial revenues from sales of Aganocide products will be derived from sales of products that may not be commercially available for at least the next several years. If we are unable to successfully advance or develop our Aganocide compounds, it will have a material adverse effect on our business.

***We have three commercialized products, Avenova, CelleRx and NeuroPhase, and if these products do not gain market acceptance, our business will suffer. \****

A number of factors may affect the market acceptance of Avenova, CelleRx and NeuroPhase, or any other products we develop or acquire, including, among others:

the price of our products relative to other products for the same or similar treatments;

the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their indicated applications and treatments;

our ability to find the right distributor; and

the effectiveness of the sales and marketing efforts of our distributor.

If our products do not gain market acceptance, we may not be able to support funding of our future operations, including developing, testing and obtaining regulatory approval for new product candidates, which would cause our business to suffer.

***Our commercialized products are not approved by the FDA as a drug, so we rely solely on the 510(k) clearance of Neurox 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 have limited experience in developing drugs and medical devices, and we may be unable to commercialize some of the products we develop.***

Development and commercialization of drugs and medical devices involves a lengthy and complex process. We have limited experience in developing products and have only one commercialized product in the market. In addition, no one has ever developed or commercialized a product based on our Aganocide compounds, and we cannot assure you that it is possible to develop, obtain regulatory approval for or commercialize any products based on these compounds or that we will be successful in doing so.

Before we can develop and commercialize any new products, we will need to expend significant resources to:

- undertake and complete clinical trials to demonstrate the efficacy and safety of our product candidates;
- maintain and expand our intellectual property rights;
- obtain marketing and other approvals from the FDA and other regulatory agencies; and
- select collaborative partners with suitable manufacturing and commercial capabilities.

The process of developing new products takes several years. Our product development efforts may fail for many reasons, including:

- the failure of our product candidates to demonstrate safety and efficacy;
- the high cost of clinical trials and our lack of financial and other resources; and
- our inability to partner with firms with sufficient resources to assist us in conducting clinical trials.

Success in early clinical trials often is not replicated in later studies, and few research and development projects result in commercial products. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would eliminate or adversely impact the timing for revenues from those product candidates. For example, in August 2014 we announced that our ophthalmic formulation of auriclosene did not meet the primary or secondary endpoints in a Phase 2 clinical study in patients with adenoviral conjunctivitis, and that we do not intend to initiate any new studies of auriclosene for this indication. If any future clinical study fails to demonstrate the safety and effectiveness of our product candidates, we may abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

Even if we develop products for commercial use, these products may not be accepted by the medical and pharmaceutical marketplaces or be capable of being offered at prices that will enable us to become profitable. We cannot assure you that our products will be approved by regulatory authorities or ultimately prove to be useful for commercial markets, meet applicable regulatory standards, or be successfully marketed.

***Our current collaboration with Galderma may not result in future revenues or commercialization of future products, which would significantly limit our ability to develop and commercialize our dermatological products.***

We have an agreement with Galderma S.A. to develop and commercialize our Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and



orphan drug indications. Our collaboration with Galderma is our only major collaboration in the human field, and so unless and until we enter into additional collaborations or are able to market products on our own, our only potential source of collaboration revenues is from Galderma.

In November 2013, we announced with Galderma that the auriclosene Phase 2 clinical study of impetigo had been completed, and that while the study showed that auriclosene is safe and well tolerated, it did not meet its primary clinical endpoint. While the collaboration is still intact, we cannot assure you that future clinical trials, if any, will be successful, or that we will receive any remaining research funding, milestone payments or royalties, or that any valuable intellectual property will be created from this arrangement. If Galderma or NovaBay were to decide to not continue forward with this collaboration, our potential to generate future collaboration revenues would be significantly impaired. There is currently no specific progress being made toward a stated collaboration milestone.

***We are funding the development of our Aganocide compounds for application in connection with the urinary tract, which we may not be able to do unless we are able to enter into a new collaboration with another collaboration partner.***

As we continue the development of auriclosene (NVC-422) for application in urology, we must fund such development ourselves unless we are able to enter into a collaboration with a collaboration partner, which we may not be able to do, especially because we previously had a collaboration and license agreement with Alcon, which was terminated in June 2011. If we are not able to enter into a new collaboration with another collaboration partner and we continue the development of auriclosene for any application, we will need to rely on our own funds, and any additional funds we may raise. If we are not able to enter into a new collaboration with another collaboration partner or are not able to raise additional funds, we may not be able to develop auriclosene for these applications.

