NovaBay Pharmaceuticals, Inc.
Form 10-Q
May 16, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2011

OR

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

For the transition period from to

Commission file number 001-33678

NOVABAY PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o Noo

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

Large accelerated filer o Accelerated filer o

Non-accelerated filer	o	Smaller reporting company	x

(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 o No x

As of May 2, 2011, there were 23,449,755 shares of the registrant's common stock outstanding.

NOVABAY PHARMACEUTICALS, INC.

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

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

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PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	March 31, 2011 (unaudited)	December 31, 2010 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$11,869	$11,534
Short-term investments	750	1,272
Accounts receivable	—	500
Prepaid expenses and other current assets	312	448
Total current assets	12,931	13,754
Property and equipment, net	1,598	1,588
Other assets	138	174
TOTAL ASSETS	$14,667	$15,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$346	$406
Accrued liabilities	1,033	726
Equipment loan	42	106
Deferred revenue	2,311	1,485
Total current liabilities	3,732	2,723
Deferred revenues - non-current	1,889	2,204
Deferred rent	104	99
Total liabilities	5,725	5,026
Stockholders' Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized; none outstanding at at March 31, 2011 and December 31, 2010	—	—
Common stock, $0.01 par value; 65,000 shares authorized at March 31, 2011 and December 31, 2010; 23,450 and 23,392 issued and outstanding at March 31, 2011 and December 31, 2010, respectively	235	234
Additional paid-in capital	38,894	38,469
Accumulated other comprehensive loss	—	(14)
Accumulated deficit during development stage	(30,187)	(28,199)
Total stockholders' equity	8,942	10,490
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$14,667	$15,516

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

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NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except per share data)	Three Months Ended March 31, 2011	2010	Cumulative Period from July 1, 2002 (inception) to March 31, 2011
Revenue:			
License and collaboration revenue	$2,490	$2,084	$ 42,096
Operating Expenses:			
Research and development	2,920	2,233	43,880
General and administrative	1,515	1,469	29,740
Total operating expenses	4,435	3,702	73,620
Operating Loss	(1,945)	(1,618)	(31,524)
Other income (expense), net	(31)	(11)	1,420
Loss before income taxes	(1,976)	(1,629)	(30,104)
Provision for income taxes	(12)	—	(83)
Net loss	$(1,988)	$(1,629)	$ (30,187)
Net loss per share:			
Basic and diluted	$(0.08)	$(0.07)	
Shares used in per share calculations:			
Basic and diluted	23,428	23,300	

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

NOVABAY PHARMACEUTICALS, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)	Three Months Ended March 31, 2011	2010	Cumulative Period from July 1, 2002 (inception) to March 31, 2011
Cash flows from operating activities:			
Net loss	$(1,988)	$(1,629)	$(30,187)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	107	106	1,611
Accretion of discount on short-term investments	—	—	(252)
Net realized loss on sales of short-term investments	17	—	17
Loss on disposal of property and equipment	—	—	121
Stock-based compensation expense for options issued to employees and directors	293	304	3,927
Compensation expense for warrants issued for services	—	7	162
Stock-based compensation expense for options and stock issued to non-employees	130	123	1,018
Taxes paid by LLC	—	—	1
Changes in operating assets and liabilities:			
Decrease in accounts receivable	500	3,714	—
(Increase) decrease in prepaid expenses and other assets	194	27	(306)
Increase (decrease) in accounts payable and accrued liabilities	252	(594)	1,460
Increase in deferred revenue	511	534	4,199
Net cash provided by (used in) operating activities	16	2,592	(18,229)
Cash flows from investing activities:			
Purchases of property and equipment	(117)	(30)	(3,211)
Proceeds from disposal of property and equipment	—	—	46
Purchases of short-term investments	(750)	(862)	(101,715)
Proceeds from maturities and sales of short-term investments	1,250	300	101,187
Cash acquired in purchase of LLC	—	—	516
Net cash provided by (used in) investing activities	383	(592)	(3,177)
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	8	37	1,924
Proceeds from initial public offering, net of costs	—	—	17,077
Proceeds from (payment on) shelf offering, net of costs	(8)	—	1,934
Proceeds from stock subscription receivable	—	—	873
Proceeds from issuance of notes	—	—	405
Principal payments on capital lease	—	(7)	(157)
Proceeds from borrowings under equipment loan	—	—	1,216

Principal payments on equipment loan	(64)	(98)	(1,174)
Net cash provided by (used in) financing activities	(64)	(68)	33,275
Net increase in cash and cash equivalents	335	1,932	11,869
Cash and cash equivalents, beginning of period	11,534	10,992	—
Cash and cash equivalents, end of period	$11,869	$12,924	$11,869

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

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals Inc. is a clinical stage biotechnology company (incorporated under the laws of the State of Delaware) developing a first-in-class, anti-infective platform of compounds, called the Aganocide® compounds, for the topical 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 June 2010, we changed the state in which we are incorporated (the Reincorporation), and are now incorporated under the laws of the State of Delaware. All references to “we,” “us,” “our,” or “the Company” herein refer to the California corporation prior to the date of the Reincorporation, and to the Delaware corporation on and after the date of the Reincorporation. We currently operate in one business segment.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited 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 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, 2010. The consolidated balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

The Company believes these 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.

