

NovaBay Pharmaceuticals, Inc.
Form 10-Q
November 12, 2009

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

EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2009

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)

California
(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 (§232.405 of this chapter) 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):

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

Large accelerated filer	<input type="radio"/> Accelerated filer	<input type="radio"/>
Non-accelerated filer	<input type="radio"/> Smaller reporting company	<input checked="" type="radio"/>

(Do not check if a smaller reporting company)

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

As of November 5, 2009, there were 23,253,235 shares of the registrant's common stock outstanding.

-1-

NOVABAY PHARMACEUTICALS, INC.

TABLE OF CONTENTS

Part		Page
<u>I. Financial Information</u>		
<u>Item 1.</u>	<u>Financial Statements</u>	3
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operation</u>	26
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>Item 4.</u>	<u>Controls and Procedures</u>	33
<u>Item 4T.</u>	<u>Controls and Procedures</u>	33
<u>II. Other Information</u>		
<u>Item 1.</u>	<u>Legal Proceedings</u>	34
<u>Item 1A.</u>	<u>Risk Factors</u>	34
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	52
<u>Item 6.</u>	<u>Exhibits</u>	53

SIGNATURES

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 Pharma®, Aganocide®, NovaBay™, AgaDerm™, AgaNase™, and NeutroPhase™ are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

Table of Contents

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2008	September 30, 2009 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,099	\$ 10,630
Short-term investments (Note 3)	-	1,050
Accounts receivable and other receivables	-	1,037
Prepaid expenses and other current assets	414	740
Total current assets	12,513	13,457
Property and equipment, net (Note 4)	1,456	1,784
TOTAL ASSETS	\$ 13,969	\$ 15,241
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	\$ 406	\$ 314
Accrued liabilities (Note 5)	1,166	965
Capital lease obligation (Note 4)	42	18
Equipment loan (Note 6)	366	397
Deferred revenue	2,500	3,742
Total current liabilities	4,480	5,436
Capital lease obligation - non-current (Note 4)	7	-
Equipment loan - non-current (Note 6)	470	168
Deferred revenue - non-current	1,667	50
Total liabilities	6,624	5,654
Stockholders' Equity:		
Common stock, \$0.01 par value; 65,000 and 65,000 shares authorized at December 31, 2008 and September 30, 2009, respectively, 21,471 and 23,251 issued and outstanding at December 31, 2008 and September 30, 2009, respectively	215	233

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

Additional paid-in capital	33,718	36,661
Accumulated deficit during development stage	(26,588)	(27,307)
Total stockholders' equity	7,345	9,587
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 13,969	\$ 15,241

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

Table of Contents

-3-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Cumulative Period from July 1, 2002 (date of development stage inception) to				
	Three Months Ended September 30,		Nine Months Ended September 30,		September 30,
	2008	2009	2008	2009	2009
	(unaudited)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
REVENUE					
License and collaboration revenue	\$ 1,592	\$ 3,224	\$ 4,526	\$ 8,192	\$ 22,360
EXPENSES					
Operating Expenses:					
Research and development	1,614	2,004	6,861	4,809	29,816
General and administrative	1,544	1,309	4,575	4,078	21,043
Total operating expenses	3,158	3,313	11,436	8,887	50,859
Interest expense	(28)	(56)	(77)	(98)	(244)
Other income (expense), net	105	34	411	75	1,450
Total Other income (expense), net	77	(22)	334	(23)	1,206
Net loss before income taxes	(1,489)	(111)	(6,576)	(718)	(27,293)
Provision for income taxes	-	-	2	-	14
Net loss	\$(1,489)	\$(111)	\$(6,578)	\$(718)	\$ (27,307)
Net loss per share:					
Basic and diluted	\$(0.07)	\$(0.00)	\$(0.31)	\$(0.03)	
Weighted average shares used in per share calculations:					
Basic and diluted	21,443	23,251	21,313	22,117	

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

Table of Contents

-4-

NOVABAY PHARMACEUTICALS, INC.

(a development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine Months Ended September 30,		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30, 2009
	2008 (unaudited)	2009 (unaudited)	(unaudited)
Cash flows from operating activities:			
Net loss	\$ (6,578)	\$ (718)	\$ (27,307)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	222	268	972
Accretion of discount on short-term investments	(40)	-	(301)
Net realized gain loss on sales of short-term investments	(4)	-	(3)
Loss on disposal of property and equipment	-	-	121
Stock-based compensation expense for options issued to employees and directors	667	514	1,976
Compensation expense for warrants and stock issued for services	44	286	386
Stock-based compensation expense for options and stock issued to non-employees	(9)	138	663
Taxes paid by LLC	-	-	1
Changes in operating assets and liabilities:			
(Increase) in prepaid expenses and other current assets	(354)	(1,363)	(1,772)
Increase (decrease) in accounts payable and accrued liabilities	524	(293)	1,304
(Increase) decrease in deferred revenue	(1,510)	(376)	3,791
Net cash used in operating activities	(7,038)	(1,544)	(20,169)
Cash flows from investing activities:			
Purchases of property and equipment	(521)	(596)	(2,756)
Proceeds from disposal of property and equipment	-	-	44
Purchases of short-term investments	(32,103)	(1,050)	(95,594)
Proceeds from maturities and sales of short-term investments	40,129	-	94,847
Cash acquired in purchase of LLC	-	-	516
Net cash provided by (used in) investing activities	7,505	(1,646)	(2,943)
Cash flows from financing activities:			
Proceeds from preferred stock issuances, net	-	-	11,160
Proceeds from common stock issuances	-	-	17
Proceeds from exercise of options and warrants	153	78	1,839
Proceeds from initial public offering, net of costs	-	-	17,077

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

Proceeds from shelf offering, net of costs	-	1,945	1,945
Proceeds from stock subscription receivable	-	-	873
Proceeds from issuance of notes	-	-	405
Principal payments on capital lease	(28)	(31)	(139)
Proceeds from borrowings under equipment loan	422	-	1,216
Principal payments on equipment loan	(216)	(271)	(651)
Net cash provided by financing activities	331	1,721	33,742
Net increase (decrease) in cash and cash equivalents	798	(1,469)	10,630
Cash and cash equivalents, beginning of period	10,941	12,099	-
Cash and cash equivalents, end of period	\$ 11,739	\$ 10,630	\$ 10,630

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

Table of Contents

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months September 30, Ended		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30, 2009
	2008 (unaudited)	2009 (unaudited)	2009 (unaudited)
Supplemental disclosure of cash flow information:			
Interest paid	\$76	\$98	\$ 244
Income taxes paid	—	2	2
Non-cash activities:			
Issuance of stock, options and warrants for stock offering costs	—	—	\$ 801
Property and equipment acquired under capital lease obligation	\$62	—	\$ 229

Table of Contents

-6-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the “Company”) is a development stage biopharmaceutical company focused on developing innovative product candidates for the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid rise in drug resistance. The Company has discovered and is developing a class of non-antibiotic anti-infective compounds, which it has named Aganocide compounds. These compounds are based upon small molecules that are naturally generated by white blood cells when defending the body against invading pathogens. The Company believes that its Aganocide compounds could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial and viral infections. In laboratory testing, the Company’s Aganocide compounds have demonstrated the ability to destroy all bacteria against which they have been tested. Furthermore, because of their mechanism of action, the Company believes that bacteria are unlikely to develop resistance to its Aganocide compounds.

The Company was incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc. The Company had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, the Company changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, the Company formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which may conduct research and development in Canada, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. The Company currently operates in one business segment.