***A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.***

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and if we do enter into collaborations, these collaborations may not be successful. Our current and future success depends in part on our ability to enter into successful collaboration arrangements and maintain the collaboration arrangement we currently have with Galderma. There is currently no specific progress being made toward a stated collaboration milestone. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;

our shortage of capital resources may impact a willingness on the part of potential companies to collaborate with us;

our contracts for collaborative arrangements may be terminable for convenience on written notice and may otherwise expire or terminate, and we may not have alternative funding available;

our partners may choose to pursue alternative technologies, including those of our competitors;

we may have disputes with a partner that could lead to litigation or arbitration;

we do not have day-to-day control over the activities of our partners and have limited control over their decisions;

our ability to receive milestones and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;

we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

our partners may not devote sufficient capital or resources towards our product candidates; and

our partners may not comply with applicable government regulatory requirements.

If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Consequently, if we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

***Our long-term success depends upon the successful development and commercialization of products other than auriclosene from our research and development activities.***

Our long-term viability and growth will depend upon the successful development and commercialization of products other than auriclosene from our research and development activities. Product development and commercialization is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current good clinical practice requirements. We are in many cases using the services of third-party contract clinical trial providers. If we fail to adequately manage the design, execution and regulatory aspects of our clinical trials, our studies and ultimately our regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether.

***If we do not successfully execute our growth initiatives through the acquisition, partnering and in-licensing of products, technologies or companies, our future performance could be adversely affected.***

In addition to our internal development projects, we anticipate growing through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to complete or manage these external growth opportunities successfully, we may not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to identify suitable candidates or complete transactions on terms that are acceptable to us. To pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all.

***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. Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

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 drug 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 drugs may be delayed or there may be a shortage in supply and our business may be harmed as a result.

***If third party vendors upon whom we intend to rely to conduct our preclinical studies or clinical trials do not perform, or fail to comply with strict regulations, the studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.***

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

***We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability. Also, we currently rely on a contract salesforce for marketing our Avenova product. Success in our product sales depends on our ability to hire and manage effective salesforce.***

Our success largely depends on the skills, experience and efforts of our officers, especially our Chief Executive Officer, Chief Financial Officer, Senior Vice President, Ophthalmology, Senior Vice President of MediBay Division, Senior Vice President, Business Development, Vice President, Sales and Marketing Avenova, and other key employees. The efforts of each of these persons is critical to us as we continue to develop our technologies and as we attempt to transition into a company with commercial products. 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 weaken our management expertise and harm our ability to compete effectively, develop our technologies and implement our business strategies.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. Our research and development programs and collaborations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We have also encountered difficulties in recruiting qualified personnel from outside the San Francisco Bay Area, due to the high housing costs in the area.

We currently rely on a contract salesforce for marketing our Avenova product. Success in our product sales depends on our ability to hire effective salesforce and keep salesforce motivated if sales growth becomes slow or future products do not materialize.

***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.



***If our facilities become inoperable, we will be unable to perform our research and development activities, fulfill the requirements under our collaboration agreement and continue developing products and, as a result, our business will be harmed.***

We do not have redundant laboratory facilities. We perform substantially all of our research, development and testing in our laboratory located in Emeryville, California. Emeryville is situated on or near active earthquake fault lines. Our facility and the equipment we use to perform our research, development and testing would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and testing for some period of time. The inability to perform our research and development activities may result in the loss of partners or harm our reputation, and we may be unable to regain those partnerships in the future. Our insurance coverage for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to us on acceptable terms, or at all.

However, we do have redundant manufacturing and supply chain facilities.

***Obtaining regulatory approval in the United States does not ensure we will obtain regulatory approval in other countries.***

We aim to obtain regulatory approval in the U.S. as well as in other countries. To obtain regulatory approval to market our proposed products outside of the U.S., we and any collaborator must comply with numerous and varying regulatory requirements in other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ significantly from that required to obtain FDA approval. The regulatory approval process in other countries includes all of the risk associated with FDA approval as well as additional, presently unanticipated risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the U.S., including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed. In addition, failure to comply with applicable regulatory requirements in other countries can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution.