The financial statements have been prepared under the guidelines for Development Stage Entities. 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 therefrom. As of March 31, 2011, we continued to conduct clinical trials and had not commenced our planned principal operations.

Certain amounts for prior periods have been reclassified to conform to current period presentation.

Principles of Consolidation

The accompanying 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.

Use of Estimates

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

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of March 31, 2011, the Company's cash and cash equivalents were held in financial institutions in the United States and include deposits in money market funds, which were unrestricted as to withdrawal or use.

The Company classifies all highly liquid investments with a stated maturity of greater than three months at the date of purchase as short-term investments. Short-term investments generally consist of 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. The 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.

Concentrations of Credit Risk and Major Partners

Financial instruments which potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. We maintain 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. We do not believe we are exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, we have established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

During the quarters ended March 31, 2011 and 2010, 100% of our operating revenues were derived from two of our collaborative partners. As of December 31, 2010, 100% of our accounts receivables were from one of our collaborative partners.

Comprehensive Loss

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

Fair Value Measurement 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.

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)

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

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 undiscounted 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.

Revenue Recognition

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

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

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

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

Milestones—Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

Royalties—We recognize royalty revenues from licensed products upon the sale of the related products.

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services. Research and development expenses under the collaborative agreements approximate the revenue recognized, excluding milestone and upfront payments received under such arrangements.

Patent Costs

We expense patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718, Compensation-Stock Compensation. Under the fair value recognition provisions, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model. See Note 7 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Income Taxes

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

Net Loss per Share

Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share gives effect to all dilutive potential common shares outstanding during the period including stock options and stock warrants, using the treasury stock method, using the if-converted method. Potentially dilutive common share equivalents are excluded from the diluted net loss per share computation since their effect would be anti-dilutive. The following table sets forth the reconciliation between basic net loss per share and diluted net loss per share:

Three Months Ended March 31,

(in thousands, except per share amounts)	2011	2010
Net loss	$ (1,988)	$ (1,629)
Basic shares	23,428	23,300
Add: shares issued upon assumed exercise of stock options	—	—
Diluted shares	23,428	23,300
Basic net loss per share	$ (0.08)	$ (0.07)
Diluted net loss per share	$ (0.08)	$ (0.07)

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

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

	Three Months Ended March 31,	
(In thousands)	2011	2010
Stock options	5,137	4,377
Stock warrants	1,375	1,725
	6,512	6,102

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued ASU No. 2010-17 (Topic 605), Revenue Recognition—Milestone Method. This standard provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The amendments in this update provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all applicable criteria. The amendments in this update are effective for the Company on a prospective basis for milestones achieved after December 31, 2010. The implementation of this standard is not expected to have a significant impact on our financial position or results of operations.

In September 2009, the FASB issued update 2009-13, ASC 605, Revenue Recognition: Multiple-Deliverable Revenue Arrangements-a consensus of the FASB Emerging Issues Task Force. 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 adoption is not expected to have a material impact on our consolidated financial statements.

NOTE 3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

Short-term investments at March 31, 2011 and December 31, 2010 consisted of the following:

	March 31, 2011			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Market Value
Certificates of Deposit	$ 750	$ —	$ —	$ 750
	$ 750	$ —	$ —	$ 750

December 31, 2010

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Corporate bonds	$ 767	$ 19	$ (14)	$ 772
Certificates of deposit	500	—	—	500
	$ 1,267	$ 19	$ (14)	$ 1,272

All short-term investments at March 31, 2011 and December 31, 2010 mature in less than one year. Unrealized holding gains and losses classified as available-for-sale are recorded in accumulated other comprehensive income (loss).

We recognized realized losses of $17,000 and $0 for the three months ended March 31, 2011 and 2010.

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.