In October 2007, the Company completed an initial public offering of its common stock (“IPO”) in which it sold and issued 5,000,000 shares of its common stock at a price to the public of \$4.00 per share. The Company raised a total of \$20.0 million from the IPO, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million. Upon the closing of the IPO, all shares of convertible preferred stock outstanding automatically converted into 9,613,554 shares of common stock. In connection with the IPO, the Company also issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of \$4.00 per share. The warrants are exercisable on or after October 31, 2008 and expire on October 31, 2010.

In August 2009, the Company completed a sale of equity securities from its shelf registration statement (“Shelf Registration Offering”) in which the Company sold and issued 1,225,000 units, with each unit consisting of one share of the Company’s common stock and a warrant to purchase one share of the Company’s common stock. The purchase price for each unit was \$2.00. Each warrant has an exercise price of \$2.75 per share, and will be exercisable 180 days after issuance and will expire five years from the date of issuance. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together in the Shelf Registration Offering. The Company raised a total of \$2.5 million from the Shelf Registration Offering, or approximately \$ 1.9 million in net proceeds after deducting underwriting commissions of \$156,000 and other offering costs of \$348,761.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of NovaBay Pharmaceuticals, Inc. have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") for interim reporting including the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. These condensed statements do not include all disclosures for annual audited financial statements required by accounting principles generally accepted in the United States of America ("U.S. GAAP") and should be read in conjunction with the Company's audited consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

Table of Contents

-7-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company believes these condensed consolidated financial statements reflect all adjustments (consisting only of normal, recurring adjustments) that are necessary for a fair presentation of the financial position and results of operations for the periods presented. Results of operations for the interim periods presented are not necessarily indicative of results to be expected for the year. Certain prior period amounts have been reclassified to conform to the current period presentation.

The financial statements have been prepared under the guidelines for Development Stage Enterprises. A development stage enterprise is one in which planned principal operations have not commenced, or if its operations have commenced, there have been no significant revenues there from. As of September 30, 2009, the Company had not commenced its planned principal operations.

Principles of Consolidation

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

Reverse Stock Split

On August 10, 2007, the Company filed an amendment to its articles of incorporation to effect a 1-for-2 reverse stock split of its common stock. All share and per share amounts relating to the common stock, stock options and warrants and the conversion ratios of preferred stock included in the financial statements and footnotes have been restated to reflect the reverse stock split.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents and Short-Term Investments

The Company considers all highly liquid instruments with a stated maturity of three months or less to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of September 30, 2009, 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.

Table of Contents

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company classifies all highly liquid investments with a stated maturity of greater than three months as short-term investments. Short-term investments generally consist of United States government, 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. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. The amortization and accretion, interest income and realized gains and losses are included in other income, net within the consolidated statements of operations. Interest income is recognized when earned.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, the Company's other comprehensive loss consists solely of unrealized gains and losses on investments. Comprehensive loss for the three and nine months ended September 30, 2008 and 2009 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2009	2008	2009
Net loss	\$(1,489)	\$(111)	\$(6,578)	\$(718)
Change in unrealized gains (losses) on investments	7	3	34	-
Comprehensive loss	\$(1,482)	\$(108)	\$(6,544)	\$(718)

Concentrations of Credit Risk

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

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

Table of Contents

-9-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash and cash equivalents and short term investments, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of capital lease obligations and equipment loans approximates its carrying amounts as a market rate of interest is attached to their repayment.

The Company measures the fair value of financial assets and liabilities based on authoritative guidance which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. Effective January 1, 2008, the Company adopted the provisions for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. Effective January 1, 2009, the Company adopted the provisions for non-financial assets and liabilities that are required to be measured at fair value. The adoption of these provisions did not materially impact the Company's consolidated financial position and results of operations.

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)

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 their useful life or the life of the lease term. Amortization of assets recorded under capital leases is included in depreciation expense.

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 by considering 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. Should there be impairment in the future, the Company would recognize the

amount of the impairment based on the discounted expected future cash flows from the impaired assets. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Table of Contents

-10-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 authoritative guidance, the Company analyzes its multiple element arrangements to determine whether the element 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 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 continuing involvement through research and development services that are required because its know-how and expertise related to the technology is proprietary to it, or can only be performed by it, then such up-front fees are deferred and recognized over the period of continuing involvement.

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. 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 the Company completes its performance obligations.

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

Table of Contents

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Advertising Costs

There were no advertising costs incurred for any of the periods presented.

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.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included as general and administrative expenses in the Company's statements of operations.

Stock-Based Compensation

On January 1, 2006, the Company adopted new authoritative accounting guidance requiring the recognition of the fair value of stock-based compensation. Under this guidance, 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. The Company was required to utilize the prospective application method, under which prior periods are not revised for comparative purposes. Under this method, non-public entities that previously used the minimum value method continued to account for non-vested equity awards outstanding at the date of adoption in the same manner as they had been accounted for prior to adoption. See Note 9 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

The Company is required to account for stock compensation arrangements with non-employees by recording their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Nonemployee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

Table of Contents

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 carry-forwards. 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 all of the deferred tax asset will not be recognized.

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 (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and stock warrants, using the treasury stock method, and convertible preferred stock, 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 as their effect would be anti-dilutive. There is no difference between basic and diluted net loss per share for all periods presented due to the Company’s net losses.

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

	Nine Months Ended	
	September 30,	
(In thousands)	2008	2009
Convertible preferred stock	-	-
Stock options	3,502	3,827
Stock warrants	650	1,875

Recent Accounting Pronouncements

During the third quarter of 2009, the Company adopted the FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles in accordance with FASB ASC Topic 105, “Generally Accepted Accounting Principles” (the Codification). The Codification has become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental

entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. Effective with the Company's adoption on July 1, 2009, the Codification has superseded all prior non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification has become non-authoritative. As the adoption of the Codification only affected how specific references to GAAP literature have been disclosed in the notes to the Company's condensed consolidated financial statements, it did not result in any impact on the Company's results of operations, financial condition, or cash flows.

In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance addresses how to separate deliverables and how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company is currently evaluating the effect that this guidance will have on consolidated financial position and results of operations.

Table of Contents

-13-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

ASC 855-10-20, “Subsequent Events” establishes accounting and reporting standards for events that occur after the balance sheet date but before financial statements are issued or are available to be issued and requires the disclosure of the date through which a company has evaluated subsequent events. This statement is effective for the Company’s third quarter ended September 30, 2009 and the adoption did not have an impact on the condensed consolidated financial statements. See Note 13 for the required disclosures.

In April 2009, the FASB issued ASC 820-10-65 formerly FASB Staff Position FAS 157-4, “Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly” (“FSP 157-4”). This provides significant guidance for determining when a market has become inactive as well as guidance for determining whether transactions are not orderly. It also provides guidance on the use of valuation techniques and the use of broker quotes and pricing services. It reiterates that fair value is based on an exit price and also that fair value is market-driven and not entity-specific. The accounting standard of codification applies to all assets and liabilities within the scope of ASC 820 and is effective for all interim and annual periods ending after June 15, 2009. The adoption of ASC 820-10-65 did not have a material effect on the Company’s results of operations, financial position, and cash flows.

In April 2009, the FASB issued ASC 320-10-65, formerly FASB Staff Position FAS 115-2, FAS 124-2 and EITF 99-20-2, “Recognition and Presentation of Other-Than-Temporary Impairments” (“FSP 115-2”). This accounting standard provides guidance related to determining the amount of an other-than-temporary impairment (OTTI) of debt securities and prescribes the method to be used to present information about an OTTI in the financial statements. It is effective for all interim and annual periods ending after June 15, 2009. The adoption of ASC 320-10-65 did not have a material effect on the Company’s results of operations, financial position, and cash flows.

