

NovaBay Pharmaceuticals, Inc.  
Form 10-Q  
November 12, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

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

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

Commission file number 001-33678

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

Delaware  
(State or other jurisdiction of incorporation or  
organization)

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

5980 Horton Street, Suite 550, Emeryville CA 94608  
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes  No

As of November 10, 2010, there were 23,335,938 shares of the registrant's common stock outstanding.

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



PART I  
FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2010 (unaudited)	December 31, 2009 (Note 2)
(in thousands, except per share data)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$9,415	\$10,992
Short-term investments	1,383	300
Accounts receivable and other receivables	—	3,801
Deferred tax asset	—	34
Prepaid expenses and other current assets	372	479
Total current assets	11,170	15,606
Other assets	281	105
Property and equipment, net	1,663	1,812
<b>TOTAL ASSETS</b>	<b>\$13,114</b>	<b>\$17,523</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Current liabilities:		
Accounts payable	\$291	\$272
Accrued liabilities	1,130	1,228
Capital lease obligation	—	7
Equipment loan	168	364
Deferred revenue	1,451	2,167
Total current liabilities	3,040	4,038
Deferred tax liability	—	34
Deferred rent	96	—
Equipment loan - non-current	—	106
Total liabilities	3,136	4,178
Stockholders' Equity:		
Common stock, \$0.01 par value; 65,000 shares authorized at September 30, 2010 and December 31, 2009; 23,335 and 23,254 issued and outstanding at September 30, 2010 and December 31, 2009, respectively	233	233
Additional paid-in capital	38,108	37,003
Accumulated other comprehensive loss	(3	) —
Accumulated deficit during development stage	(28,360	) (23,891
Total stockholders' equity	9,978	13,345
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$13,114</b>	<b>\$17,523</b>

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

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

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30, 2010
	2010	2009	2010	2009	2010
Revenue:					
License and collaboration revenue	\$2,086	\$3,224	\$6,718	\$8,192	\$ 36,570
Operating Expenses:					
Research and development	2,245	2,004	6,607	4,809	38,951
General and administrative	1,487	1,309	4,567	4,078	27,138
Total operating expenses	3,732	3,313	11,174	8,887	66,089
Net loss from operations	(1,646 )	(89 )	(4,456 )	(695 )	(29,519 )
Other income (expense), net	4	(22 )	(13 )	(23 )	1,180
Loss before income taxes	(1,642 )	(111 )	(4,469 )	(718 )	(28,339 )
Provision for income taxes	—	—	—	—	(21 )
Net loss	\$(1,642 )	\$(111 )	\$(4,469 )	\$(718 )	\$ (28,360 )
Net loss per share:					
Basic and diluted	\$(0.07 )	\$(0.00 )	\$(0.19 )	\$(0.03 )	
Shares used in per share calculations:					
Basic and diluted	23,335	23,251	23,317	22,117	

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)	Nine Months Ended September 30,		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30, 2010
	2010	2009	2010
<b>Cash flows from operating activities:</b>			
Net loss	\$(4,469 )	\$(718 )	\$(28,360 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	319	268	1,396
Accretion of discount on short-term investments	—	—	(259 )
Net realized loss on sales of short-term investments	7	—	4
Loss on disposal of property and equipment	—	—	121
Stock-based compensation expense for options and stock awards issued to employees and directors	857	725	3,362
Stock-based compensation expense for warrants, options and stock issued to non-employees	194	178	974
Taxes paid by LLC	—	—	1
Changes in operating assets and liabilities:			
(Increase) decrease in accounts receivable	3,695	—	(106 )
(Increase) decrease in prepaid expenses and other assets	78	(1,328 )	(418 )
Increase (decrease) in accounts payable and accrued liabilities	(30 )	(293 )	1,497
Increase (decrease) in deferred revenue	(716 )	(376 )	1,450
Net cash used in operating activities	(65 )	(1,544 )	(20,338 )
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(170 )	(596 )	(3,061 )
Proceeds from disposal of property and equipment	—	—	46
Purchases of short-term investments	(2,196 )	(1,050 )	(100,715 )
Proceeds from maturities and sales of short-term investments	1,100	—	99,582
Cash acquired in purchase of LLC	—	—	516
Net cash used in investing activities	(1,266 )	(1,646 )	(3,632 )
<b>Cash flows from financing activities:</b>			
Proceeds from preferred stock issuances, net	—	—	11,160
Proceeds from common stock issuances	—	—	17
Proceeds from exercise of options and warrants	66	78	1,901
Proceeds from initial public offering, net of costs	—	—	17,077
Proceeds from (payments on) shelf offering	(2 )	1,945	1,942
Proceeds from stock subscription receivable	—	—	873



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Proceeds from issuance of notes	—	—	405
Principal payments on capital lease	(8 )	(31 )	(158 )
Proceeds from borrowings under equipment loan	—	—	1,216
Principal payments on equipment loan	(302 )	(271 )	(1,048 )
Net cash provided by (used in) financing activities	(246 )	1,721	33,385
Net increase (decrease) in cash and cash equivalents	(1,577 )	(1,469 )	9,415
Cash and cash equivalents, beginning of period	10,992	12,099	—
Cash and cash equivalents, end of period	\$9,415	\$10,630	\$9,415

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. (“NovaBay” or the “Company”) is a clinical stage biotechnology company developing first-in-class anti-infectives for the treatment and prevention of infections due to bacteria, fungi and virus, including antibiotic-resistant infections. 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, fungal 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.