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

The following table presents the Company's investments measured at fair value on a recurring basis as of March 31, 2011:

		Fair Value Measurements Using		
	Balance at March 31, 2011	Quoted Prices in Active Markets for Identical Items (Level 1)	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 11,869	$ 11,869	$ —	$ —
Short-term investments:				
Corporate bonds	—	—	—	—
Municipal bonds	—	—	—	
Certificates of deposit	750	—	750	—
Total short-term investments	750	—	750	—
Total	$ 12,619	$ 11,869	$ 750	$ —

NOTE 4. EQUIPMENT LOAN

As of March 31, 2011, the Company had an outstanding equipment loan balance of approximately $42,000 carrying a weighted-average interest rate of 11.44%. The principal and interest due under the loan will be repaid in equal monthly installments through June 2011.

NOTE 5. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases laboratory facilities and office space under an operating lease which will expire on October 31, 2015. Rent expense was approximately $253,000 and $240,000 for the three months ended March 31, 2011 and 2010, respectively.

The Company's monthly rent payments fluctuate under the master lease agreement. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis. The Company records deferred rent for the difference between the amounts paid and recorded as expense. At March 31, 2011 and December 31, 2010, the Company had $104,000 and $99,000 of deferred rent, respectively.

Directors and Officers Indemnity

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving at our request in such capacity. The term of

the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, we have a director or officer insurance policy that limits our exposure and may enable us to recover a portion of any future payments. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of March 31, 2011.

In the normal course of business, we provide indemnifications of varying scope under our agreements with other companies, typically our clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of our products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to our products. The term of these indemnification agreements is generally perpetual. The potential future payments we could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. We also maintain various liability insurance policies that limit our exposure. As a result, we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of March 31, 2011.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at March 31, 2011 that, in the opinion of management, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

NOTE 6. STOCKHOLDERS' EQUITY

Stock Warrants

At March 31, 2011, there were outstanding warrants to purchase 150,000 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 a Shelf Registration Offering at the exercise price of $2.75 per share. All outstanding warrants were exercisable at March 31, 2011.

There were no new warrants issued and no warrant expirations during the three month period ended March 31, 2011.

NOTE 7. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to our Initial Public Offering (IPO), the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. 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 935,665 and 930,177 shares of common stock were authorized for issuance under the 2007 Plan in January 2011 and January 2010, respectively. As of March 31, 2011, there were 914,379 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.

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding at March 31, 2011 and activity during the three-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, 2010	4,968	$ 1.78		
Options granted	239	$ 1.43		
Options exercised	(16)	$ 0.38		
Options forfeited/cancelled	(39)	$ 2.71		
Outstanding at March 31, 2011	5,152	$ 1.78	6.67	$ 3,261
Vested and expected to vest at March 31, 2011	5,045	$ 1.78	6.64	$ 3,215
Vested at March 31, 2011	3,251	$ 1.67	5.43	$ 2,570
Exercisable at March 31, 2011	3,251	$ 1.67	5.43	$ 2,570

Stock Options and Awards to Employees and Directors

The Company grants options to purchase common stock its employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. The Company has estimated the value of stock option awards as of the date of 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:

	Three Months Ended March 31,	
Assumption	2011	2010
Expected price volatility	93%	86%
Expected term (in years)	5.23	5.45
Risk-free interest rate	2.10%	2.67%
Dividend yield	0.00%	0.00%

Weighted-average fair value of options granted during the period	$1.21	$1.46

For the three months ended March 31, 2011 and 2010, the Company recognized stock-based compensation expense of $293,000 and $304,000, respectively, for option awards to employees and directors. As of March 31, 2011, total unrecognized compensation cost related to unvested stock options was $2.0 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 2.56 years.

Stock-Based Awards to Non-Employees

During the three months ended March 31, 2011 and 2010, the Company granted options to purchase an aggregate of 47,000 and 45,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. Additionally, during the three months ended March 31, 2011 and 2010 the Company issued 42,612 and 32,893 shares of common stock, respectively, to non-employees. The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

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

	Three Months Ended March 31,	
Assumption	2011	2010
Expected price volatility	92%	87%
Expected term (in years)	5.51	6.1
Risk-free interest rate	2.21%	2.48%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	$1.53	$2.19

For the three months ended March 31, 2011 and 2010, the Company recognized stock-based compensation expense of $130,000 and $123,000, respectively, related to non-employee stock and option grants.

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 discussed above is as follows:

	Three Months Ended March 31,	
(in thousands)	2011	2010
Research and development	$ 138	$ 221
General and administrative	285	206
Total stock-based compensation expense	$ 423	$ 427

NOTE 8. COLLABORATION AND LICENSE AGREEMENTS

Alcon Manufacturing, Ltd.

In August 2006, we 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. This agreement was amended in November 2010 to extend the period of the agreement through December 2015. 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 was amortized into revenue on a straight-line basis over the four-year funding term of the agreement through August 2010. Additionally, we receive semi-annual payments to support on-going research and development activities over the 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. Effective 2011, Alcon reduced its on-going financial support of the company's research and development efforts particularly relating to the funding of the number of personnel engaged in collaboration activities. Our obligation to perform research and development activities under the agreement expires at the end of 2015. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments upon the achievement of specified milestones. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compound.