In April 2009, the FASB issued ASC 825-10-65, formerly FASB Staff Position FAS 107-1 and APB 28-1, “Interim Disclosures about Fair Value of Financial Instruments” (“FSP 107-1”), which increases the frequency of fair value disclosures to a quarterly basis instead of an annual basis. The guidance relates to fair value disclosures for any financial instruments that are not currently reflected on the balance sheet at fair value. This ASC is effective for interim and annual periods ending after June 15, 2009. The adoption of ASC 825-10-65 did not have a material effect on the Company’s results of operations, financial position, and cash flows.

Table of Contents

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

There were no short-term investments at December 31, 2008. Short-term investments at September 30, 2009 consisted of the following:

September 30, 2009					
(in thousands)	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Certificates of Deposit	1,050	-	-	-	1,050
	\$ 1,050	\$ -	\$ -	\$ -	\$ 1,050

Contractual maturities of short-term investments as of September 30, 2009 were as follows:

September 30, 2009		
(in thousands)	Cost	Fair Value
Due in one year or less	\$ 1,050	\$ 1,050
Due after 1 year	-	-
Total	\$ 1,050	\$ 1,050

We did not recognize any realized gains or losses for the three and nine months ended September 30, 2008 and 2009 respectively. For the cumulative period from July 1, 2002 (date of development stage inception) to September 30, 2009, the Company recognized a net realized gain of \$3,000.

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 following table presents the Company's investments measured at fair value on a recurring basis as of September 30, 2009:

Fair Value Measurements Using				
(in thousands)	Total	Level 1	Level 2	Level 3
Cash Equivalents	\$ 10,630	\$ 10,630	\$ -	\$ -
Short-term investments:				
Certificates of Deposit	1,050	-	1,050	-
Total short-term investments	1,050	-	1,050	-
Total	\$ 11,680	\$ 10,630	\$ 1,050	\$ -

Table of Contents

-15-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2008	September 30, 2009
(in thousands)		
Office and laboratory equipment	\$1,728	\$2,312
Furniture and fixtures	113	113
Software	110	119
Leasehold improvement	143	146
Total property and equipment, at cost	2,094	2,690
Less: accumulated depreciation	(638)	(906)
Total property and equipment, net	\$1,456	\$1,784

Depreciation expense was \$304,000 and \$268,454 for the year ended December 31, 2008 and the nine months ended September 30, 2009, respectively and \$972,454 for the cumulative period from July 1, 2002 (date of development stage inception) to September 30, 2009.

During the first quarter of 2007, the Company commenced a lease for a portion of its laboratory equipment. This arrangement is accounted for as a capital lease. Assets under capital leases that are included in property and equipment are as follows:

	December 31, 2008	September 30, 2009
(in thousands)		
Office and laboratory equipment	\$229	\$229
Less: accumulated depreciation	(47)	(72)
Capital lease assets, net	\$182	\$157

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

	December 31, 2008	September 30, 2009
(in thousands)		
Research and development	\$509	\$48
Employee payroll and benefits	423	370
Professional fees	182	286

Other	52	261
Total accrued liabilities	\$1,166	\$965

Table of Contents

-16-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 6. EQUIPMENT LOAN

During April 2007, the Company entered into a master security agreement to establish a \$1.0 million equipment loan facility with a financial institution. The purpose of this loan is to finance equipment purchases, principally in the build-out of the Company's laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. In April 2008, the agreement was extended to April 2009, and as a result no further borrowings are permitted on this loan. There are no loan covenants specified in the agreement.

As of September 30, 2009, the Company had an outstanding equipment loan balance of \$565,308 carrying a weighted-average interest rate of 10.98%.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases laboratory facilities and office space under operating leases which will all expire on October 31, 2015. Rent expense was \$158,000 and \$516,000 for the three and nine months ended September 30, 2008. Rent expense was \$213,504 and \$653,226 for the three and nine months ended September 30, 2009. For the cumulative period from July 1, 2002 (date of development stage inception) to September 30, 2009, rent expense was \$2,594,918.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at September 30, 2009 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 8. STOCKHOLDERS' EQUITY

Preferred Stock

In 2002 and 2003, the Company issued 3.2 million shares of Series A Convertible Preferred Stock for net proceeds of \$647,000. In 2003 and 2004, the Company issued 6.9 million shares of Series B Convertible Preferred Stock for net proceeds of \$3.0 million. In 2004 and 2005, the Company issued 6.7 million shares of Series C Convertible Preferred Stock for net proceeds of \$5.4 million. In 2005 and 2006, the Company issued 2.5 million shares of Series D Convertible Preferred Stock for net proceeds of \$3.6 million. All outstanding shares of convertible preferred stock automatically converted into 9.6 million shares of common stock upon the closing of the Company's IPO in October 2007. In connection with the IPO, the Company amended its articles of incorporation to provide for the issuance of up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the board of directors. As of December 31, 2008, and September 30, 2009 there were no shares of preferred stock outstanding.

Table of Contents

-17-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Common Stock

Under the Company's amended articles of incorporation, the Company is authorized to issue 65,000,000 shares of \$0.01 par value common stock. Each holder of common stock has the right to one vote but does not have cumulative voting rights. Shares of common stock are not subject to any redemption or sinking fund provisions, nor do they have any preemptive, subscription or conversion rights. Holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared or paid as of December 31, 2008, and September 30, 2009. In August 2007, the Company filed an amendment to its articles of incorporation to effect a 1-for-2 reverse stock split of its common stock. All share and per share amounts relating to the common stock, stock options and warrants and the conversion ratios of preferred stock included in the condensed consolidated financial statements and footnotes have been restated to reflect the reverse stock split. In October 2007, the Company completed an initial public offering of its common stock in which the Company sold and issued 5,000,000 shares of its common stock at a price to the public of \$4.00 per share. The Company raised a total of \$20.0 million from the IPO, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million. The Company sold and issued 1,225,000 units of its common stock at a price of \$2.00 per unit from a Shelf Registration Offering. Each unit consisted of one share of the Company's common stock and a warrant to purchase one share of the Company's common stock. The Company raised a total of \$2.5 million from the Shelf Registration Offering, or approximately \$1.9 million in net proceeds after deducting underwriting commissions of \$156,000 and other offering costs of \$348,761.

Stock Warrants

At September 30, 2009, there were outstanding warrants to purchase 650,000 shares of common stock at a weighted-average exercise price of \$4.00 per share. Additionally, there were outstanding warrants to purchase 1,225,000 shares of common stock from the registered direct shelf offering of August 26, 2009 at the exercise price of \$2.75 per share.

NOTE 9. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to the IPO, the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. At the inception of the 2007 Plan, 2,000,000 shares were reserved for issuance under the Plan. Beginning in January 2009, the number of shares of common stock authorized for issuance under the 2007 Plan increases annually in an amount equal to the lesser of (a) 1,000,000 shares or (b) 4% of the

number of shares of the Company's common stock outstanding on the last day of the preceding year or (c) such lesser number as determined by the board of directors. Accordingly, an additional 858,766 shares of common stock were authorized for issuance under the 2007 Plan in January 2009. As of September 30, 2009, there were 732,912 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.

Table of Contents

-18-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding at September 30, 2009 and activity during the nine-month period then ended.

(in thousands, except per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	3,371	\$ 1.71		
Options granted	734	\$ 1.79		
Options exercised	(119)	\$ 0.62		
Options forfeited/cancelled	(189)	\$ 1.81		
Outstanding at September 30, 2009	3,797	\$ 1.75	6.9	\$1,668
Vested and expected to vest at September 30, 2009	3,655	\$ 1.72	6.9	\$1,666
Vested at September 30, 2009	2,313	\$ 1.41	5.7	\$1,561
Exercisable at September 30, 2009	2,521	\$ 1.55	5.8	\$1,574

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 Amex as of September 30, 2009. The Company received cash payments for the exercise of stock options in the amount of \$20,000 and \$78,000 during the three and nine months ended September 30, 2009, respectively, and the aggregate intrinsic value of stock option awards exercised was \$38,000 and \$148,000, respectively for the same periods, as determined at the date of option exercise. For the three months and nine months ended September 30, 2008, the Company received cash payments in the amount of \$11,000 and \$143,900 respectively, and the aggregate intrinsic value of stock option awards exercised was \$25,000 and \$103,000, respectively, for the same periods.

