NovaBay Pharmaceuticals, Inc.
Form 10-Q
November 14, 2008

10-Q NOVABAY PHARMACEUTICALS, INC. 10-Q 3RD QUARTER
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2008

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-33678

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

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

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

(510) 899-8800
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant 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.

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

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

As of October 31, 2008, 21,468,574 shares of the registrant's common stock, $0.01 par value, were outstanding.

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NOVABAY PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

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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®, Aganocide®, AgaDerm™, AgaNase™ and NeutroPhase™ are our trademarks. All other trademarks and trade names appearing in this report are the property of their respective owners.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVABAY PHARMACEUTICALS, INC
(formerly NovaCal Pharmaceuticals Inc.)
(a developmental stage company)
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,739	$ 10,941
Short-term investments	3,463	11,412
Prepaid expenses and other current assets	773	419
Total current assets	15,975	22,772
Property and equipment, net	1,449	1,150
TOTAL ASSETS	$ 17,424	$ 23,922
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 457	$ 142
Accrued liabilities	1,350	1,141
Capital lease obligation	40	37
Equipment loan	357	219
Deferred revenue	3,468	3,039
Total current liabilities	5,672	4,578
Capital lease obligation - non-current	18	49
Equipment loan - non-current	565	497
Deferred revenue - non-current	2,539	4,478
Total liabilities	8,794	9,602
Stockholders' Equity:		
Common stock, $0.01 par value; 65,000 and 65,000 shares authorized at September 30, 2008 and December 31, 2007, respectively, 21,457 and 21,269 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	214	212
Additional paid-in capital	33,437	32,585
Accumulated other comprehensive income (loss)	31	(3)
Accumulated deficit during development stage	(25,052)	(18,474)
Total stockholders' equity	8,630	14,320
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,424	$ 23,922

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

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NOVABAY PHARMACEUTICALS, INC
(formerly NovaCal Pharmaceuticals Inc.)
(a developmental stage company)
CONSOLIDATED STATEMENT OF OPERATIONS
(in thousands, except per share data
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30,
	2008	2007	2008	2007	2008
REVENUE					
License and collaboration revenue	$ 1,592	$ 1,444	$ 4,526	$ 4,392	$ 11,972
Total revenue	1,592	1,444	4,526	4,392	11,972
EXPENSES					
Operating Expenses:					
Research and development	1,443	2,051	6,263	5,580	21,675
General and administrative	1,715	1,021	5,173	3,125	16,501
Total operating expenses	3,158	3,072	11,436	8,705	38,176
Other income, net	77	72	334	307	1,166
Net loss before income taxes	(1,489)	(1,556)	(6,576)	(4,006)	(25,038)
Provision for income taxes	-	-	(2)	-	(14)
Net loss	$ (1,489)	$ (1,556)	$ (6,578)	$ (4,006)	$ (25,052)
Net loss per share:					
Basic and diluted	$ (0.07)	$ (0.24)	$ (0.31)	$ (0.62)	
Shares used in per share calculations:					
Basic and diluted	21,443	6,564	21,313	6,494	

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

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NOVABAY PHARMACEUTICALS, INC.
(formerly NovaCal Pharmaceuticals, Inc.)
(a development stage company)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,		Cumulative Period from July 1, 2002 (date of development stage inception) to September 30,
	2008	2007	2008
Cash flows from operating activities:			
Net loss	$ (6,578)	$ 4,006)	$ (25,052)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	222	128	622
Accretion of discount on short-term investments	(40)	(81)	(318)
Net realized (gain) loss on sales of short-term investments	(4)	(88)	28
Loss on disposal of property and equipment	-	-	121
Stock-based compensation expense for options issued to employees and directors	667	287	1,408
Compensation expense for warrants issued for services	44	-	44
Stock-based compensation expense for options and stock issued to non-employees	(9)	130	354
Taxes paid by LLC			1
Changes in operating assets and liabilities:			
Decrease in prepaid expenses and other assets	(354)	(138)	(768)
Increase in accounts payable and accrued liabilities	524	992	1,832
(Increase) decrease in deferred revenue	(1,510)	(839)	6,007
Net cash provided by (used in) operating activities	(7,038)	(3,615)	(15,721)
Cash flows from investing activities:			
Purchases of property and equipment	(521)	(371)	(2,071)
Proceeds from disposal of property and equipment	-	1	44
Purchases of short-term investments	(32,103)	(30,028)	(94,550)
Proceeds from maturities and sales of short-term investments	40,129	30,200	91,405
Cash acquired in purchase of LLC	-	-	516
Net cash provided by (used in) investing activities	7,505	(198)	(4,656)
Cash flows from financing activities:			
Proceeds from preferred stock issuances, net	-	-	11,160
Proceeds from common stock issuances	-	-	17
Proceeds from exercise of options and warrants	153	99	1,761