The Company was incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, we changed our name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, we formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which may conduct research and development in Canada, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. In June 2010, we changed the state in which we are incorporated (the “Reincorporation”), and are now incorporated under the laws of the State of Delaware. All references to “we,” “us,” “our,” or “the Company” herein refer to the California corporation prior to the date of the Reincorporation, and to the Delaware corporation on and after the date of the Reincorporation. We currently operate in 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 U.S. generally accepted accounting principles (“U.S. GAAP”) for interim information including the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements do not include all disclosures for annual audited financial statements required by 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, 2009. The consolidated balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and notes 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 or for any other period. Certain prior period amounts have been reclassified to conform to the current period presentation.

The financial statements have been prepared under the guidelines for Development Stage Enterprises. A development stage enterprise is one in which planned principal operations have not commenced, or if its operations have commenced, there have been no significant revenues therefrom. As of September 30, 2010, the Company had not commenced its planned principal operations.

#### 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.

NOVABAY PHARMACEUTICALS, INC.

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

(unaudited)

Use of Estimates

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

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of September 30, 2010, 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. 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 three and nine months ended September 30, 2010 and 2009, 100% of our operating revenues were derived from two collaborative partners. As of December 31, 2009, 100% of our accounts receivables were from one of our collaborative partners.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on available-for-sale securities. At each balance sheet date presented, the Company's other comprehensive loss consists solely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the three and nine months ended September 30, 2010 and 2009 are as follows (in thousands):

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NOVABAY PHARMACEUTICALS, INC.  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss	\$ (1,642 )	\$ (111 )	\$ (4,469 )	\$ (718 )
Other comprehensive income:				
Change in unrealized gains (losses) on available-for-sale securities	2	3	(3 )	—
Comprehensive loss	\$ (1,640 )	\$ (108 )	\$ (4,472 )	\$ (718 )

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

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

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

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

- Level 1 – quoted prices in active markets for identical assets or liabilities
- Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable
- Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

#### Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, the

Company analyzes its multiple element arrangements to determine whether the element can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured.

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

**Upfront Fees**—The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology licensed has no utility to the licensee. If the Company has continuing involvement through research and development services that are required because its know-how and expertise related to the technology is proprietary to it, or can only be performed by it, then such up-front fees are deferred and recognized over the period of continuing involvement.

NOVABAY PHARMACEUTICALS, INC.

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

(unaudited)

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

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

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

#### Stock-Based Compensation

The Company accounts for share-based compensation under the provisions of ASC 718, Compensation-Stock Compensation which requires the recognition of compensation expense using a fair-value based method. 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. See Note 7 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

The Company accounts for stock compensation arrangements with non-employees in accordance with ASC 505-50, Equity - Equity-Based Payments to Non-Employees which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

#### Income Taxes

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



Net Loss per Share

Basic net loss per share is computed using 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, and convertible preferred stock, using the if-converted method. In computing diluted net loss per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted net loss per share computation in net loss periods because the inclusion of such shares would be anti-dilutive. During the three and nine months ended September 30, 2010 and 2009, there is no difference between basic and diluted net loss per share due to the Company's net losses.

NOVABAY PHARMACEUTICALS, INC.  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
(unaudited)

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:

(In thousands)	Nine Months Ended September 30,	
	2010	2009
Stock options	4,427	3,827
Stock warrants	1,725	1,875
	6,152	5,702

#### Recent Accounting Pronouncements

In April 2010, the 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 will be effective for the Company on a prospective basis for milestones achieved after December 31, 2010. We have evaluated the potential impact of this standard and expect it will have no significant impact on our financial position or results of operations.

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-06 (Topic 820) Fair Value Measurements and Disclosures. This standard amends the disclosure guidance with respect to fair value measurements for both interim and annual reporting periods. Specifically, disclosure is required for significant transfers between Level 1 and Level 2 in the fair value hierarchy; additional disclosures are required for transaction in Level 3 assets and liabilities; and additional disclosure is required of the valuation techniques and inputs used to measure assets and liabilities that fall into Level 2 and Level 3. Except for the additional disclosures for transactions Level 3 items, which will be effective for us as of January 1, 2011, the remaining new disclosure requirements were effective for the Company as of January 1, 2010. The implementation of this standard had no significant impact on our financial position or results of operations.

#### NOTE 3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

Short-term investments at September 30, 2010 and December 31, 2009 consisted of the following:

## NOVABAY PHARMACEUTICALS, INC.

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
(unaudited)

(in thousands)	Amortized Cost	September 30, 2010		Market Value
		Gross Unrealized Gains	Gross Unrealized (Losses)	
Corporate bonds	\$766	\$—	\$5	\$771
Municipal Bonds	50	—	—	50
Government Securities	308	—	4	312
Certificates of Deposit	250	—	—	250
	\$1,374	\$—	\$9	\$1,383

(in thousands)	Amortized Cost	December 31, 2009		Market Value
		Gross Unrealized Gains	Gross Unrealized (Losses)	
Certificates of Deposit	\$300	\$—	\$—	\$300
	\$300	\$—	\$—	\$300

All short-term investments at September 30, 2010 and December 31, 2009 mature in less than one year. Unrealized holding gains and losses on short-term investments classified as available-for-sale are recorded in accumulated other comprehensive loss. We recognized realized losses of \$7,000 for the three and nine months ended September 30, 2010. No realized gains or losses were recognized for the three and nine months ended September 30, 2009.

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 municipal bonds.