The options outstanding and vested by exercise price at September 30, 2009 were as follows (number of options in thousands):

Range of Exercise Prices	Number Outstanding	Options Outstanding		Number Vested	Options Vested	
		Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price		Weighted-Average Exercise Price	
\$ 0.20	494	2.4	\$ 0.20	494	\$ 0.20	
\$ 0.30	318	4.3	\$ 0.30	318	\$ 0.30	
\$ 0.56	162	4.7	\$ 0.56	154	\$ 0.56	
\$ 1.20-\$1.56	504	8.5	\$ 1.39	175	\$ 1.24	

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

\$ 1.70-\$1.95	1,245	7.8	\$	1.83	702	\$	1.75
\$ 2.00-\$2.41	415	8.6	\$	2.25	141	\$	2.25
\$ 3.56-\$4.00	659	8.2	\$	3.72	329	\$	3.73
	3,797	6.9	\$	1.75	2,313	\$	1.41

Table of Contents

-19-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock Option Awards to Employees and Directors

The Company grants options to purchase common stock to some of 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 certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation 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.

The weighted-average assumptions used in determining the value of options granted and a summary of the methodology applied to develop each assumption are as follows:

Assumption	Nine Months Ended September 30,			
	2008		2009	
Expected price volatility	70	%	86	%
Expected term (in years)	6.1		6.1	
Risk-free interest rate	3.1	%	2.2	%
Dividend yield	0.0	%	0.0	%
Weighted-average fair value of options granted during the period	\$1.57		\$1.27	

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 comparable companies from a representative peer group selected based on industry and market capitalization data. An increase in the expected price volatility will increase the value of the option granted and the related compensation expense.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. Because there is insufficient historical information available to estimate the expected term of the stock-based awards, the Company adopted the simplified method for estimating the expected term pursuant to SAB No. 110. On this basis, the Company estimated the expected term of options granted by taking the average of the vesting term and the contractual term of the option. An increase in the expected life will increase the value of the option granted and the related compensation expense.

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. An increase in the risk-free interest rate will increase the value of the option granted and the related compensation expense.

Dividend Yield—The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease the value of the option granted and the related compensation expense.

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. For the nine months ended September 30, 2009 and 2008, the Company applied an estimated forfeiture rate of 5% to employee grants and 0% to director grants.

For the three months ended September 30, 2009 and 2008, the Company recognized stock-based compensation expense of \$173,837 and \$157,672, respectively, for option awards to employees and directors. For the nine months ended September 30, 2009 and 2008, the Company recognized stock-based compensation expense of \$513,957 and \$500,945 respectively. As of September 30, 2009, total unrecognized compensation cost related to unvested stock options granted or modified on or after January 1, 2006 was \$1.7 million. This amount is expected to be recognized as stock-based compensation expense in the Company's statements of operations over the remaining weighted average vesting period of 2.6 years.

Table of Contents

-20-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Common Stock Awards to Directors

In connection with the close of the IPO in October 2007, the Company adopted a new plan to compensate the independent members of the Board of Directors for their services. Under the terms of the Director Compensation Plan, each independent member is entitled to a combination of cash and unrestricted common stock for each board and committee meeting attended, up to specified annual maximums.

In accordance with these provisions, the Company issued 126,675 and 106,381 shares of common stock to independent directors during the nine months ended September 30, 2009 and 2008, respectively. These shares were issued out of the 2007 Plan. The fair market value of the stock issued to directors was recorded as an operating expense in the period in which the meeting occurred, resulting in total compensation expense of \$40,794 and \$211,163 for common stock awards to directors during the three and nine months ended September 30, 2009, respectively, and \$21,598 and \$114,885 respectively, during the three and nine months ended September 30, 2008, respectively.

Summary of Stock-Based Compensation Expense

Stock-based compensation expense is classified in the statements of operations in the same expense line items as cash compensation. Since the Company continues to operate at a net loss, it does not expect to realize any current tax benefits related to stock options.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2009	2008	2009
Research and development	\$81	\$88	\$336	\$271
General and administrative	98	127	331	454
Total stock-based compensation expense	\$179	\$215	\$667	\$725

Stock-Based Awards to Non-Employees

During the nine months ended September 30, 2009 and 2008, the Company granted options to purchase an aggregate of 273,191 and 16,000 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 weighted-average assumptions:

Assumption	Nine Months Ended September 30,			
	2008		2009	
Expected price volatility	70	%	87	%
Expected term (in years)	6.1		5.6	
Risk-free interest rate	3.1	%	1.9	%

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

Dividend yield	0.0	%	0.0	%
Weighted-average fair value of options granted during period	\$1.26		\$1.41	

For the three and nine months ended September 30, 2009, the Company recognized stock-based compensation expense of \$59,243 and \$138,243, respectively, related to non-employee option grants. For the three months ended September 30, 2008, the Company recognized expense of \$3,000, and, for the nine months ended on the same date, the Company reversed previously recognized expense of \$11,000 due to the required revaluation of unvested non-employee grants.

Table of Contents

-21-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 10. COLLABORATION AND LICENSE AGREEMENTS

Alcon Manufacturing, Ltd.

In August 2006, the Company entered into a collaboration and license agreement with Alcon Manufacturing, Ltd. (“Alcon”) to license to Alcon the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solution. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. This up-front fee was recorded as deferred revenue and is being amortized into revenue on a straight-line basis over the four-year funding term of the agreement, through August 2010. Additionally, the Company will receive semi-annual payments to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. The Company’s obligation to perform research and development activities under the agreement expires at the end of the four year funding term. As product candidates are developed and proceed through clinical trials and approval, the Company will receive milestone payments. If the products are commercialized, the Company will also receive royalties on any sales of products containing the Aganocide compound. Alcon has the right to terminate the agreement in its entirety upon nine months’ notice, or terminate portions of the agreement upon 135 days’ notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days’ notice.

Table of Contents

-22-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Revenue has been recognized under the Alcon agreement as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2009	2008	2009
Amortization of Upfront Technology Access Fee	\$625	\$625	\$1,875	\$1,875
On-going Research and Development (FTE)	675	1,075	2,025	2,794
Materials, Equipment, and Contract Study Costs	259	398	518	398
Milestone payments	-	-		1,000
Total	\$1,559	\$2,098	\$4,418	\$6,067

At December 31, 2008 and September 30, 2009, the Company had deferred revenue balances of \$4.2 million and \$3.1 million, respectively, related to the Alcon agreement which was comprised of the upfront technology access fee for all periods shown.

[Table of Contents](#)

-23-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Galderma

On March 25, 2009, the Company announced that it entered into an 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, excluding onychomycosis (nail fungus) and orphan drug indications. The agreement is exclusive and worldwide in scope, with the exception of Asian markets where the Company has commercialization rights, and North America, where the Company has an option to exercise co-promotion rights. Galderma will be responsible for the development costs of the acne and other indications, except in Japan, in which Galderma has the option to request that we share such development costs, and for the ongoing development program for impetigo, upon the achievement of a specified milestone. Galderma will also reimburse NovaBay for the use of its personnel in support of the collaboration. NovaBay retains the right to co-market products resulting from the agreement in Japan. In addition, NovaBay has retained all rights in other Asian markets outside Japan, and has the right to co-promote the products developed under the agreement in the hospital and other healthcare institutions in North America. Upon the termination of the agreement under certain circumstances, Galderma will grant NovaBay certain technology licenses which would require NovaBay to make royalty payments to Galderma for such licenses with royalty rates in the low-to mid-single digits.