Initial public offering costs	-	(926)	17,077
Proceeds from stock subscription receivable	-	-	873
Proceeds from issuance of notes	-	-	405
Principal payments on capital lease	(28)	(22)	(99)
Proceeds from borrowings under equipment loan	422	494	1,216
Principal payments on equipment loan	(216)	(46)	(294)
Tax benefit from stock plans	-	-	-
	331	(401)	32,116
Net cash provided by (used in) financing activities			
Net increase (decrease) in cash and cash equivalents	798	(4,214)	11,739
Cash and cash equivalents, beginning of period	10,941	4,903	-
Cash and cash equivalents, end of period	$ 11,739	$ 689	$ 11,739

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

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NOVABAY PHARMACEUTICALS, INC.

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION

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

We were 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 will explore and pursue dermatological opportunities. We currently operate in one business segment.

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

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The interim financial statements for the three and nine months ended September 30, 2008 and 2007 and the cumulative period from July 1, 2002 to September 30, 2008 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in our opinion, reflect all adjustments necessary for a fair statement of our financial position, results of operations and cash flows. The results for the three and nine months ended September 30, 2008 are not necessarily indicative of the expected results for the

year ended December 31, 2008. The consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries.

Intercompany transactions and balances have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars. The financial statements have been prepared under the guidelines of Statement of Financial Accounting Standard ("SFAS") No. 7, "Accounting and Reporting by 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, 2008 we had not commenced our planned principal operations.

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

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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.

Reverse Stock Split

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

Use of Estimates

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

Cash and Cash Equivalents and Short-Term Investments

We consider all highly liquid instruments with a stated maturity of three months or less to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximate their fair value. As of September 30, 2008, our 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.

We classify all highly liquid investments with a stated maturity of greater than three months as short-term investments. Short-term investments generally consist of United States government, municipal and corporate debt securities. We have classified our short-term investments as available-for-sale. We do 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, we occasionally sell these securities prior to their stated maturities. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other than temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. The amortization and accretion, interest income and realized gains and losses are included in other income, net within the consolidated statements of operations. Interest income is recognized when earned.

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Concentrations of Credit Risk

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.

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, 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.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets of five to seven years for office and laboratory equipment, three years for software and seven years for furniture and fixtures. Leasehold improvements are depreciated on the shorter of seven years or the life of the lease term. Depreciation of assets recorded under capital leases is included in depreciation expense. The costs of normal maintenance, repairs, and minor replacements are charged to operations when incurred.

Impairment of Long-Lived Assets

We account for long-lived assets in accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of”, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets and has determined that there was no impairment as of all periods presented. Should there be impairment in the future, we would recognize the amount of the impairment based on the expected future cash flows from the impaired assets. The cash flow estimates would be based on management’s best estimates, using appropriate and customary assumptions and projections at the time.

Accumulated Other Comprehensive Income

Accumulated other comprehensive income consists of unrealized gains and losses on short-term investments classified as available-for-sale.

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Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our 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 Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our 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.

We recognize revenue in accordance with SEC Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", as amended by SAB No. 104 (together, "SAB 104"). In accordance with SAB 104, 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 collectibility is reasonably assured.

Assuming the elements meet the EITF No. 00-21 criteria for separation and the SAB 104 requirements for recognition, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

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

Funded Research and Development—Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue in accordance with EITF Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent," and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

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

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

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Advertising Costs

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

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services.

Patent Costs

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

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, “Share-Based Payment”. SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board (“APB”) Opinion No. 25,

“Accounting for Stock Issued to Employees” and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, 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. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method.