***If we are unable to design, conduct and complete clinical trials successfully, we will not be able to obtain regulatory approval for our product candidates.***

To obtain FDA approval for our drug product candidates, we must submit to the FDA a New Drug Application, or NDA, demonstrating that the product candidate is safe and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Any clinical trials we conduct or that are conducted by our partners may not demonstrate the safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of one or more of our clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies or clinical trials before we can submit NDAs or obtain FDA approvals for our product candidates, and positive results of a clinical trial may not be replicated in subsequent trials.

Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time-consuming. Furthermore, if participating patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believe that participating patients are being exposed to unacceptable

health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies. Further, because our product candidates are all in the same class of compounds, failure in one clinical trial may cause us or our partners to have to suspend or terminate other clinical trials. For example, if toxicity issues were to arise in one clinical trial, it could indicate that all of our product candidates have toxicity issues.

In addition, the completion of clinical trials can be delayed by numerous factors, including:

delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;

slower than expected rates of patient recruitment and enrollment;

increases in time required to complete monitoring of patients during or after participation in a trial; and

unexpected need for additional  
patient-related data.

Any of these delays, if significant, could impact the timing, approval and commercialization of our product candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our products are safe and effective for indicated uses. Such failure would cause us to abandon a product candidate for some indications and could delay development of other product candidates.

***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.

***Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action or indication for use and prior precedent, and a change in the classification may have an adverse impact on our revenues or our ability to obtain necessary regulatory approvals.***

Our Neutrox products are regulated under the medical device regulations of the FDA administered by the Center for Devices and Radiological Health and the same physical product for another indication and our Agancocide product candidates may be regulated by the FDA's Center for Drug Evaluation and Research. Alternatively the products could be classified as combination products, in which case both the device and drug centers jointly review the submission. The products may be designated by the FDA as a drug or a medical device depending upon the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims.

The use of Avenova, CelleRx and NeutroPhase as a skin and wound-cleansing solution has been cleared by the FDA. The determination as to whether a particular indication is considered a drug or a device is also based in part upon precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development or post-commercialization for that indication could have a significant adverse impact due to the more rigorous and lengthy approval process required for drugs, as compared to medical devices. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a drug to a device could result in a change in classification for reimbursement

***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, the costs of compliance with these new laws and regulations could be substantial or could impose significant changes in 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, develop non-infringing technology, stop selling any products we develop, cease using technology that contains the allegedly infringing intellectual property or 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 and NeutroPhase, 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 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 function 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 there under 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. As of March 31, 2014, we owned ten (10) issued patents in the U.S., eighty nine (89) issued foreign patents and thirty seven (37) pending patent applications in the U.S. and various foreign jurisdiction. 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 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, CelleRx or NeutroPhase with a similar composition that does not fall within the scope of the method of treatment 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, CelleRx or NeutroPhase composition, and any revenues arising from such protection would be adversely impacted.

***If our competitors develop products similar to Avenova, CelleRx or NeutroPhase, we may need to modify or alter our business strategy, which may delay the achievement of our goals.***

Competitors may develop products with similar characteristics to Avenova, CelleRx or NeutroPhase. Such similar products marketed by larger competitors can hinder our efforts to penetrate the market. As a result, we may be forced to modify or alter our business and regulatory strategy and sales and marketing plans, as a response to changes in the market, competition and technology limitations, among others. Such modifications may pose additional delays in achieving our goals.

***If bacteria develop resistance to Aganocide compounds, Avenova, CelleRx or NeutroPhase, our potential revenues could be significantly reduced.***

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds and Avenova, CelleRx or NeutroPhase, we do not expect bacteria to be able to develop resistance to either of these compounds. However, we cannot assure you that one or more strains of bacteria will not develop resistance to our compounds, either because our hypothesis of the mechanism of action is incorrect or because a strain of bacteria undergoes some unforeseen genetic mutation that permits it to survive. Since we expect lack of resistance to be a major factor in the commercialization of our product candidates, the discovery of such resistance would have a major adverse impact on the acceptability and potential sales of our products.