Galderma will pay 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.

Revenue has been recognized under the Galderma agreement as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2008	2009	2008	2009
Amortization of Upfront Technology Access Fee	\$ -	\$ 150	\$ -	\$ 350
On-going Research and Development (FTE)	-	400	-	1,200
Materials, Equipment, and Contract Study Costs	-	575	-	575
Milestone payments	-	-	-	-
Total	\$ -	\$ 1,125	\$ -	\$ 2,125

The Company had deferred revenue balances of \$0 and \$650,000 respectively, at December 31, 2008 and September 30, 2009, related to the Galderma agreement, which consisted of the remaining amount to be amortized for the upfront technology access fee. As of September 30, 2009, the Company had not earned or received any milestone or royalty payments under the Galderma agreement.

KCI International VOF GP

In June 2007, the Company entered into a license agreement with an affiliate of Kinetic Concepts, Inc. ("KCI"), under which the Company granted KCI the exclusive rights to develop, manufacture and commercialize NVC-101, or NeutroPhase, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to the Company a non-refundable technology access fee of \$200,000. The up-front technology access fee was recorded as deferred revenue and has been amortized into revenue on a straight-line basis over the 18-month performance obligation period, through December 2008. Under the agreement, the Company is also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, the Company is entitled to receive payments of up to \$1.25 million if certain milestones are met. If products covered by the license are commercially launched, the Company will also receive royalty payments based on net revenues from sales by KCI of such products. KCI has the right to terminate the agreement without penalty upon 60 days' notice. The Company has the right to terminate the agreement if KCI has not commercially launched a product incorporating NVC-101, or any other product containing hypochlorous acid, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days' notice. As of December 31, 2008 all of the upfront fees related to KCI have been fully amortized.

Table of Contents

-24-

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 11. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan covering all eligible employees. The Company is not required to contribute to the plan and has made no contributions through September 30, 2009.

NOTE 12. INCOME TAXES

As of December 31, 2008 the Company had net operating loss carryforwards for both federal and state income tax purposes of \$20.0 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2014 and 2027. 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, the Company's 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.

The Company tracks the portion of its federal and state net operating loss carryforwards attributable to stock option benefits in a separate memo account. Therefore, these amounts are not included in gross or net deferred tax assets. The benefit of these net operating loss carryforwards will only be recorded to equity when they reduce cash taxes payable. The Company elected to use the "with-and-without" approach for utilizing the tax benefits of stock option exercises. These benefits would result in a credit to additional paid-in-capital when they reduce income taxes payable.

Uncertain Income Tax Positions

The Company follows authoritative guidance for uncertain tax positions. This accounting guidance prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements and it also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

The Company adopted the relevant accounting guidance on January 1, 2007. There was no impact on the Company's consolidated financial position, results of operations and cash flows as a result of adoption. The Company has no unrecognized tax benefit as of December 31, 2008, including no accrued amounts for interest and penalties. The Company's policy will be to recognize interest and penalties related to income taxes as a component of income tax expense. The Company is subject to income tax examinations for U.S. income taxes and state income taxes from 2002 forward. The Company does not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2009.

NOTE 13. SUBSEQUENT EVENTS

In October 2009, the Company has announced that its Aganocide® compounds demonstrate potent antifungal activity in an established pre-clinical infected nail model of onychomycosis. The study data was presented on October 31st at the 47th Annual Meeting of the Infectious Diseases Society of America (IDSA) in Philadelphia.

The Company has evaluated events that occurred through November 12, 2009, the date of issuance of these condensed consolidated financial statements.

Table of Contents

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. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as “expects,” “anticipates,” “targets,” “goals,” “projects,” “intends,” “plans,” “believes,” “seeks,” “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 development stage biopharmaceutical company focused on developing innovative product candidates for the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid rise in drug resistance. We have discovered and are developing a class of non-antibiotic anti-infective compounds, which we have named Aganocide compounds. These compounds are based upon small molecules that are naturally generated by white blood cells when defending the body against invading pathogens. We believe that our Aganocide compounds could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial and viral infections. In laboratory testing, our Aganocide compounds have demonstrated the ability to destroy all bacteria against which they have been tested. Furthermore, because of their mechanism of action, we believe that bacteria are unlikely to develop resistance to our Aganocide compounds.

In August 2006, we entered into a collaboration and license agreement with Alcon, to license to Alcon the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. In addition to the technology access fee, we are entitled to receive semi-annual payments from Alcon to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compounds. Alcon has the right to terminate the agreement in its entirety upon nine months' notice, or terminate portions of the agreement upon 135 days' notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

Table of Contents

Alcon is responsible for all of the costs that it incurs in developing the products using the Aganocide compounds. We announced the clearance of an Investigational New Drug (IND) application submitted by Alcon to the FDA to permit the clinical development of Novabay's NVC-422 for infection of the eye. The IND clearance has triggered the immediate payment of the first milestone of \$1,000,000 from Alcon to Novabay. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized product.

On March 25, 2009, we announced that we entered into 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. The agreement is exclusive and worldwide in scope, with the exception of Asian markets where we have commercialization rights, and North America, where we have an option to exercise co-promotion rights. Galderma will be responsible for the development costs of acne and other indications, except in Japan, in which Galderma has the option to request that we share such development costs, and for the ongoing development program for impetigo, upon the achievement of a specified milestone. Galderma will also reimburse NovaBay for the use of its personnel in support of the collaboration. NovaBay retains the right to co-market products resulting from the agreement in Japan. In addition, NovaBay has retained all rights in other Asian markets outside Japan, and has rights to promote the products developed under the agreement in the hospital and other healthcare institutions in North America. Galderma will pay 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 this agreement then NovaBay will receive royalties whose rates escalate as sales increase. Upon the termination of the agreement under certain circumstances, Galderma will grant NovaBay certain technology licenses which would require NovaBay to make royalty payments to Galderma for such licenses with royalty rates in the low- to mid-single digits.

Our business model is to develop our Aganocide compounds and enter into collaboration and license agreements with other entities for different indications using our Aganocide compounds.

To date, we have generated no revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock, and the technology access fee from Alcon. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of September 30, 2009, we had an accumulated deficit of \$27.3 million. Our accumulated deficit resulted from research and development expenses and general and administrative expenses. We expect to continue to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

Table of Contents

-27-

Recent Events

In June 2009, we filed a shelf registration statement on Form S-3 registering up to \$20,000,000 of our securities, which may be in the form of common stock, preferred stock, warrants or debt securities, or units comprising a combination of these securities. The shelf registration statement was declared effective in August 2009. On August 26, 2009, we closed a registered direct offering of 1,225,000 units, under this shelf registration statement, with each unit consisting of (i) one share of the NovaBay common stock, par value \$0.01 per share, and (ii) one warrant to purchase one share of NovaBay common stock. The purchase price for each unit was \$2.00. Each warrant has an exercise price of \$2.75, which will be exercisable 180 days after issuance and will expire five years from the date of issuance. The units were not issued or certificated and neither the units nor warrants trade on any exchange or are listed for quotation on any market. Maxim Group LLC served as placement agent for the offering.

In July 2009, we announced that Alcon has begun treating patients in a Phase 2 clinical trial of NovaBay's patented lead Aganocide® compound, NVC-422, for viral conjunctivitis, a type of "pink eye."

In September 2009, we announced that we initiated our Phase 2a proof-of-concept study for the treatment of impetigo.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim reporting. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions 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 condensed 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, income taxes, intangible assets, long-term service contracts 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 Condensed Consolidated Financial Statements, 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, 2008. We have not materially changed these policies from those reported in our Annual Report on Form 10-K for the year ended December 31, 2008.