The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified. The adoption of SFAS No. 123R had a material effect on our financial position and results of operations. See Note 10 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Prior to the adoption of SFAS No. 123R, we valued our stock-based awards using the minimum value method and provided pro-forma information regarding stock-based compensation and net income required by SFAS No. 123. We did not recognize stock-based compensation expense in our statements of operations for option grants to our employees or directors for the periods prior to our adoption of SFAS No. 123R because the exercise price of options granted was generally equal to the fair market value of the underlying common stock on the date of grant.

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services”, 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

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

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Net Income (Loss) per Share

We compute net income (loss) per share in accordance with SFAS No. 128, "Earnings per Share" which requires presentation of both basic and diluted earnings (loss) per share ("EPS"). Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and stock warrants, using the treasury stock method, and convertible preferred stock, using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods as their effect would be anti-dilutive.

Recent Accounting Pronouncements

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities". SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities by requiring enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and how derivative instruments and related hedged items affect an entity's operating results, financial position, and cash flows.

SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. Early adoption is permitted. We are currently reviewing the provisions of SFAS No. 161 and have not yet adopted the statement. However, as the provisions of SFAS No. 161 are only related to disclosure of derivative and hedging activities, we do not believe the adoption of SFAS No. 161 will have a material impact on our consolidated operating results, financial position, or cash flows.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. The intent of the position is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the intangible asset. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are assessing the potential impact that the adoption of FSP FAS 142-3 may have on our consolidated financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement shall be effective 60 days following the Securities and Exchange Commission's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not believe that implementation of this standard will have a material impact on our consolidated financial position, results of operations or cash flows.

In June 2008, the FASB issued FSP No. EITF 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities," (FSP EITF 03-6-1). FSP EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. Management has determined that the adoption of FSP EITF 03-6-1 will not have an impact on the Financial Statements.

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NOTE 3. SHORT-TERM INVESTMENTS

Short-term investments at September 30, 2008 and December 31, 2007 consisted of the following:

	September 30, 2008			
(in thousands)	Amortized Cost	Gross Unrealized/Realized Gains	Gross Unrealized/ Realized Losses	Market Value
Corporate bonds	$ 390	$ -	$ (1)	$ 389
U.S. Agencies	-	-	-	-
Municipal Bonds	-	-	-	-
Certificates of Deposit	-	-	-	-
Other Fixed Income	3,070	4	-	3,074
	$ 3,460	$ 4	$ (1)	$ 3,463

	December 31, 2007			
(in thousands)	Amortized Cost	Gross Unrealized/ Realized Gains	Gross Unrealized/Realized Losses	Market Value
Corporate bonds	$ 5,362	$ -	$ (4)	$ 5,358
U.S. Agencies	5,553	1	-	5,554
Municipal Bonds	500	-	-	500
Certificates of Deposit	-	-	-	-
Other Fixed Income	-	-	-	-
	$ 11,415	$ 1	$ (4)	$ 11,412

Contractual maturities of short-term investments as of September 30, 2008 and December 31, 2007 were as follows:

	September 30, 2008	
(in thousands)	Amortized Cost	Market Value
Due in one year or less	$ 2,985	$ 2,988
Due after 10 years	475	475
Total	$ 3,460	$ 3,463

	December 31, 2007

(in thousands)	Amortized Cost	Market Value
Due in one year or less	$ 9,915	$ 9,912
Due after 10 years	1,500	1,500
Total	$ 11,415	$ 11,412

We did not recognize any realized gains or losses for the year ended December 31, 2007. For the three and nine months ended September 30, 2008, we had $4,000 of net realized gain. For the cumulative period from July 1, 2002 (date of development stage inception) to September 30, 2008, we recognized a net realized loss of $28,000.

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NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	September 30, 2008	December 31, 2007
Office and laboratory equipment	$ 1,646	$ 1,243
Furniture and fixtures	113	96
Software	106	72
Leasehold improvement	140	73
Total property and equipment, at cost	2,005	1,484
Less: accumulated depreciation	(556)	(334)
Total property and equipment, net	$ 1,449	$ 1,150

Depreciation expense was $183,000 for the year ended December 31, 2007, $222,400 for the nine months ended September 30, 2008, and $622,400 for the cumulative period from July 1, 2002 (date of development stage inception) to
September 30, 2008.