The following table presents the Company's investments, measured at fair value on a recurring basis, as of September 30, 2010:

(in thousands)	Balance at September 30, 2010	Fair Value Measurements		
		Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$9,415	\$9,415	\$—	\$—
Short-term investments:				
Corporate bonds	771	—	771	—

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Municipal bonds	50	—	50	—
Government Securities	312	—	312	—
Certificates of deposit	250	—	250	—
Total short-term investments	1,383	—	1,383	—
Total	\$10,798	\$9,415	\$1,383	\$—

NOTE 4. EQUIPMENT LOAN

As of September 30, 2010, the Company had an outstanding equipment loan balance of approximately \$168,000 carrying a weighted-average interest rate of 11.17%. The principal and interest due under the loan will be repaid in equal monthly installments through June 2011.

NOVABAY PHARMACEUTICALS, INC.  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
(unaudited)

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 \$348,000 and \$214,000 for the three months ended September 30, 2010 and 2009, respectively. Rent expense was approximately \$820,000 and \$653,000 for the nine months ended September 30, 2010 and 2009, respectively.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at September 30, 2010 that, in the opinion of management, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

NOTE 6. STOCKHOLDERS' EQUITY

Stock Warrants

The significant terms of the warrants outstanding as of September 30, 2010 are as follows:

**Underwriter Warrants**—In connection with the IPO, the Company issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of \$4.00 per share. The warrants were exercisable on or after October 31, 2008 and expire on October 31, 2010.

**Advisory Services Warrants** - In April 2008, the Company issued a two-year warrant and a four-year warrant to purchase an aggregate of 300,000 shares of common stock, at an exercise price of \$4.00 per share, to PM Holdings Ltd. In April 2010, the two-year warrant for 150,000 shares expired unexercised. The remaining 150,000 warrants expire on April 1, 2012. For the three and nine months ended September 30, 2010, the Company recognized compensation expense of \$0 and \$7,000, respectively, for these warrants.

**Investor Warrants**—In August 2009, in connection with the Shelf Registration Offering, the Company issued warrants to the investors to purchase an aggregate of 1,225,000 shares of common stock at an exercise price of \$2.75 per share. The warrants are exercisable on or after February 17, 2010 and expire on August 21, 2014.

At September 30, 2010, there were outstanding warrants to purchase 500,000 shares of common stock at an exercise price of \$4.00 per share. Additionally, there were outstanding warrants to purchase 1,225,000 shares of common stock from the Shelf Registration Offering at the exercise price of \$2.75 per share. All outstanding warrants were exercisable at September 30, 2010.

The following table summarizes information about the Company's warrants outstanding at September 30, 2010 and activity during the nine months then ended.

(in thousands, except per share data)	Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2009	1,875	\$ 3.18
Warrants expired	(150)	) \$ 4.00
Outstanding at September 30, 2010	1,725	\$ 3.11

## NOTE 7. EQUITY-BASED COMPENSATION

## Equity Compensation Plans

Prior to the IPO, the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the “2007 Plan”) to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. At the inception of the 2007 Plan, 2,000,000 shares were reserved for issuance under the Plan. Beginning in January 2009, the number of shares of common stock authorized for issuance under the 2007 Plan increases annually in an amount equal to the lesser of (a) 1,000,000 shares or (b) 4% of the number of shares of the Company’s common stock outstanding on the last day of the preceding year or (c) such lesser number as determined by the board of directors. Accordingly, an additional 930,177 and 858,766 shares of common stock were authorized for issuance under the 2007 Plan in January 2010 and January 2009, respectively. As of September 30, 2010, there were 818,007 shares available for future grant under the 2007 Plan.

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Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and, if granted to an owner of more than 10% of the Company's stock, then not less than 110%. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years while options granted to directors and consultants typically vest over a shorter period, subject to continued service. All of the options granted prior to October 2007 include early exercise provisions that allow for full exercise of the option prior to the option vesting, subject to certain repurchase provisions. The Company issues new shares to satisfy option exercises under the plans.

#### Stock Option Summary

The following table summarizes information about the Company's stock options outstanding at September 30, 2010 and activity during the nine-month period then ended.

(in thousands, except per share data and years)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)
Outstanding at December 31, 2009	4,147	\$ 1.71	
Options granted	400	\$ 1.94	
Options exercised	(48 )	\$ 1.37	
Options forfeited/cancelled	(72 )	\$ 2.07	
Outstanding at September 30, 2010	4,427	\$ 1.75	6.51
Vested and expected to vest at Sept. 30, 2010	4,405	\$ 1.74	6.49
Vested at September 30, 2010	2,919	\$ 1.58	5.46
Exercisable at September 30, 2010	2,938	\$ 1.58	5.46

#### Stock Options and Awards to Employees and Directors

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

Assumption	Nine Months Ended September 30,	
	2010	2009
Expected volatility	86 %	86 %
Expected term (in years)	5.5	6.1
Risk-free interest rate	2.56 %	2.20 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	\$ 1.45	\$ 1.27





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For the three months ended September 30, 2010 and 2009, the Company recognized stock-based compensation expense of \$278,000 and \$174,000, respectively, for option awards to employees and directors. For the nine months ended September 30, 2010 and 2009, the Company recognized \$857,000 and \$514,000, respectively, for option awards to employees and directors. As of September 30, 2010, total unrecognized compensation cost related to unvested stock options granted or modified on or after January 1, 2006 was \$1.6 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 2.4 years.