Table of Contents

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2008 and September 30, 2009

License and Collaboration Revenue

Total license and collaboration revenue was \$3.2 million for the three months ended September 30, 2009, compared to \$1.6 million for the three months ended September 30, 2008, and was \$8.2 million for the nine months ended September 30, 2009, compared to \$4.5 million for the nine months ended September 30, 2008. License and collaboration revenue consisted almost exclusively of amounts earned under the license and collaboration agreements with Alcon and Galderma for amortization of the upfront technology access fees, milestones, and other amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The upfront technology access fee of \$10.0 million from Alcon is being amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront fee of \$1.0 million from Galderma is being amortized into revenue on a straight-line basis over the 20 month funding term of the agreement, through October 2010. The upfront technology access fee from KCI of \$200,000 has been amortized on a straight-line basis over 18 months through December 2008.

To the extent we earn milestone payments under the Alcon and Galderma collaborations, we would expect revenues to increase. We expect to receive approximately \$4.0 million during the 20 month initial period of the Galderma agreement, inclusive of the \$1.0 million initial payment received in March 2009. However, we cannot predict if and when we will receive any milestone or royalty payments from these collaborations.

Research and Development

Total research and development expenses increased by 24.1% to \$2.0 million for the three months ended September 30, 2009 from \$1.6 million for the three months ended September 30, 2008. Total research and development expenses decreased by 29.9% to \$4.8 million for the nine months ended September 30, 2009 from \$6.9 million for the nine months ended September 30, 2008. The increase for the three month period was primarily due to an increase in clinical studies in 2009. The decrease in the nine month period was primarily due to delays in various projects during the first half of 2009.

We expect to incur increased research and development expenses in the last quarter of 2009 and in subsequent years as we continue to increase our focus on developing product candidates, both independently and in collaboration with Alcon and Galderma. In particular, we expect to incur ongoing clinical, chemistry, and manufacturing expenses during the latter half of 2009 in connection with the common cold, dermatology, and catheter associated urinary tract infections programs.

General and Administrative

Total general and administrative expenses decreased by 15.2% to \$1.3 million for the three months ended September 30, 2009 compared to \$1.5 million for the three months ended September 30, 2008. Total general and administrative expenses decreased by 10.8% to \$4.1 million for the nine months ended September 30, 2009 compared to \$4.6 million for the nine months ended September 30, 2008. General and administrative expenses were lower overall for each of the three and nine month periods due to decreased headcount, and decreased spending on Sarbanes – Oxley implementation.

We expect that general and administrative expenses will remain flat during the last quarter of 2009. In subsequent years, there may be slight increases in general and administrative spending depending upon overall growth of the company.

Table of Contents

-29-

Other Income (Expense), Net

Other income(expense), net decreased to \$(22,000) for the three months ended September 30, 2009 from \$77,000 for the three months ended September 30, 2008. Other income/(expense), net decreased to \$(24,000) for the nine months ended September 30, 2009 from \$334,000 for the nine months ended September 30, 2008. This decrease was primarily attributable to the higher cash balances in the prior year which generated higher interest income. Interest income relates primarily to interest earned on cash, cash equivalents and investments in marketable securities. See "Note 3-Short Term Investments."

We expect that other income (expense), net will vary based on fluctuations in our cash balances and borrowings under equipment loans and the interest rate paid on such balances and borrowings.

Liquidity and Capital Resources

We have incurred cumulative net losses of \$27.3 million since inception through September 30, 2009. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the private placement of our preferred stock, our initial public offering, and the recently concluded registered direct offering of our common stock. We raised total net proceeds of \$12.6 million from sales of our preferred stock in 2002 through 2006. In October 2007, we completed our IPO in which we raised a total of \$20.0 million, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million. In August 2009, we completed a registered direct offering and had net proceeds of \$1.9 million.

In August 2006, we entered into a collaboration and license agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of \$10.0 million in September 2006. Additionally, we are entitled to receive semi-annual payments each January and July over the four year term of the agreement to support on-going research and development efforts. In both January and July 2007, we received a payment of \$1.4 million to support the performance of research and development activities throughout 2007. The Alcon agreement also provides for milestone payments upon the achievement of specified milestones in each field of use and royalty payments upon the sale of commercialized products. The aggregate milestone payments payable in connection with the ophthalmic, optic and sinus fields are \$19.0 million, \$12.0 million and \$39.0 million, respectively. In January 2009, we received \$1.0 million for the non-rejection of an IND application related to its optic indication. However, we cannot predict when, if ever, future milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.

During April 2007, we entered into a master security agreement to establish a \$1.0 million equipment loan facility with a financial institution. The purpose of the loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2009 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. In April 2008, the agreement was extended through April 2009, and as a result no further borrowings are permitted on this loan. There are no loan covenants specified in the agreement. As of September 30, 2009, we had an outstanding equipment loan balance of \$565,308 carrying a weighted-average interest rate of 10.98%. The principal and interest due under the loan will be repaid in equal monthly installments through June 2011.

In March 2009, we entered into a license agreement with Galderma. Under the terms of the agreement, we have received an initial upfront payment of \$1.0 million. In addition, Galderma will pay to Novabay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide® compounds.

Table of Contents

-30-

Cash and Cash Equivalents

As of September 30, 2009, we had cash, cash equivalents, and short-term investments of \$11.7 million compared to \$12.1 million at December 31, 2008. We expect the total cash, cash equivalents, short-term investments along with our license agreements from Alcon and Galderma and proceeds from registered direct offering of our common stock to be sufficient to fund cash requirements for the next twelve months.

Cash Flows

The following table provides information regarding our cash flows and our capital expenditures for the nine months ended September 30, 2008 and 2009.

	Nine Months Ended September 30,	
(in thousands)	2008	2009
Cash provided by (used in):		
Operating activities	\$(7,038)	\$(1,544)
Investing activities	7,505	(1,646)
Financing activities	331	1,721
Capital expenditures (included in investing activities above)	(521)	(596)

Cash Used in Operating Activities

For the nine months ended September 30, 2009 cash used in operating activities was \$1.5 million, due to the receipt of milestone and other cash payments from collaborative agreements, which offset for the most part our research and development and general and administrative expenses.

Cash Used in (Provided by) Investing Activities

For the nine months ended September 30, 2009, cash used in investing activities of \$1.6 million was attributable to purchases of short-term investments of \$1.1 million and purchases of property and equipment of \$596,000.

Cash Provided by(Used in) Financing Activities

Net cash provided in financing activities of \$1.7 million for the nine months ended September 30, 2009 was primarily attributable to the registered direct shelf offering of August 26, 2009 which provided net proceeds of \$1.9 million and was offset in part by the payments on the equipment loan and capital lease. Additionally, we received \$78,000 of proceeds from stock issuances related to the exercise of stock options during the nine months ended September 30, 2009.

Table of Contents

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2008 we had net operating loss carryforwards for both federal and state income tax purposes of \$20.0 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2014 and 2027.

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. There can be no assurances, however, that our business will not be affected by inflation.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Contractual Obligations

Our commitments consist of an operating lease, a capital lease, and an equipment loan. 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, 2015 and the total commitment as of September 30, 2009 is \$6.0 million due over the lease term. Our commitment for a capital lease consists of the total payments due under one lease of laboratory equipment. The capital lease amount of \$22,393 includes \$1,000 of interest payments over the remaining term of the lease. Our commitment for the equipment loan consists of the total payments due under the loan facility of \$615,011. This amount includes \$49,702 of interest payments over the remaining term of the loan.

We expect the total cash, cash equivalents, and short-term investments, along with committed funding under our license agreement from Alcon, will be sufficient to fund cash requirements for the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

- 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 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.

We do not anticipate that we will generate significant product revenue for a number of years. Until we can generate a sufficient amount of product revenue, if ever, 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.