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	September 30, 2008	December 31, 2007
Research and development	$ 187	$ 178
Employee payroll and benefits	730	688
Professional fees	274	197
Other	159	78
Total accrued liabilities	$ 1,350	$ 1,141

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NOTE 6. CAPITAL LEASE OBLIGATION

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

(in thousands)	September 30, 2008	December 31, 2007
Office and laboratory equipment	$ 229	$ 166
Less: accumulated depreciation	(39)	(25)
Capital lease assets, net	$ 190	$ 141

Future minimum lease payments under capital leases were as follows at September 30, 2008:

(in thousands)	Lease Commitment
Year ending December 31,	
2008	$ 11
2009	45
2010	7
Total minimum lease payments	63
Less: amount representing interest	(5)
Present value of minimum lease payments	$ 58

NOTE 7. EQUIPMENT LOAN

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 this loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Current borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement.

As of September 30, 2008, we had an outstanding equipment loan balance of $921,863 carrying a weighted-average interest rate of 10.94%. At September 30, 2008, there was $216,000 available for borrowing under this equipment loan facility.

Future minimum loan payments under equipment loans were as follows at September 30, 2008:

(in thousands)	Loan Commitment
Year ending December 31:	
2008	$ 110
2009	440

2010		396
2011		109
Total minimum loan payments	$	1,055
Less: amount representing interest		(133)
Present value of minimum loan payments	$	922

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NOTE 8. COMMITMENTS AND CONTINGENCIES

Operating Leases

We lease laboratory facilities and office space under operating leases which expire at various dates through 2015. The lease was amended as of August 13, 2008. The changes in the amendment are reflected in the minimum lease schedule.

Rent expense was $158,000 and $516,000 for the three and nine months ended September 30, 2008. Rent expense was $130,000 and $393,000 for the three and nine months ended September 30, 2007 and $1,837,000 for the cumulative period from July 1, 2002 (date of development stage inception) to September 30, 2008.

The future minimum lease payments under non-cancellable operating leases for the next five years were as follows as of September 30, 2008:

(in thousands)	Lease Commitment
Year ending December 31:	
2008	$ 216
2009	860
2010	894
2011	929
2012	966
2013	1,005
Total lease commitment	$ 4,870

Legal Matters

From time to time, we may be involved in various legal proceedings arising in the ordinary course of business.

There are no matters at September 30, 2008 that, in the opinion of management, would have a material adverse effect on our financial position, results of operations or cash flows.

NOTE 9. STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

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Stock Warrants

Warrants to acquire shares of common stock were issued in connection with the sales of the Series A and Series B Convertible Preferred Stock and certain convertible notes. Additionally, in October 2007, warrants were issued to the underwriters in connection with the IPO. The significant terms of the Series A, Series B, Note, and Underwriter warrants were as follows:

· <?xml:namespace prefix = ns1 ns = "http://www.rrd.com/pageprorwp" />Series A Warrants—The warrants issued with the sale of Series A Preferred Stock were issued on the basis of 0.20 of a warrant for every share of Series A Preferred Stock purchased. The exercise price of these warrants was $1.20 per share. We extended a limited-time offer to holders of the warrants to exercise them at a price of $0.80 per share. The warrants expired on July 1, 2005, except for warrants issued in connection with later purchases of the Series A Preferred Stock for which the expiration date was extended to July 1, 2006. <?xml:namespace prefix = o ns = "urn:schemas-microsoft-com:office:office" />

· Series B Warrants—The warrants issued with the sale of Series B Preferred Stock were issued on the basis of 0.175 of a warrant for every share of Series B Preferred Stock purchased. The exercise price of these warrants was $0.80 per share. The warrants expired on June 30, 2006.

· Note Warrants—Warrants were granted in connection with promissory notes issued to certain of our shareholders in 2002 and 2003. The warrants issued to these shareholders had an exercise price of $1.20 per share. The warrants expired on June 30, 2006.