***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 are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, revenues from any products we develop could be disappointing.***

We currently have limited sales, marketing and distribution capabilities. To commercialize our products successfully, we have to develop such capabilities internally or collaborate with third parties that can perform these services for us, such as PDI, Inc., Principle Business Enterprises in the U.S. and Pioneer Pharma Co. Ltd. in China. In the process of commercializing our products, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

If we decide to enter into co-promotion or other licensing arrangements with third parties, we may be unable to identify acceptable partners because the number of potential partners is limited and because of competition from others for similar alliances with potential partners. Even if we are able to identify one or more acceptable partners, we may not be able to enter into any partnering arrangements on favorable terms, or at all. If we enter into any partnering arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

In addition, any revenues we receive would depend upon our partners' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, and change of strategic focus, further business combinations or other factors outside of our control. Depending upon the terms of our agreements, the remedies we have against an under-performing partner may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement partner on acceptable terms, or at all.

***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. If our product candidates receive FDA approval and are launched they will compete with a number of existing and future drugs, devices and therapies developed, manufactured and marketed by others. 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 will 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 that 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. Currently we do not have any products approved for reimbursement by Medicare or any other third party healthcare providers. Although the cost of Avenova is near a common co-pay price point, 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 are not willing to pay a private payer cost that is near a common co-pay price point, market acceptance of our products could be limited.

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

***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 eye care market started at the end of 2014;

the results of preclinical or clinical trials relating to our product candidates;

the announcement of new products by us or our competitors;

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 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 limited operating history may make it difficult for you to evaluate our business and to assess our future viability.***

Our operations to date have been limited to organizing and staffing our company, developing our technology, researching and developing our compounds, and conducting preclinical studies and early-stage clinical trials of our compounds. We have not demonstrated the ability to succeed in achieving clinical endpoints, obtain regulatory approvals, formulate and manufacture products on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability are unlikely to be as accurate as they could be if we had a longer operating history.

***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.

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

On April 28, 2015 we received a letter from the NYSE MKT notifying us that our stockholders equity as of December 31, 2014 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 must submit a plan of compliance by May 28, 2015 addressing how we intend to regain compliance with the Company Guide within 18 months, or by November 28, 2016. If the plan is accepted, we may be able to continue our listing but will be subject to periodic reviews by the Exchange. If the plan is not accepted or if it is accepted but NovaBay Pharmaceuticals is not in compliance with the continued listing standards within 18 months, or if we do not make progress consistent with the plan, the exchange will initiate delisting procedures as appropriate. We are pursuing options to address the deficiency and intend to submit a compliance plan on or before the deadline set by the exchange, however we cannot guarantee that we will meet the listing requirements and therefore our common stock may be subject to delisting. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer financing opportunities for us.

**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

Date: May 14, 2015 NOVABAY PHARMACEUTICALS, INC.

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

*(duly authorized officer)*

Date: May 14, 2015 /s/ Thomas J. Paulson  
Thomas J. Paulson  
Chief Financial Officer

*(principal financial officer)*

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporation by Reference</b>			<b>Filed Herewith</b>
		<b>Form</b>	<b>File Number</b>	<b>Exhibit/ Form 8-K Item Reference Filing Date</b>	
3.1	Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	6/29/2010	
3.2	Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.1	6/04/2014	
3.3	Bylaws of NovaBay Pharmaceuticals, Inc.	8-K	001-336783.2	6/29/2010	
4.1	Form of Warrant issued in August 2009 offering.	8-K	001-336784.3	8/21/2009	
4.2	Form of Warrant issued in July 2011 offering.	8-K	001-336784.1	6/29/2011	
4.3	Form of Warrant issued in December 2012 offering.	8-K	001-336784.1	12/6/2012	
4.4	Form of Warrant issued in March 2014 offering.	8-K	001-336784.1	3/20/2014	
4.5	Form of Warrant issued in March 2015 offering.	8-K	001-336784.1	3/9/2015	
4.6	Form of Warrant issued in March 2015 offering.	8-K	001-336784.2	3/9/2015	
4.7	Registration Rights Agreement, dated March 3, 2015, by and between NovaBay Pharmaceuticals, Inc. and the investors named therein.	8-K	001-3367810.2	3/9/2015	
10.1	Common Stock Purchase Agreement, dated March 3, 2015, by and between NovaBay Pharmaceuticals, Inc. and the investors named therein.	8-K	001-3367810.1	3/3/2015	
10.2	2015 Compensation Arrangements with Named Executive Officers	8-K	001-33678Item 5.02	3/24/2015	
31.1	Certification of the Principal Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of the Principal Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or				X

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

	Rule 15d-14(a).	
32.1‡	Certification by the Chief Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).	X
32.2‡	Certification by the Chief Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

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