#### Common Stock Awards to Directors

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

In accordance with these provisions, the Company issued 126,675 shares of common stock to independent directors during the nine months ended September 30, 2009. These shares were issued out of the 2007 Plan. The fair market value of the stock issued to directors was recorded as an operating expense in the period in which the meeting occurred, resulting in total compensation expense related to common stock awards to directors of approximately \$41,000 and \$211,000 during the three and nine months ended September 30, 2009, respectively.

In December 2009, the Company adopted a new plan to compensate the independent members of the Board of Directors for their services. Under the terms of the Director Compensation Plan, each independent member is entitled to a combination of cash and stock options, at their discretion, for their participation in the board and various committees. If the director elects to receive stock options these are issued to the director at the beginning of the year and vest over the term of the year. Cash payments are made quarterly at the beginning of each quarter. In accordance with these provisions, the Company did not issue any common stock awards to independent directors during the three and nine months ended September 30, 2010.

#### Summary of Stock-Based Compensation Expense

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

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Research and development	\$94	\$88	\$311	\$271
General and administrative	184	127	546	454
<b>Total stock-based compensation expense</b>	<b>\$278</b>	<b>\$215</b>	<b>\$857</b>	<b>\$725</b>

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

During the three and nine months ended September 30, 2010, the Company granted options to purchase an aggregate of 5,000 and 90,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. During the three and nine months ended September 30, 2009, the Company granted options to purchase an aggregate of 93,000 and 273,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. Additionally, during the three and nine months ended September 30, 2010 the Company issued 0 and 32,893 shares of common stock 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 weighted-average assumptions:

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Assumption	Nine Months Ended September 30,			
	2010		2009	
Expected volatility	90	%	87	%
Expected term (in years)	5.6		5.6	
Risk-free interest rate	1.78	%	1.90	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of options granted during the period	\$ 1.54		\$ 1.41	

For the three and nine months ended September 30, 2010, the Company recognized stock-based compensation expense of \$24,000 and \$194,000, respectively, related to non-employee warrant, stock and option grants. For the three and nine months ended September 30, 2009, the Company recognized stock-based compensation expense of \$24,000 and \$178,000, respectively, related to non-employee warrant, stock and option grants.

#### 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. 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. Alcon has committed to funding certain projects through December 2010 and discussions of 2011 funding levels are in progress. Additionally, we receive semi-annual payments to support on-going research and development activities. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compound. Alcon has the right to terminate the agreement in its entirety upon nine months’ notice, or terminate portions of the agreement upon 135 days’ notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days’ notice.

Revenue has been recognized under the Alcon agreement as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Amortization of Upfront Technology Access Fee	\$ 416	\$ 625	\$ 1,667	\$ 1,875
On-going Research and Development (FTE)	1,401	1,075	4,019	2,794

Materials, Equipment, and Contract Study Costs	119	399	312	398
Milestone Payment	—	—	—	1,000
	\$ 1,936	\$ 2,099	\$ 5,998	\$ 6,067

At September 30, 2010 and December 31, 2009, the Company had deferred revenue balances of \$1.4 and \$1.7 million, respectively, related to the Alcon agreement, which were comprised of the upfront technology access fee and upfront reimbursements to fund personnel. In January 2009, the Company received a \$1.0 million milestone payment under the Alcon agreement for non-rejection of the IND application for the Company's otic indication.

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Galderma

On March 25, 2009, the Company announced that it entered into an agreement with Galderma S.A. to develop and commercialize the Company's Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications. The Company amended this agreement on December 17, 2009. This agreement is exclusive and worldwide in scope, with the exception of Asian markets where the Company has commercialization rights, and North America, where the Company has an option to exercise co-promotion rights. Galderma will be responsible for the development costs of the acne and other indications, except in Japan, in which Galderma has the option to request that we share such development costs, and for the ongoing development program for impetigo, upon the achievement of a specified milestone. Galderma will also reimburse NovaBay for the use of its personnel in support of the collaboration. NovaBay retains the right to co-market products resulting from the agreement in Japan. In addition, NovaBay has retained all rights in other Asian markets outside Japan, and has the right to co-promote the products developed under the agreement in the hospital and other healthcare institutions in North America. Upon the termination of the agreement under certain circumstances, Galderma will grant NovaBay certain technology licenses, which would require NovaBay to make royalty payments to Galderma for such licenses with royalty rates in the low- to mid-single digits.

Galderma will pay to NovaBay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. If products are commercialized under the agreement, NovaBay's royalties will escalate as sales increase. The Company received a \$1.0 million upfront technology access fee payment in the first quarter of 2009. The upfront fee is being amortized into revenue on a straight-line basis over the 20 month funding term of the agreement, through October 2010. Additionally, NovaBay received \$200,000 for each of the first six months of the agreement to fund ongoing research, totaling \$2.2 million in cash received in the first six months of the agreement.

Revenue has been recognized under the Galderma agreement as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Amortization of Upfront Technology Access Fee	\$ 150	\$ 150	\$ 450	\$ 350
On-going Research and Development	—	400	270	1,200
Materials, Equipment, and Contract Study Costs	—	575	—	575
Total	\$ 150	\$ 1,125	\$ 720	\$ 2,125

The Company had deferred revenue balances of \$50,000 and \$500,000 respectively, at September 30, 2010 and December 31, 2009, related to the Galderma agreement, which consisted of the remaining amount to be amortized for the upfront technology access fee. As of September 30, 2010, the Company has earned \$3.75 million in milestone payments and has not earned or received any royalty payments under the Galderma agreement.