Alcon has the right to terminate: (a) the agreement in its entirety upon nine months' notice; (b) portions of the agreement upon 135 days' notice, subject to certain provisions; (c) the funding term with six months prior written notice in advance of the next funding date. Both parties have the right to terminate the agreement for breach upon 60 days' notice." Both parties have the right to terminate the agreement for breach upon 60 days' notice.

Revenue has been recognized as follows:

	Three Months Ended March 31,	
(in thousands)	2011	2010
Amortization of Upfront Technology Access Fee	$ —	$ 625
On-going Research and Development (FTE)	1,050	1,309
Milestone Payment	—	—
	$ 1,050	$ 1,934

At March 31, 2011 and December 31, 2010, the Company had deferred revenue balances of $1.1 million and $0, respectively, related to the Alcon agreement which amounts were comprised entirely of upfront reimbursements to fund personnel.

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

Galderma

In March, 2009, the Company announced that it entered into a license and collaboration 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 Company amended this agreement on December 17, 2009 and again on December 2, 2010. This agreement, with respect to impetigo, is exclusive and worldwide in scope, with the exception of select Middle East Countries and Japan, where the Company has an option to exercise co-promotion rights. With respect to the other dermatological indications, Galderma has exclusive world-wide rights with the exception of Asia Pacific and Japan.

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. 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 hospitals and other healthcare institutions in North America. Upon 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 and a $3.25 million continuation fee and a $500,000 fee to expand the license to include the Asia-Pacific Territory in December 2010. These fees were recorded as deferred revenues and recognized as earned on a straight-line basis over the Company's expected performance period. The initial upfront technology access fee was recognized over the initial 20 month funding term of the agreement through October 2010, and the continuation and license fees are being recognized over the additional three year funding term of the agreement through November 2013.

Revenue has been recognized under the Galderma agreement as follows:

	Three Months Ended March 31,	
(in thousands)	2011	2010
Amortization of Upfront Technology Access Fee	$ 315	$ 150
On-going Research and Development (FTE)	388	—
Materials, Equipment, and Contract Study Costs	237	—
Milestone payments	500	—
Total	$ 1,440	$ 150

The Company had deferred revenue balances of $3.1 million and $3.7 million at March 31, 2011 and December 31, 2010, respectively, related to the Galderma agreement, which consisted of the unamortized balances on the upfront technology and access fee and the continuation and license fee and support for ongoing research and development. As of March 31, 2011, the Company has earned $4.75 million in milestone payments. As of March 31, 2011, the Company has not earned or received any royalty payments under the Galderma agreement.

NOTE 9. SUBSEQUENT EVENTS

We evaluated subsequent events through the issuance date of the financial statements. We are not aware of any significant events that occurred subsequent to the balance sheet date but prior to the filing of this Annual Report on Form 10-K that would have a material impact on our consolidated financial statements

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

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part I, Item 1 of this report, and with our consolidated financial statements and related notes, and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2010, which was filed with the Securities and Exchange Commission on March 10, 2011. 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

NovaBay is a clinical stage biotechnology company developing a first-in-class, anti-infective platform of compounds called the Aganocide® compounds. In laboratories, these compounds have demonstrated equivalent activity to the active antimicrobial molecules generated within white blood cells. The Aganocide compounds are being developed for the topical treatment and prevention of a wide variety of topical infections, including those that are antibiotic resistant.

NovaBay is developing commercial opportunities for its portfolio of anti-infective Aganocide compounds in four distinct healthcare markets: dermatology, ophthalmology, urology and hospital infections. Each of these market segments are underserved by current products and therefore the opportunity exists for improved treatments. NovaBay's strategy is to address these market opportunities either through partnerships and collaborations or by building an internal organization to strategically market its own products when appropriate from a commercial standpoint.