Table of Contents

-32-

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. 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. We have recently formed a wholly-owned subsidiary, which is incorporated under the laws of British Columbia (Canada), which may conduct research and development activities in Canada. To the extent we conduct operations in Canada, fluctuations in the exchange rates of the U.S. and Canadian currencies may affect our operating results.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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 our disclosure controls and procedures were effective 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

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2009, and has concluded that there was no change during the quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 4T. CONTROLS AND PROCEDURES

Not applicable.

[Table of Contents](#)

-33-

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 6, 2009, Pathogenics, Inc. filed a complaint against us in the United States District Court for the District of Massachusetts, Case No. 09-CV-11142-RGS. The complaint asserts that we breached a contract, dated April 7, 2009, between Novabay and Pathogenics because we did not register 250,000 shares of Novabay common stock issued to Pathogenics pursuant to such agreement on our recently filed universal shelf registration statement. Under such agreement, Novabay terminated its commercial relationship with Pathogenics for consideration, including the issuance of such 250,000 shares of common stock. The agreement provides Pathogenics with registration rights in certain circumstances. Pathogenics complaint sought monetary damages and certain injunctive relief, including an order to compel registration of the shares held by Pathogenics and enjoin our registration of stock. We have not been served with the complaint, and on August 13, 2009 the parties entered into a settlement agreement settling the matter. Novabay does not consider this matter to be material. This matter was also reported in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.

ITEM 1A. RISK FACTORS

The risk factors facing our company have not changed materially from those set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 31, 2009, except that the risk factor relating to shares subject to lock up agreements held by certain of our officers and directors has been revised to reflect intervening events.

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 when assessing our business and the forward-looking statements made in this Quarterly Report on Form 10-Q. The risks and uncertainties described below are not the only ones facing our business. 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.

Risks Relating to Our Business

Current worldwide economic conditions may limit our access to capital, adversely affect our business and financial condition, as well as further decrease our stock price.

General worldwide economic conditions have experienced a downturn due to the effects of the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Although the impact of the downturn on our business is uncertain at this time, the downturn may adversely affect our business and operations in a number of ways, including making it more difficult for us to raise capital as well as making it more difficult to enter into collaboration agreements with other parties. Like many other stocks, our stock price has been subject to fluctuations and has decreased substantially in recent months. Our stock price could further decrease due to concerns that our business, operating results and financial condition will be negatively impacted by a worldwide economic downturn.

Table of Contents

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.

We expect our capital outlays and operating expenditures to substantially increase over at least the next several years as we expand our product pipeline and increase research and development efforts and clinical and regulatory activities. 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 any of our 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 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 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.

We do not currently have any commitments for future external funding. 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 and the credit crisis, 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 shareholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing shareholders. 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.

[Table of Contents](#)

-35-

We are an early stage company with a history of losses. We expect to incur net losses for the foreseeable future and we may never achieve or maintain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2006, 2007 and 2008 we had net losses of approximately \$5.3 million, \$5.4 million, and \$8.1million, respectively. Through September 30, 2009, we had an accumulated deficit of approximately \$27.3 million. We have been, and expect to remain for the foreseeable future, mostly in a research and development stage. Since our inception, we have not generated revenue, except for modest revenue in 2006, 2007, 2008 and first nine months of 2009 relating to three research and development collaboration and license agreements. We have incurred substantial research and development expenses, which were approximately \$4.1 million, \$7.4 million, and \$9.6 million for the years ended December 31, 2006, 2007, and 2008, respectively and \$4.8 million for the nine months ended September 30, 2009. We expect to continue to make, for at least the next several years, significant 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 do not expect any of our current product candidates to be commercialized within the next several years, if at all. We expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- 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 develop, obtain regulatory approval for and commercialize our product candidates, either independently or with partners, we will not be able to generate such revenues or 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 very limited data on the use of our products in humans and will need to perform costly and time consuming clinical trials in order to bring our products to market.

Most of the data that we have on our products is from in-vitro (laboratory) studies or in-vivo animal studies and our human data is from Phase I safety studies or small-scale Phase IIa exploratory- studies. We will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain approval from the FDA of our drug product candidates. Often, positive in-vitro or in-vivo animal studies are not followed by positive results in human clinical trials, and we may not be able to demonstrate that our products are safe and effective for indicated uses in humans. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials.

Table of Contents

We currently do not have any marketable products, and if we are unable to develop and obtain regulatory approval for products that we develop, we may never generate product revenues.

To date, our revenues have been derived solely from research and development collaboration and license agreements. We have never generated revenues from sales of products and we cannot guarantee that we will ever have marketable drugs or other products. 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. Before proceeding with clinical trials, we will conduct pre-clinical studies, which may, or may not be, valid predictors of potential outcomes in humans. If pre-clinical studies are favorable, we will then begin clinical trials. 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. Our commercial revenues from sales of products will be derived from sales of products that may not be commercially available for at least the next several years, if at all.

We have limited experience in developing drugs and medical devices, and we may be unable to commercialize any 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 never commercialized, any of our product candidates. 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.

Table of Contents

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. If a 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.

We must maintain and expand expensive finance and accounting systems, procedures and controls in order to grow our business and organization, which will increase our costs and require additional management resources.

We completed our initial public offering, or IPO, in October 2007. As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC and Canadian securities regulatory authorities, including expanded disclosure and accelerated reporting requirements and more complex accounting rules. We are also required to comply with marketplace rules and the heightened corporate governance standards of the NYSE Amex. Compliance with these rules has been expensive, and there are additional rules with which we have not yet needed to comply but which we will need to comply with in the future. For example, beginning with our Annual Report on Form 10-K for the year ended December 31, 2010, we will be required to have our independent auditors audit our internal control over financial reporting. If our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our Annual Report on Form 10-K for 2010, or our business grows and we are not able to comply with accelerated reporting obligations, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed with the SEC and with Canadian securities regulatory authorities. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

If we do not maintain our current research collaborations with Alcon and Galderma, and enter into additional collaborations, a portion of our funding may decrease and inhibit our ability to develop new products.

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. We also recently entered into 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.

We cannot assure you that our collaborations with Alcon or Galderma or any other collaborative arrangement will be successful, or that we will receive the full amount of research funding, milestone payments or royalties, or that any commercially valuable intellectual property will be created, from these arrangements. If Alcon or Galderma were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research contemplated by our collaboration with them could be delayed or terminated and our costs of performing studies may increase. We plan on entering into additional collaborations and licensing arrangements. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and 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. If we are unable

to enter into, maintain or extend successful collaborations, our business may be harmed.

Table of Contents

-38-

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

Our long-term viability and growth will depend upon the successful development and commercialization of other products 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 the expansion of our pipeline through spending on 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. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets.

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

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, and enter into technology or pharmaceutical compound licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to enhance our ability to commercialize our product candidates and expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of commercial partnering agreements, strategic alliances, joint ventures or in-licensing of compounds. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we in-license any additional compounds, we may fail to develop the product candidates, and spend significant resources before determining whether a compound we have in-licensed will produce revenues. Any future acquisitions or in-licensing by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute our shareholders' interests 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.

Table of Contents

-39-

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

We do not currently operate manufacturing facilities for clinical or commercial production of our product NeutroPhase and other product candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture NeutroPhase or 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 the potential for product revenues.

Our products, if developed and commercialized, 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 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.

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.

Our success largely depends on the skills, experience and efforts of our officers, especially our Chief Executive Officer, Chief Financial Officer, Vice President of Research and Development, Vice President of Medical Affairs, 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.

Table of Contents

-40-

If we 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 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.

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

We will aim to obtain regulatory approval in the United States as well as in other countries. To obtain regulatory approval to market our proposed products outside of the United States, 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 United States, 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.

[Table of Contents](#)

-41-

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

In order 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.