NOTE 9. SUBSEQUENT EVENTS

We are not aware of any significant events that occurred subsequent to the balance sheet date but prior to the filing of this Quarterly Report on Form 10-Q 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. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as “expects,” “anticipates,” “targets,” “goals,” “projects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, such as those set forth under the section entitled “Risk Factors” in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Readers are cautioned that these forward-looking statements are only predictions based upon assumptions made that we believed to be reasonable at the time, and are subject to risks and uncertainties. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.

### Overview

We are a clinical stage biotechnology company developing first-in-class anti-infectives for the treatment and prevention of viral, bacterial and fungal infections, including those that are resistant to antibiotics. 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, fungal 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.

We hold three issued patents in the United States and one issued patent in each of several foreign countries including China, India, South Korea, Mexico, Israel, Hong Kong, Singapore and New Zealand. We file and prosecute patent applications relating to new chemical compositions, formulations, methods of use, and other technologies in the United States and major foreign countries. Our trademarks NovaBay, the NovaBay Pharma design, and Aganocide are registered in the United States and pending registration in various foreign countries. Our other trademarks include AgaDerm, AgaNase, Neutrophase, and Going Beyond Antibiotics.

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 care. Under the terms of the agreement, Alcon paid an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. In addition to the technology access fee, we were entitled to receive semi-annual payments from Alcon to support on-going research and development activities over the four-year funding term of the agreement, which ended in August 2010. However, Alcon committed to funding certain projects through December 2010 and discussions for 2011 funding levels are in progress. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse NovaBay for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compounds. Alcon has the right to terminate the agreement in its entirety upon nine months' notice, or terminate portions of the agreement upon 135 days' notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach

upon 60 days' notice. In addition, NovaBay retains the rights to market, via a third-party co-marketing partner, any products developed for ear or sinus indications in the major Asian markets, including Japan, China, India and South Korea. NovaBay has also retained such rights in other markets where Alcon is not committing reasonably sufficient sales and marketing resources to the particular product. In each instance, the appointment of the co-marketing partner would be subject to certain conditions, including that the co-marketing partner be approved by Alcon. The co-marketing partner, or NovaBay on its behalf, would be required to pay Alcon a royalty based on net sales of the product in the applicable market and would also be required to reimburse Alcon for part of its local development costs or, in markets in which Alcon is not committing reasonably sufficient sales and marketing resources, all of its local development costs. These products may also be marketed in those markets by Alcon, its affiliates or distributors.



Alcon is responsible for all of the costs that it incurs in developing the products using the Aganocide compounds. In 2009, Alcon increased its on-going financial support of the company's research and development efforts by more than \$2.0 million for the 2010 year. The additional funding is being used to enhance NovaBay's pre-clinical and clinical development programs in the areas of eye, ear and sinus infections, as well as for the care of contact lenses. We recently announced that Alcon has concluded a Phase II "proof of concept" trial of NovaBay's lead compound, NVC-422, for the treatment of viral conjunctivitis, a type of "pink eye". The viral conjunctivitis trials were conducted at over 30 medical centers around the U.S. and internationally. Alcon and NovaBay are currently conducting a comprehensive analysis of all microbiological data and clinical signs and symptoms.

The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized product.

On March 25, 2009, we announced that we had entered into an agreement with Galderma S.A. to develop and commercialize our Aganocide compounds for the treatment of acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications. We amended this agreement in December 2009. The agreement is exclusive and worldwide in scope, with the exception of Asian markets and North American healthcare institutions and hospitals. In Asian markets we have commercialization rights. In North America we have an option to exercise co-promotion rights in hospital and healthcare institutions.

Galderma will be responsible for the development costs of the acne program and for other indications with two exceptions. First, in Japan Galderma has the option to request that we share such development costs. Second, at this time we are supporting the ongoing development program for impetigo; however, upon the achievement of a specified milestone, Galderma will reimburse NovaBay for associated expenses. 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 to hospitals and other healthcare institutions in North America.

Galderma paid to NovaBay a \$1.0 million upfront technology access fee and \$200,000 for each of the first six months of the agreement to fund ongoing research, totaling \$2.2 million in the first six months. Galderma will continue to pay ongoing fees, reimbursements, and milestone payments related to the development and commercialization of its Aganocide compounds. If products are commercialized under the agreement, NovaBay's royalties will escalate as sales increase. Upon the termination of the agreement under certain circumstances, Galderma will grant NovaBay certain technology licenses which would require NovaBay to make royalty payments to Galderma for such licenses with royalty rates in the low- to mid-single digits.

In early 2010, we announced that we had received \$3.75 million in milestone payments from Galderma: a \$2.0 million milestone payment was triggered by the completion of formulation feasibility studies with our Aganocide compound for topical use; and a \$1.75 million milestone payment was received for the completion of an exploratory clinical study for the treatment of adult acne. These milestones were reached in 2009 and therefore the revenue was recorded in 2009. The related receivable is included in our balance sheet as of December 31, 2009; we received payment on these receivables in January 2010.

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. We are a development-stage company that devotes substantially all of our resources to research and development; therefore, we have incurred significant losses since commencement of our operations in July 2002. As of September 30, 2010, we had an accumulated deficit of \$28.4 million. Our accumulated deficit resulted from research and development

expenses and general and administrative expenses. Although we were profitable in 2009, 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

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.

In April 2010, we reported positive results of an open-label Phase 2a trial of NVC-422 in chronically catheterized patients with significant bacteriuria, or bacteria in the urine. The study showed that NVC-422 was well tolerated and reduced or eliminated certain pathogens in the urine.