· Underwriter Warrants—In connection with the IPO, we issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of $4.00 per share. The warrants are exercisable on or after October 31, 2008 and expire on October 31, 2010. The warrants were valued at approximately $524,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 50.0%, (2) a risk-free interest rate of 3.94% and (3) a contractual life of 3 years. We accounted for the fair value of the Underwriter Warrants as an expense of the IPO resulting in a charge to stockholders' equity.

· Advisory Services Warrants - In April 2008, we issued a two year warrant and a four year warrant to purchase an aggregate of 300,000 of common stock to PM Holdings Ltd. as part of our consideration for the revision of the agreement dated February 13, 2007 with PM Holdings. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of $264,000 and the issuance of warrants to purchase 300,000 of common stocks at an exercise price of $4.00 per share.

At September 30, 2008, there were outstanding warrants to purchase 650,000 shares of common stock at a weighted-average exercise price of $4.00 per share. None of the warrants were exercisable at September 30, 2008.

NOTE 10. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to the IPO, we 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, we 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. As of September 30, 2008, there were 538,131 shares available for future grants under the 2007 Plan.

Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and , if granted to an owner of more than 10% of our 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. We issue new shares to satisfy option exercises under the plans.

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Stock Options Summary

The following table summarizes information about our stock options outstanding at September 30, 2008 and activity during the period then ended.

(in thousands, except per share data)	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	2,896	$ 1.57		
Options granted	877	$ 2.41		
Options exercised	(122)	$ 1.18		
Options forfeited/cancelled	(149)	$ 2.90		
Outstanding at September 30, 2008	3,502	$ 1.74	7.3	1,631
Vested and expected to vest at September 30, 2008	3,315	$ 1.68	7.2	1,626
Vested at September 30, 2008	1,943	$ 0.98	5.6	1,591
Exercisable at September 30, 2008	2,368	$ 1.29	6.2	1,631

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as quoted on the American Stock Exchange as of September 30, 2008. The aggregate intrinsic value of stock option awards exercised was $25,000 for the three months and $103,000 for the nine months ended September 30, 2008, as determined at the date of option exercise. We received cash payments for the exercise of stock options in the amount of $11,000 during the three months and $150,000 during the nine months ended September 30, 2008.

The options outstanding and vested by exercise price at September 30, 2008 were as follows (number of options in thousands):

Range of Exercise Prices	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Number Vested	Weighted Average Exercise Price
$ 0.20	544	$ 0.20	3.4	544	$ 0.20
$ 0.30	318	$ 0.30	5.3	318	$ 0.30
$ 0.56	191	$ 0.56	5.7	184	$ 0.56
$ 0.94 - $1.20	278	$ 1.15	5.9	215	$ 1.14
$ 1.70 - $1.95	1,189	$ 1.82	8.7	535	$ 1.70
$ 2.00 - $2.90	243	$ 2.22	8.6	83	$ 2.21
$ 3.56 - $4.00	739	$ 3.71	9.2	64	$ 4.00

3,502	$ 1.74	7.3	1,943	$ 0.98	

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Stock Option Awards to Employees and Directors

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

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

	Nine Months Ended September 30	
Assumption	2008	2007
Expected price volatility	70%	72%
Expected term (in years)	6.1	6
Risk-free interest rate	3.1%	4.8%
Dividend yield	0%	0%
Weighted-average fair value of options granted during the period	$ 1.57	$ 0.77

Expected Price Volatility—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. Prior to the adoption of SFAS No. 123R, we assumed 0% price volatility in accordance with the minimum value method requirements of SFAS No. 123. Under SFAS No. 123R, which we adopted on January 1, 2006, the computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization data. An increase in the expected price volatility will increase the value of the option granted and the related compensation expense.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. Because there is insufficient historical information available to estimate the expected term of the stock-based awards, we adopted the simplified method for estimating the expected term pursuant to SAB No. 107 “Share Based Payment”. On this basis, we estimated the expected term of options granted by taking the average of the vesting term and the contractual term of the option. An increase in the expected life will increase the value of the option granted and the related compensation expense.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase the value of the option granted and the related compensation expense.

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

Under SFAS No. 123R, forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. For the three and nine months ended September 30, 2008, we applied an estimated forfeiture rate of 5% to employee grants and 0% to director grants.