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.

Table of Contents

-42-

Government agencies may establish usage guidelines that directly apply to our 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 products that we may develop. In addition there can be no assurance that government regulations applicable to our 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 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 United States or in other countries.

Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action, 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.

Several potential indications for our product candidates may be regulated under the medical device regulations of the FDA administered by the Center for Devices and Radiological Health and the same physical product may be regulated by the FDA's Center for Drug Evaluation and Research for another indication. Our products may be classified by the FDA as a drug or a medical device depending upon their mechanism of action, indications for use or claims. For example, for NVC-422, if the indication is for bladder lavage, we believe it would be classified as a medical device, whereas we believe it would be considered a drug when it is indicated for the prevention of urinary tract infection. Similarly, the use of NVC-101 as a solution for cleansing and debriding wounds is considered a medical device. The determination as to whether a particular indication is considered a drug or a device is based in part upon prior precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development for that indication could have a significant adverse impact due to the more rigorous 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. In many cases, reimbursement for devices is significantly lower than for drugs and there could be a significant negative impact on our revenues.

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 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 (as further described below), 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.

Table of Contents

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 \$3.0 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 nine months of exclusivity as a generic product under the Waxman-Hatch 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 in order 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 attorneys 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.

Table of Contents

-44-

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 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 trials, 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. At this point in time, 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 United States. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies like NovaBay. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e. for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to function profitably in the future.

Table of Contents

-45-

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.

Our business and future growth depend on the development, use and ultimate 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.

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.

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 United States 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.

NovaBay aggressively protects and enforces its patent rights worldwide. However, certain risks remain. There is no assurance that patents will issue from any of our applications or, for those patents we have or that do issue, that the claims will be sufficiently broad to protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the NVC-101 composition. If a potential competitor introduces a similar method of using NVC-101 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 NVC-101 composition, and any revenues arising from such protection would be adversely impacted.

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

Table of Contents

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 United States. 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.

If bacteria develop resistance to Aganocide compounds, our revenues could be significantly reduced.

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds, we do not expect bacteria to be able to develop resistance to Aganocide 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 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 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.

Table of Contents

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 no internal sales, marketing or distribution capabilities. In order to commercialize any product candidates approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any products we develop, 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, 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 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.

[Table of Contents](#)

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 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.

Our ability to commercialize our product candidates will depend, in part, on the extent to which health insurers, government authorities and other third-party payers will reimburse the costs of products which may be developed by us or our partners. We expect that a portion of our economic return from partnering arrangements with pharmaceutical companies and other collaborators will be derived from royalties, fees or other revenues linked to final sales of products that we or our partners develop. Newly-approved pharmaceuticals and other products which are developed by us or our partners will not necessarily be reimbursed by third-party payers or may not be reimbursed at levels sufficient to generate significant sales. Government and other third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs or medical devices. Cost control initiatives such as these could adversely affect our or our collaborators' ability to commercialize products. In addition, real or anticipated cost control initiatives for final products may reduce the willingness of pharmaceutical companies or other potential partners to collaborate with us on the development of new products.

Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic data on any of our product candidates. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and medical devices, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Adequate third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of our product candidates could be limited.

Table of Contents

Risks Relating to Owning Our Common Stock

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

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

- the 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' earning 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 shareholder 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 directors, executive officers and principal shareholders have significant voting power and may take actions that may not be in the best interests of our other shareholders.

As of September 30, 2009, our officers and directors collectively controlled approximately 5,048,824 shares of our outstanding common stock (and approximately 911,950 shares of our common stock when including options held by them which were exercisable as of or within 60 days of September 30, 2009). Furthermore, as of September 30, 2009, our largest shareholder, a family trust established and controlled by Dr. Ramin Najafi, our Chairman and Chief Executive Officer, beneficially owned 3,128,700 shares or 13.4% of our outstanding common stock. As a result, Dr. Najafi can significantly influence the management and affairs of our company and most matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other shareholders.

Table of Contents

Future sales of shares by our officers and directors could cause the market price of our common stock to drop significantly, even if our business is doing well.

Up to 5,048,824 shares held by certain of our officers and directors (including shares issuable upon exercise of outstanding stock options) will become eligible for sale in the public market on November 24, 2009, as the shares are released from lock-up agreements with the placement agent in connection with this offering. Sales of these shares could cause our stock to drop significantly, even if our business is doing well.

In addition, at any time and without public notice, we and the underwriters may release, at our respective discretions, all or some of the securities subject to our respective lock-up agreements, subject to applicable regulatory requirements. As restrictions on resale end, the market price of our stock could drop significantly if the holders of those shares sell them or are perceived by the market as intending to sell them. These declines in our stock price could occur even if our business is otherwise doing well.

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 articles of incorporation and bylaws and California law contain provisions that could discourage a third party from making a takeover offer that is beneficial to our shareholders.

Anti-takeover provisions of our amended and restated articles of incorporation, amended and restated bylaws and California law may have the effect of deterring or delaying attempts by our shareholders 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 shareholder nominations and proposals;
 - the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a California corporation, we are subject to California 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 California Corporations Code 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 shareholders could receive a premium for their shares, or effect a proxy contest for control of NovaBay or other changes in our management.

[Table of Contents](#)

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.

We may be considered a “foreign investment entity” which may have adverse Canadian tax consequences for our Canadian investors.

Although we believe that we are not currently a “foreign investment entity” within the meaning of the Canadian tax laws, no assurances can be given in this regard or as to our status in the future. If we become a “foreign investment entity” within the meaning of the Canadian tax laws, there may be certain adverse tax consequences for our Canadian investors.

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

Use of Proceeds from Sales of Registered Securities

On October 24, 2007, a Registration Statement on Form S-1 (File. No. 333-140714) relating to our initial public offering was declared effective by the SEC. The closing was held October 31, 2007. The net proceeds to NovaBay from the offering were approximately \$17.1 million. From the effective date of the registration statement until September 30, 2009, we estimate we have used \$9.85 million for research and development, \$2.1 million for working capital and \$2.6 million for other general purposes. The remaining estimated \$2.55 million have been invested in various interest-bearing money market accounts and marketable securities.

The amounts reflected above included expenditures for: the Phase I and II clinical development of NVC-422 in pre-surgical nasal preparation; pre-clinical, Phase I and initial Phase II studies of NVC-422 in the prevention of catheter associated urinary tract infections; and pre-clinical studies to select among additional indications to be taken into development. These expenditures did not represent a material change from the use of proceeds described in the prospectus related to the offering.

[Table of Contents](#)

-52-

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.

Table of Contents

-53-

SIGNATURES

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

Date: November 12, 2009

NOVABAY PHARMACEUTICALS, INC.

/s/ Ramin Najafi

Ramin (“Ron”) Najafi, Ph.D.
President and Chief Executive Officer
(duly authorized officer)

Date: November 12, 2009

/s/ Thomas J. Paulson

Thomas J. Paulson
Chief Financial Officer
(principal financial officer)

Table of Contents

-54-

EXHIBIT INDEX

EXHIBIT INDEX

Exhibit No.	Description
1.1	Placement Agent Agreement, dated August 21, 2009, by and between NovaBay Pharmaceuticals, Inc. and Maxim Group LLC. (Incorporated by reference to the exhibit with the same description from the Company's current report on Form 8-K , as filed with the SEC on August 21, 2009.)
3.1	Amended and Restated Articles of Incorporation of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
3.2	Amended and Restated Bylaws of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
4.1	Specimen common stock certificate (Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-138379) initially filed with the Securities and Exchange Commission on November 2, 2006, as amended.)
4.2	Form of Warrant issued in the August 2009 offering. (Incorporated by reference to the exhibit with the same description from the Company's current report on Form 8-K , as filed with the SEC on August 21, 2009.)
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002