In July 2010, we announced that we received a Notice of Allowance from the United States Patent and Trademark Office on a patent application for a broad portfolio of anti-infective compounds, including NVC-612. The patent is expected to broaden protection for NovaBay's first-in-class Aganocide family of compounds, which are designed to fight infections without causing drug resistance.

In July 2010, we announced that our lead product candidate was shown to be safe and efficacious against the highly contagious skin infection impetigo in a Phase 2a proof-of-concept clinical trial. This dose-ranging study showed that the drug cleared impetigo infections, including those in the trial caused by a drug-resistant strain of bacteria called methicillin-resistant *Staphylococcus aureus* or MRSA.

In September 2010, we delivered four poster presentations on our Aganocide compounds at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Boston, MA. The presentations included new data from studies of our Aganocide compounds, which indicated that the Aganocide compounds are highly effective against bacteria, including some multi-drug resistant strains (such as MRSA), viruses and fungi in preclinical testing.

In October 2010, we announced that Alcon has concluded its "proof of concept" clinical trial of NVC-422 for the treatment of viral conjunctivitis. Alcon and NovaBay now intend to conduct a comprehensive analysis of all microbiological data and clinical signs and symptoms.

#### 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, 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, 2009. We have not materially changed these policies from those reported in our Annual Report on Form 10-K for the year ended December 31, 2009.

#### Recent Accounting Pronouncements

In April 2010, the 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 will be effective for us on a prospective basis for milestones achieved after December 31, 2010. We have evaluated the potential impact of this standard and expect it will have no significant impact on our financial position or results of operations.

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-06 (Topic 820) Fair Value Measurements and Disclosures. This standard amends the disclosure guidance with respect to fair value measurements for both interim and annual reporting periods. Specifically, disclosure is required for significant transfers between Level 1 and Level 2 in the fair value hierarchy; additional disclosures are required for transactions in Level 3 assets and liabilities; and additional disclosure is required of the valuation techniques and inputs used to measure assets and liabilities that fall into Level 2 and Level 3. Except for the additional disclosures for transactions in Level 3 items, which will be effective for us as of January 1, 2011, the remaining new disclosure requirements were effective for us as of January 1, 2010. The implementation of this standard had no impact on our financial position or results of operations.

## Results of Operations

The following table sets forth our results of operations for the three and nine months ended September 30, 2010 and 2009, including the dollar and percentage variances between such periods. Percentage variances have been omitted where they are not considered meaningful.

(in thousands)	Three Months Ended		Variance		Nine Months Ended		Variance		
	September 30, 2010	September 30, 2009	\$	%	September 30, 2010	September 30, 2009	\$	%	
<b>Revenue:</b>									
License and collaboration revenue	\$ 2,086	\$ 3,224	\$ (1,138 )	-35 %	\$ 6,718	\$ 8,192	\$ (1,474 )	-18 %	
<b>Operating Expenses:</b>									
Research and development	2,245	2,004	241	12 %	6,607	4,809	1,798	37 %	
General and administrative	1,487	1,309	178	14 %	4,567	4,078	489	12 %	
Total operating expenses	3,732	3,313	419	13 %	11,174	8,887	2,287	26 %	
Other income (expense), net	4	(22 )	26	-118 %	(13 )	(23 )	10	-43 %	
Loss before income taxes	(1,642 )	(111 )	(1,531 )		(4,469 )	(718 )	(3,751 )		
Provision for income taxes	—	—	—		—	—	—		
Net loss	\$ (1,642 )	\$ (111 )	\$ (1,531 )		\$ (4,469 )	\$ (718 )	\$ (3,751 )		

Comparison of the Three and Nine months Ended September 30, 2010 and September 30, 2009

### 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, or \$625,000 per quarter, through August 2010. The upfront fee of \$1.0 million from Galderma is being amortized into revenue on a straight-line basis over the 20 month funding term of the agreement, or \$150,000 per quarter, through October 2010.

Total license and collaboration revenue was \$2.1 million for the three months ended September 30, 2010, compared to \$3.2 million for the three months ended September 30, 2009, and was \$6.7 million for the nine months ended September 30, 2010, compared to \$8.2 million for the nine months ended September 30, 2009. The Alcon upfront payment is now fully amortized causing a decrease in our three and nine month revenue totals of \$209,000. In addition, our reimbursements from Galderma were significantly higher in 2009 as we were reimbursed for significant costs related to our clinical trials. These reimbursements tapered off as the costs declined towards the end of the trials in 2010. These decreases were partially offset by an increase in the FTE reimbursements from Alcon.

With the Alcon and Galderma upfront technology access fees becoming fully amortized, we expect our license and collaboration revenues will decrease in the near term. Further, with the expiration of Alcon's obligation to fund on-going research and development activities in August 2010, to the extent that Alcon ceases to fund these activities we expect our license and collaboration revenues will decrease. However, Alcon committed to funding certain projects through December 2010 and discussions for 2011 funding levels are in progress. In addition, we are in negotiations with Galderma to determine their future levels of funding. To the extent we earn milestone or royalty payments under the Alcon and Galderma 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 12% to \$2.3 million for the three months ended September 30, 2010 from \$2.0 million for the three months ended September 30, 2009. Total research and development expenses increased by 37% to \$6.6 million for the nine months ended September 30, 2010 from \$4.8 million for the nine months ended September 30, 2009. The increases for each of the three and nine month periods were primarily due to increased clinical and salaries expenses as we entered into clinical trials for catheter patency and completed our phase IIa clinical trial for impetigo.