For the three months ended September 30, 2008 and 2007, we recognized stock-based compensation expense of $179,000 and $67,000, respectively, for option awards to employees and directors. For the nine months ended September 30, 2008 and 2007, we recognized $667,000 and $287,000, respectively. As of September 30, 2008, total unrecognized compensation cost related to unvested stock options granted or modified on or after January 1, 2006 was $2.2 million. This amount is expected to be recognized as stock-based compensation expense in our statements of operations over the remaining weighted average vesting period of 3.14 years.

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Common Stock Awards to Directors

In connection with the close of the IPO in October 2007, we adopted a new Director Compensation Plan to compensate our non-employee directors for their services. Under the terms of the Director Compensation Plan, each non-employee director 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, we issued an aggregate of 45,946 shares of common stock to our non-employee directors during the nine months ended September 30, 2008. These shares were issued out of the 2007 Plan. The fair market value of the stock issued to directors was recorded as an operating expense in the period in which the meeting occurred, resulting in total compensation expense of $21,598 and $114,885, respectively, for common stock awards to directors during the three and nine months ended September 30, 2008.

Stock-Based Awards to Non-Employees

During the three and nine months ended September 30, 2008, we granted options to purchase an aggregate of 16,000 shares of common stock to non-employees in exchange for advisory and consulting services. During the nine months ended September 30, 2007, we granted an aggregate of 51,208 options to purchase 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 assumptions:

	Nine Months Ended September 30,	
Assumption	2008	2007
Expected price volatility	70%	72%
Expected term (in years)	6.1	5.3
Risk-free interest rate	3.1%	4.8%
Dividend yield	0%	0%
Weighted average fair values of option granted during the period	$ 1.26	$ 1.44

For the three months ended September 30, 2008 and 2007, we recognized stock-based compensation expense of $3,000 and $7,000, respectively, related to non-employee option grants. For the nine months ended September 30, 2008 we reversed previously recognized expense of $11,000 due to the required revaluation of unvested non-employee grants. For the nine months ended September 30, 2007, we recognized $51,000 of expense related to non-employee grants.

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Summary of Stock-Based Compensation Expense Under SFAS No. 123R

Upon the adoption of SFAS No. 123R on January 1, 2006, we began recognizing stock-based compensation expense in the statements of operations for all employee and director equity awards granted or modified on or after the adoption date. Stock-based compensation expense is classified in the statements of operations in the same expense line items as cash compensation. Since we continue to operate at a net loss, we do not expect to realize any current tax benefits related to stock options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2008	2007	2008	2007
Research and development	$ 81	$ 36	$ 336	$ 126
General and administrative	98	31	331	161
Total stock-based compensation expense	$ 179	$ 67	$ 667	$ 287

NOTE 11. 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 is being amortized into revenue on a straight-line basis over the four-year funding term of the agreement, through August 2010. Additionally, we will receive semi-annual payments to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. Our obligation to perform research and development activities under the agreement expires at the end of the four year funding term. As product candidates are developed and proceed through clinical trials and approval, 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.

For the three months ended September 30, 2008 and 2007, we recognized revenue of $0.6 million and $0.6 million, respectively, for amortization of the upfront technology access fee. For the three months ended September 30, 2008 and 2007 we also recognized $0.7 million and $0.7 million, respectively, for the on-going research and development activities performed. During the three months ended September 30, 2008 and 2007, we recognized $259,000 and $84,000 respectively, for materials, equipment and contract study costs which have been or will be reimbursed by

Alcon. In total, we recognized revenue of $1.6 million and $1.4 million for the three months ended September 30, 2008 and 2007.

For the nine months ended September 30, 2008 and 2007, we recognized revenue of $1.9 million and $1.9 million, respectively, for amortization of the upfront technology access fee. For the nine months ended September 30, 2008 and 2007 we also recognized $2.0 million and $2.0 million, respectively, for the on-going research and development activities performed. During the nine months ended September 30, 2008 and 2007, we also recognized $518,000 and $427,000, respectively, for materials, equipment and contract study costs which have been or will be reimbursed by Alcon. In total, we recognized revenue of $4.4 million and $4.3 million for the nine months ended September 30, 2008 and 2007.