In August 2006, we entered into a collaboration and license agreement with Alcon Manufacturing Ltd. (Alcon), that provides Alcon with the exclusive rights to develop, manufacture and commercialize products incorporating our Aganocide compounds for the treatment of eye, ear and sinus infections as well as for use in contact lens care. Under the terms of the agreement, Alcon paid an up-front technology access fee of $10.0 million upon the effective date of the agreement. Under the terms of the agreement we also received semi-annual payments from Alcon to support on-going research and development activities during the four year funding term of the agreement, which ended on August 2010. In November 2010 Alcon extended the funding term to December 2015, subject to earlier termination of the agreement or, at Alcon's election, with six months prior written notice. The collaboration also calls for Alcon to pay for all developmental and clinical costs. 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. Effective 2011, Alcon reduced its on-going financial support of the company's

research and development efforts particularly relating to the funding of the number of personnel engaged in collaboration activities. 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. NovaBay has the potential to receive up to $70.0 million in milestones from Alcon, and royalties ranging in single digits on net sales of products once commercialized. During 2010, Alcon concluded a Phase 2 human proof of concept trial of NovaBay's lead compound, NVC-422, for the treatment of adenoviral conjunctivitis, a type of "Pink Eye". The results of the trial have been analyzed for the safety, microbiological and clinical efficacy. The trial results are expected to be released during May 2011. The Company will continue to review the data with its partner and other experts in the ophthalmic community to determine its next steps. If Alcon were to determine that the data does not warrant continuation of development of NVC-422 for the treatment of adenoviral conjunctivitis, further payments from Alcon may not be received.

In March 2009, we announced that we entered into a collaboration and license agreement with Galderma S.A. to develop and commercialize our Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions. We amended this agreement in December 2009 and 2010. Galderma will be responsible for the development costs of the acne and impetigo product candidates except for costs incurred in Japan. In Japan, Galderma has the option to request that we share such development costs. From the inception of the agreement to March 31, 2011, we have received $13.2 million from Galderma including the technology access fee, milestone payments and R&D funding. NovaBay has the potential to receive up to $62.0 million in predetermined fees, including milestones and personnel reimbursement, with additional funding available to cover product and clinical development. We are entitled to royalties ranging from 10% to 30% on cumulative net sales of products once commercialized, subject to some reductions based on any development costs incurred directly by Galderma. 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.

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 fees received from Alcon and Galderma. As we are a development stage company, we have incurred significant losses since commencement of our operations in July 2002, since we have devoted substantially all of our resources to research and development. As of March 31, 2011, we had an accumulated deficit of $30.2 million. This deficit resulted from research and development expenses as well as general and administrative expenses. We expect 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.

Significant Events in 2010 and 2011

In March 2011, we announced that we initiated a Phase 2 clinical trial for the treatment of urinary catheter blockage and encrustation in December 2010. The trial is focused on chronically catheterized spinal cord injury patients prone to catheter encrustation and urinary tract infections. We expect the trial to be completed in Q3 2011 with results available in Q4 2011.

In December 2010, we expanded our agreement with Galderma and Galderma exercised their option to continue with the impetigo program. The expanded agreement has the potential to generate up to $62.0 million in predetermined fees, including milestones and personnel reimbursement, with additional funding available to cover product and clinical development. As part of this expansion we received $3.75 million from Galderma.

In November 2010, we received a cash grant award of $244,000 under the U.S. Government’s Qualifying Therapeutic Discovery Program for our impetigo program.

In November 2010, we announced the amendment of our collaboration with Alcon, extending the funding term from August 29, 2010 to December 31, 2015, the term of the discovery research program under the agreement. During the said term, Alcon will fund the costs for a specified number of personnel engaged in collaboration activities pursuant to the agreed discovery research plan and development plans described in the agreement, provided that these plans are subject to earlier termination of the agreement or, at Alcon’s election, with six months prior written notice. Effective 2011, pursuant to their rights under this agreement, Alcon reduced its on-going financial support of the company’s research and development efforts particularly relating to the funding of the number of personnel engaged in collaboration activities.

In January 2010, we announced that we received $3.75 million in milestone payments from Galderma: a $2.0 million milestone payment having been triggered by the completion of formulation feasibility studies with our Aganocide compounds for topical use and a $1.75 million milestone payment for completing an exploratory clinical study for the

treatment of adult acne. Both of these studies were concluded in 2009 and the resulting revenues were recorded in our 2009 results.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim reporting. The preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, research and development costs, patent costs, stock-based compensation, income taxes and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements (unaudited), included in Part I, Item 1 of this report, and are also described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2010. We have not materially changed these policies from those reported in our Annual Report on Form 10-K for the year ended December 31, 2010.

Recent Accounting Pronouncements

See Note 2 to the accompanying unaudited consolidated financial statements included in Part I, Item 1 of this quarterly report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

Comparison of the Three Months Ended March 31, 2011 and March 31, 2010

License and Collaboration Revenue

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 was 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 was amortized into revenue on a straight-line basis over the 20 month funding term of the agreement, through October 2010.

Total license and collaboration revenue was $2.5 million for the three months ended March 31, 2011, compared to $2.1 million for the three months ended March 31, 2010. This increase resulted from a $500,000 milestone received from Galderma in 2011, additional funding of personnel in 2011 and amortization of the continuation payment received in December 2010. These increases were partially offset by reduced reimbursements from Alcon and the reduction in amortization from the upfront payments received from both Alcon and Galderma as these were fully amortized in 2010 and is therefore not included in the 2011 revenues.