We expect to incur increased research and development expenses in 2010 and in subsequent years as we continue to increase our focus on developing product candidates, both independently and in collaboration with Alcon and Galderma. In particular, we expect to incur ongoing clinical, chemistry, and manufacturing expenses during 2010 in connection with the dermatology, and catheter patency programs.

#### General and Administrative

Total general and administrative expenses increased by 14% to \$1.5 million for the three months ended September 30, 2010 from \$1.3 million for the three months ended September 30, 2009. Total general and administrative expenses increased by 12% to \$4.6 million for the nine months ended September 30, 2010 from \$4.1 million for the nine months ended September 30, 2009. The increases in both the three and nine month periods are due to additional staff needed to support our growing operations. Additionally, we experienced an increase in our stock-based compensation expense due in part to the increase in staff and in part to a change in the timing of the board compensation arrangements.

We expect that general and administrative expenses will remain steady for the remainder of 2010 and will increase in subsequent years due to increasing audit costs related to compliance with Sarbanes Oxley as our market cap increases, business development costs and our expanding operational infrastructure. In particular, we expect to incur increasing legal, accounting, investor relations, equity administration and insurance costs in order to operate as a growing public company.

#### Other Income (Expense), Net

Other income was \$4,000 for the three months ended September 30, 2010 compared to an expense of \$22,000 for the three months ended September 30, 2009. Other expense was \$13,000 for the nine months ended September 30, 2010 compared to an expense of \$23,000 for the nine months ended September 30, 2009. This decrease in expense was primarily attributable to higher interest expense on our capital lease during 2009 as the lease was fully repaid in 2010.

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

## Liquidity and Capital Resources

In August 2006, we entered into a collaboration and license agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of \$10.0 million in September 2006. Additionally, we were entitled to receive semi-annual payments each January and July over the four-year term of the agreement to support on-going research and development efforts. The initial four-year term ended in August 2010; however, Alcon committed to funding certain projects through December 2010 and discussions for 2011 funding levels are in progress. 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 January 2009, we received \$1.0 million for the non-rejection of an IND application related to our otic indication. 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, future milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.



During April 2007, we entered into a master security agreement to establish a \$1.0 million equipment loan facility with a financial institution. The purpose of the loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2009 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. In April 2008, the agreement was extended through April 2009, and as a result no further borrowings are permitted on this loan. There are no loan covenants specified in the agreement. As of September 30, 2010 we had an outstanding equipment loan balance of \$168,000 carrying a weighted-average interest rate of 11.17%. The principal and interest due under the loan will be repaid in equal monthly installments through June 2011.

In March 2009, we entered into a license agreement with Galderma, which we amended in December 2009. Under the terms of the agreement, we received a \$1.0 million upfront technology access fee, \$200,000 for each of the first six months of the agreement to fund ongoing research, reimbursements, and milestones payments of \$3.75 million to date. In addition, Galderma will pay to NovaBay ongoing fees, reimbursements, and additional milestone payments related to achieving development and commercialization of NovaBay's Aganocide compounds.

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

As of September 30, 2010, we had cash, cash equivalents, and short-term investments of \$10.8 million compared to \$11.3 million at December 31, 2009.

#### Cash Flows

The following table provides information regarding our cash flows and our capital expenditures for the nine months ended September 30, 2010 and 2009.

(in thousands)	Nine Months Ended	
	September 30,	
	2010	2009
Cash provided by (used in):		
Operating activities	\$(65 )	\$(1,544 )
Investing activities	(1,266 )	(1,646 )
Financing activities	(246 )	1,721
Capital expenditures (included in investing activities above)	170	596

#### Cash Provided by Operating Activities

For the nine months ended September 30, 2010 cash used in operating activities of \$65,000 was primarily attributable to our operating expenses. These expenses were almost entirely offset by receipt of a \$3.75 million milestone payment from Galderma that was included in outstanding receivables as of December 31, 2009 and \$4.6 million received in 2010 from Galderma and Alcon in support of our ongoing research and development activities.

#### Cash Used in Investing Activities

For the nine months ended September 30, 2010, cash used in investing activities of \$1.3 was attributable to purchases of short-term investments (net of maturities or sales) of \$1.1 million and purchases of property and equipment of \$170,000.

#### Cash Used in Financing Activities

Net cash used in financing activities of \$246,000 for the nine months ended September 30, 2010 was primarily attributable to the payments on the equipment loan, offset in part by proceeds from the exercise of stock options.

We have a cumulative deficit of \$28.4 million from inception through September 30, 2010. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the private placement of our preferred stock, our initial public offering, and the registered direct offering of our common stock. We raised total net proceeds of \$12.6 million from sales of our preferred stock in 2002 through 2006. In October 2007, we completed our IPO in which we raised a total of \$20.0 million, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million. In August 2009, we completed a registered direct offering from which we received net proceeds of \$1.9 million.

#### Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2009 we had net operating loss carryforwards for both federal and state income tax purposes of \$20.0 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2016 and 2029.

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 September 30, 2010 is \$4.7 million due over the lease term. Our commitment for the equipment loan consists of the total payments due under the loan facility of \$175,000. This amount includes \$7,000 of interest payments over the remaining term of the loan.

We expect the total cash, cash equivalents, and short-term investments, along with funding under our license agreement from Alcon and Galderma will be sufficient to fund cash requirements for the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future and we are frequently in discussions with investors to ensure we are in a position to take advantage of the best market conditions. 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 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 stockholders 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.

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

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

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital; assurance of liquidity needs; best available return on invested capital; and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. As of September 30, 2010 and December 31, 2009, a 10% change in interest rates would have had an immaterial affect 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

#### Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective 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

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2010, and has concluded that there was no change in our internal control over financial reporting during the quarter 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, 2009, as filed with the SEC on March 30, 2010, which risk factors are set forth below, except for those risk factors denoted by an asterisk (\*).

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

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 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 since our inception through the first nine months of 2010. For the years ended December 31, 2007 and 2008 we had net losses of approximately \$5.4 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, we may not be able to continue to be profitable. For example, we had a net loss of \$4.5 million for the nine months ended September 30, 2010. Through September 30, 2010, we had an accumulated deficit of approximately \$28.4 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 \$7.4 million, \$9.6 million and \$7.3 million for the years ended December 31, 2007, 2008 and 2009, respectively, and \$6.6 million for the nine months ended September 30, 2010. 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 I safety studies or small-scale Phase IIa exploratory-studies. We will need to conduct additional Phase I, II and III 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. 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 million we will be required to do so. If we reach the \$75 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 substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. 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. Alcon has committed to funding certain projects through December 2010 and discussions of 2011 funding levels are in progress; however, there is no guarantee that Alcon will commit to further funding under the agreement.

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

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 United States as well as in other countries. To obtain regulatory approval to market our proposed products outside of the United States, we and any collaborator must comply with numerous and varying regulatory requirements in other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ significantly from that required to obtain FDA approval. The regulatory approval process in other countries 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 United States, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed. In addition, failure to comply with applicable regulatory requirements in other countries can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution.

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 United States or in other countries.

Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action 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. Our products may be classified by the FDA as a drug or a medical device depending upon their mechanism of action or indications for use or claims. For example, for NVC-422, if the indication is for bladder lavage, we believe it would be classified as a medical device, whereas we believe it would be considered a drug when it is indicated for the prevention of urinary tract infection. Similarly, the use of NVC-101 as a solution for cleansing and debriding wounds is considered a medical device. The determination as to whether a particular indication is considered a drug or a device is based in part upon prior precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development for that indication could have a significant adverse impact due to the more rigorous approval process required for

drugs, as compared to medical devices. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a drug to a device could result in a change in classification for reimbursement. In many cases, reimbursement for devices is significantly lower than for drugs and there could be a significant negative impact on our revenues.

We and our collaborators are and will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which may limit our ability to commercialize our medical device and drug products candidates.

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

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

The risk of clinical trial liability is inherent in the testing of pharmaceutical and medical device products. If we cannot successfully defend ourselves against any clinical trial claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our product candidates. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our product candidates. Our current clinical trial insurance covers individual and aggregate claims up to \$3.0 million. This insurance may not cover all claims and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

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

Our activities currently require the controlled use of potentially harmful biological materials and other hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject, on an ongoing basis, to U.S. federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In addition, if more stringent laws and regulations are adopted in the future, the costs of compliance with these new laws and regulations could be substantial or could impose significant changes in our testing and production process.

The pharmaceutical and biopharmaceutical industries are characterized by patent litigation and any litigation or claim against us may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain nine months of exclusivity as a generic product under the Waxman-Hatch Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties in order to produce our products. In addition, future patents may issue to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe.



Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorneys fees if we were to be found to have willfully infringed a third party's patent, to the party claiming infringement, develop non-infringing technology, stop selling any products we develop, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

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

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

Our business and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the United States and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

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

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

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

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

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

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

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds, we do not expect bacteria to be able to develop resistance to Aganocide compounds. However, we cannot assure you that one or more strains of bacteria will not develop resistance to our compounds, either because our hypothesis of the mechanism of action is incorrect or because a strain of bacteria undergoes some unforeseen genetic mutation that permits it to

survive. Since we expect lack of resistance to be a major factor in the commercialization of our product candidates, the discovery of such resistance would have a major adverse impact on the acceptability and sales of our products.

If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves product candidates that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
  - published studies demonstrating the cost-effectiveness of our products relative to competing products;
  - availability of reimbursement for our products from government or healthcare payers; and
  - effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

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, 2009, our officers and directors collectively controlled approximately 4,158,640 shares of our outstanding common stock (and approximately 5,445,570 shares of our common stock when including options held by them which were exercisable as of or within 60 days of December 31, 2009). Furthermore, as of December 31, 2009, 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. 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;
- the 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: November 11, 2010

NOVABAY PHARMACEUTICALS, INC.

/s/ Ramin Najafi  
Ramin ("Ron") Najafi  
Chief Executive Officer  
(duly authorized officer)

Date: November 11, 2010

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

EXHIBIT INDEX

Exhibit No. Description

- 2.1 Agreement and Plan of Merger between NovaBay Pharmaceuticals, Inc., a California corporation, and NovaBay Pharmaceuticals, Inc., a Delaware corporation, dated as of June 25, 2010 (Incorporated by reference to the exhibit of the same number from the Company's Post-Effective Amendment No. 2 to the registration statement on Form S-3 filed with the SEC on July 1, 2010 (File Nos. 333-159917))
- 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 Bylaws 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))
- 4.1 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 Form of Indemnification Agreement between NovaBay Pharmaceuticals, Inc. and its Directors and Officers (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q, as filed with the SEC on August 12, 2010 (SEC File No. 001-33678))
- 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