To the extent we earn milestone payments under our collaborations, we would expect revenues to increase. 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 31% to $2.9 million for the three months ended March 31, 2011 from $2.2 million for the three months ended March 31, 2010. The increase was due to increased research and development and clinical costs in connection with our urology and dermatology programs.

We expect to incur increased research and development expenses throughout 2011 and in subsequent years as we continue to increase our focus on clinical trials and 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 2011 in connection with our dermatology and urology programs.

General and Administrative

General and administrative expenses remained consistent at $1.5 million for the three months ended March 31, 2011 and 2010. We expect general and administrative expenses to continue to remain relatively flat in 2011.

Other Income (Expense), Net

Other income (expense), net was an expense of $31,000 for the three months ended March 31, 2011 compared to $11,000 for the three months ended March 31, 2010. This change was primarily attributable to reduced income on our investments in 2011.

We expect that other income (expense), net will vary based on fluctuations in our cash balances.

Liquidity and Capital Resources

As of March 31, 2011, we had cash, cash equivalents, and short-term investments of $12.6 million compared to $12.8 million at December 31, 2010.

We have incurred cumulative net losses of $30.2 million since inception through March 31, 2011. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the sales of our stock. We raised total net proceeds of $11.2 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.

Under the terms of August 2006 collaboration and license agreement with Alcon we received an up-front technology access fee of $10.0 million upon the effective date of the agreement. Under the terms of the agreement we also received semi-annual payments from Alcon to support on-going research and development activities during the four year funding term of the agreement, which ended on August 2010. In November 2010 Alcon extended the funding term to December 2015, subject to earlier termination of the agreement or, at Alcon’s election, with six months prior written notice. The collaboration also calls for Alcon to pay for all developmental and clinical costs. 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, otic and sinus fields are $19.0 million, $12.0 million and $39.0 million, respectively. In 2009 we achieved our first milestone under this agreement, but product has not been commercialized to date. 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 remaining milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.

In March 2009, we entered into a collaboration and license agreement with Galderma. In December 2009 and 2010, we amended this agreement. Under the terms of the agreement, we received an initial $1.0 million upfront payment that was recognized as revenue over the initial 20 month funding term of the agreement. In December 2009, we

recorded revenues of $3.75 million related to milestones from Galderma. In December 2010, we received a continuation payment of $3.25 million and a $500,000 fee to expand the license to include the Asia-Pacific territory that will be recognized as revenue over the additional three year funding period. In March 2011 we received a milestone payment related to the IND on our impetigo program. In addition, Galderma will pay to NovaBay reimbursements, and additional milestone payments related to achieving development and commercialization of its Aganocide compounds.

We expect the total cash, cash equivalents, and short-term investments, along with committed funding under our license agreements from Alcon and Galderma will be sufficient to fund cash requirements for at least 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 extent to which we receive milestone payments or other funding from Alcon and/or Galderma, if any;
- 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.

Cash Provided by Operating Activities

For the three months ended March 31, 2011 cash provided by operating activities of $16,000 was primarily attributable to our research and development and general administrative expenses of running the company, offset by the receipt of $500,000 from Galderma in January that is being amortized over the term of the contract, increased deferred revenues of $511,000 as a result of the Galderma payments, non-cash stock compensation expense of $293,000 and an increase in accounts payable of $253,000 as a result of increased billings related to our clinical trials.

For the three months ended March 31, 2010 cash provided by operating activities of $2.6 million was primarily attributable to the receipt of a $3.75 million milestone payment from Galderma that was included in outstanding receivables as of December 31, 2009. This was partially offset by our research and development and general administrative expenses.

Cash Provided by (Used in) Investing Activities

For the three months ended March 31, 2011, cash provided by investing activities of $383,000 was attributable to maturities of short-term investments (net of purchases) of $500,000, partially offset by purchases of property and equipment of $117,000.

For the three months ended March 31, 2010, cash used in investing activities of $592,000 was attributable to purchases of short-term investments (net of maturities) of $562,000 and purchases of property and equipment of $30,000.

Cash Used in Financing Activities

Net cash used in financing activities of $64,000 for the three months ended March 31, 2011 was primarily attributable to the payments on the equipment loan.

Net cash used in financing activities of $68,000 for the three months ended March 31, 2010 was primarily attributable to the payments on the equipment loan, offset, in part, by proceeds from the exercise of stock options.

Net Operating Losses and Tax Credit Carryforwards

As of March 31, 2011 we had net operating loss carryforwards for federal and state income tax purposes of $24.2 million and 25.3 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2016 and 2030.

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 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 March 31, 2011 is $4.6 million due over the lease term, compared to $4.7 million as of December 31, 2010. Our commitment for the equipment loan consists of the total payments due under the loan facility of $42,000, compared to $106,000 million as of December 31, 2010. This amount includes $1,000 of interest payments over the remaining term of the loan.

ITEM 3.
QUANTITATIVE
AND
QUALITATIVE
DISCLOSURES
ABOUT
MARKET RISK

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

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital; assurance of liquidity needs; best available return on invested capital; and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. As of March 31, 2011 and December 31, 2010, a 10% change in interest rates would have had an immaterial effect on the value of our short-term marketable securities. 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 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

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 at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended March 31, 2011, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

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, 2010, as filed with the SEC on March 10, 2011, which risk factors are set forth below.

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

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, 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 in recent months. Our stock price could decrease due to concerns that our business, operating results and financial condition will be negatively impacted by a worldwide economic downturn.

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 extent to which we receive milestone payments or other funding from Alcon and/or Galderma, if any;
- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the 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 stockholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing stockholders. If we raise additional capital through strategic alliance and licensing arrangements, we may have to trade our rights to our technology, intellectual property or products to others on terms that may not be favorable to us. If we raise additional capital through debt financing, the financing may involve covenants that restrict our business activities.

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

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

We are an early stage company with a history of losses. Although we were profitable in 2009, we reported a net loss in 2010 and the first quarter of 2011, we do not have any commercial products, and expect that we will incur net

losses in the future, and that we may never achieve or maintain sustained profitability.

We have incurred net losses each year since our inception through March 31, 2011, with the exception of 2009. For the years ended December 31, 2010 and 2008 we had net losses of approximately $4.3 million and $8.1 million, respectively, and for the year ended December 31, 2009, we had net income of $2.7 million. We were able to record a profit in 2009 due to our receipt of a $3.75 million milestone payment under our agreement with Galderma; however, there is no assurance that we will receive any additional large milestone payments under this agreement and, as a result, may not be able to achieve or maintain profitability in the future. Through March 31, 2011, we had an accumulated deficit of approximately $30.2 million. We have been, and expect to remain for the foreseeable future, mostly in a research and development stage. We have incurred substantial research and development expenses, which were approximately $8.6 million, $7.3 million and $9.6 million for the years ended December 31, 2010, 2009 and 2008, respectively, and $2.9 million in the three months ended March 31, 2011. 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 incur substantial losses for the foreseeable future, and we may never achieve or maintain sustained profitability. 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;
- 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 1 safety studies or small-scale Phase 2a exploratory-studies. We will need to conduct additional Phase 1, 2 and 3 human clinical trials to confirm such results in larger patient populations 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 or that they are active against antibiotic resistant microbes, do not allow pathogens to develop resistance or are active against bacteria in biofilm. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials.

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.

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 may need to comply with in the future.

Following the passage of the Dodd-Frank Wall Street Reform and Consumer Protection Act we are not required to have our independent auditors audit our internal control over financial reporting, but if the value of our common stock not held by our affiliates at the end of the second quarter in a fiscal year exceeds $75.0 million we will be required to do so. If we reach the $75.0 million value described above and 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, 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.

Our current research collaborations with Alcon and Galderma may fail, and entering into additional collaborations may not happen, resulting in a decrease in funding and inhibition of our ability to continue developing products.

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and have relied upon them for a significant portion of our 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. Under the terms of the agreement we received semi-annual payments from Alcon to support on-going research and development activities over the four-year funding term of the agreement, which ended in August 2010. On November 18, 2010 Alcon extended the funding term to December 31, 2015, subject to earlier termination of the agreement, at Alcon's election, with six months prior written notice.

During 2010, Alcon concluded a Phase 2 human proof of concept trial of NovaBay's lead compound, NVC-422, for the treatment of adenoviral conjunctivitis, a type of "Pink Eye". The results of the trial have been analyzed for the safety, microbiological and clinical efficacy. The trial results are expected to be released during May 2011. The Company will continue to review the data with its partner and other experts in the ophthalmic community to determine its next steps. If Alcon were to determine that the data does not warrant continuation of development of NVC-422 for the treatment of adenoviral conjunctivitis, we may not receive any further payments from Alcon, which would have a significant adverse effect on our company and our stock price.

We have also 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 also rely on Galderma for a significant portion of our revenues.

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. We cannot assure you that the recent change in ownership in Alcon by virtue of the acquisition by Novartis of Alcon's majority stake, will not result in management redirection which in turn, could negatively impact our collaboration with Alcon. 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.

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 your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions by incurring indebtedness. Additional funds may not be available on terms that are favorable to us, or at all.

We do not have our own manufacturing capacity, and we 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 candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we have partnered and expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing 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, Chief Scientific Officer, Chief Alliance Officer and Vice President of Product Development, Vice President of Medical Affairs, Vice President of Business and Corporate Development 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.

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

If we are unable to design, conduct and complete clinical trials successfully, we will not be able to obtain regulatory approval for our 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. Further, because our product candidates are all in the same class of compounds, failure in one clinical trial may cause us or our partners to have to suspend or terminate other clinical trials. For example, if toxicity issues were to arise in one clinical trial, it could indicate that all of our product candidates have toxicity issues.

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

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- increases in time required to complete monitoring of patients during or after participation in a trial; and

- unexpected need for additional patient-related data.

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

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

Government agencies may establish usage guidelines that directly apply to our 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 U.S. or in other countries.

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

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. Alternatively the products could be classified as combination products, in which case both the device and drug centers jointly review the submission. The products may be designated by the FDA as a drug or a medical device depending upon the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims. For example, for NVC-422, if the indication is for flushing of urinary catheters, 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. The use of NVC-101 as a solution for cleansing and debriding was cleared as a Class I medical device. The determination as to whether a particular indication is considered a drug or a device is also based in part upon precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development for that indication could have a significant adverse impact due to the more rigorous and lengthy approval process required for drugs, as compared to medical devices. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a drug to a device could result in a change in classification for reimbursement. 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.

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 six months of exclusivity as a generic product under the Hatch-Waxman Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties 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.

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

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

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.

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

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

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

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.

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.

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.

Health care reform measures could limit the prices we or our collaborative partners can obtain for our potential products, or impose additional costs on us.

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation through the passage of the Patient Protection and Affordable Health Care Act (H.R. 3590) and the Health Care and Education Reconciliation Act (H.R. 4872). While we anticipate that this legislation may, over time, increase the number of patients who have insurance coverage for pharmaceutical products, it also imposes cost containment measures that may adversely affect the amount of reimbursement for pharmaceutical products. In addition, such legislation contains a number of provisions designed to generate the revenues necessary to fund the coverage expansion, including new fees or taxes on certain health-related industries.

Many of the details of the new law will be included in new and revised regulations, which have not yet been promulgated, and require additional guidance and specificity to be provided by the Department of Health and Human Services, Department of Labor and Department of the Treasury. Accordingly, while it is too early to understand and predict the ultimate impact of the new legislation on our business, the legislation could have a material adverse effect on our business.

Risks Relating to Owning Our Common Stock

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

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

- 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 stockholder wishing to sell his/her stock may cause a significant fluctuation in the price of our stock. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

Our directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2010, our officers and directors collectively controlled approximately 4,088,481 shares of our outstanding common stock (and approximately 5,556,279 shares of our common stock when including options held by them which were exercisable as of or within 60 days from January 31, 2011). Furthermore, as of December 31, 2010, our largest stockholder, 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 (and approximately 3,321,551 shares of our common stock when including options held by Dr. Najafi which were exercisable as of or within 60 days from January 31, 2011). As a result, Dr. Najafi can significantly influence the management and affairs of our company and most matters requiring stockholder 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 stockholders.

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

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

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

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

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

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

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

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

ITEM 6.
EXHIBITS

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

SIGNATURES

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

Date: May 16, 2011	NOVABAY PHARMACEUTICALS, INC.
	/s/ Ramin Najafi Ramin (“Ron”) Najafi Chairman and Chief Executive Officer (duly authorized officer)
Date: May 16, 2011	/s/ Thomas J. Paulson Thomas J. Paulson Chief Financial Officer (principal financial officer)

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of NovaBay Pharmaceuticals, Inc., a Delaware corporation (Incorporated by reference to the exhibit of the same number from the Company's current report on Form 8-K, as filed with the SEC on June 29, 2010 (SEC File No. 001-33678))
3.2	Amended and Restated Bylaws of registrant (Incorporated by reference to the exhibit of the same number from the Company's current report on Form 8-K as filed with the SEC on June 29, 2010 (SEC File No. 001-33678).)
4.1*	Specimen common stock certificate
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 (SEC File No. 001-33678).)
10.1	Executive Officer Cash Compensation Arrangements (Bonus structure is incorporated by reference to Exhibit 10.19 of the Company's annual report on Form 10-K for the year end December 31, 2009 as filed with the SEC on March 30, 2010; 2010 bonus and 2011 salaries and target bonuses are set forth in this exhibit).
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.

* Incorporated by reference to the exhibit of the same description from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.