At September 30, 2008, we had a deferred revenue balance of $5.3 million related to the Alcon agreement which was comprised of $4.8 million for the upfront technology access fee and $513,000 for other prepaid reimbursements. As of September 30, 2008, we had not earned or received any milestone or royalty payments under the Alcon agreement.

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KCI International VOF GP

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

For the three months ended September 30, 2008 and 2007, we recognized revenue of $33,000 and $33,000 respectively, for amortization of the upfront technology access fee. For the three months ended September 30, 2008 and 2007 we recognized $0 and $26,000 of revenue for consulting and materials costs reimbursable by KCI. In total, we recognized revenue of $33,000 and $59,000 for the three months ended September 30, 2008 and 2007.

For the nine months ended September 30, 2008 and 2007, we recognized revenue of $100,000 and $39,000, respectively, for amortization of the upfront technology access fee. For the nine months ended September 30, 2008 and 2007 we also recognized $8,000 and $26,000, respectively, for consulting and materials cost which have been or will be reimbursed by KCI. In total, we recognized revenue of $108,000 and $65,000 for the nine months ended September 30, 2008 and 2007.

At September 30, 2008, we had a deferred revenue balance of $28,000 related to the KCI agreement which consisted of the remaining amount to be amortized for the upfront technology access fee. As of September 30, 2008, we had not earned or received any milestone or royalty payments under the KCI agreement.

NOTE 12. EMPLOYEE BENEFIT PLAN

We have a 401(k) plan covering all eligible employees. We are not required to contribute to the plan and have made no contributions through September 30, 2008.

NOTE 13. INCOME TAXES

As of December 31, 2007 we had net operating loss carryforwards for both federal and state income tax purposes of $10.1 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2014 and 2027. Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized. We track the portion of our federal and state net operating loss carryforwards attributable to stock option benefits in a separate memo account pursuant to SFAS No. 123R. Therefore, these amounts are not included in gross or net deferred tax assets. Pursuant to SFAS No. 123R, the benefit of these net operating loss carryforwards will only be recorded to equity when they reduce cash taxes payable. We elected to use the "with-and-without" approach for utilizing the tax benefits of stock option exercises under SFAS No. 123R. These benefits would result in a credit to additional paid-in-capital when they reduce income taxes payable.

Uncertain Income Tax Positions

In July 2006, the FASB released Interpretation No. 48, “Accounting for Uncertainty in Income Taxes” (“FIN 48”). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of the adoption. We have no unrecognized tax benefit as of December 31, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of income tax expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 2002 forward. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2008.

NOTE 14. SUBSEQUENT EVENTS

None.

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ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The information contained in this Quarterly Report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this report and in our other filings with the SEC before deciding to purchase, hold or sell our common stock.

This report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. These forward-looking statements include but are not limited to statements regarding our product candidates, market opportunities, competition, strategies, anticipated trends and challenges in our business and the markets in which we operate, and anticipated expenses and capital requirements.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions inte identify forward-looking statements. Forward-looking statements speak only as of the date of this report and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed under the heading "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K and in Part II, Item 1A of this report and in other documents we file from time to time with the SEC. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

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

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

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Alcon is responsible for all of the costs that it incurs in developing the products using the Aganocide compounds. We have not achieved any milestones nor has any product been commercialized to date. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized product.

In June 2007, we entered into a license agreement with KCI, under which we granted KCI the exclusive rights to develop, manufacture and commercialize NeutroPhase, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to us a non-refundable technology access fee of $200,000. We are also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, we are entitled to receive payments of up to $1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. KCI has the right to terminate the agreement without penalty upon 60 days' notice. We have the right to terminate the agreement if KCI has not commercially launched a product incorporating NVC-101, or any other product containing hypochlorous acid, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

We cannot control whether or when KCI will launch any products incorporating NeutroPhase, or any other products containing hypochlorous acid as the principal active ingredient, and therefore cannot predict whether or when we will receive royalties on sales of commercialized products. 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. We have also recently begun to generate revenue under our agreements with Alcon and KCI. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of September 30, 2008, we had an accumulated deficit of $25.0 million. Our accumulated deficit resulted from research and development expenses and general and administrative expenses. We expect to continue to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

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Recent Events

In July 2008, we have our second issued patent in the U.S. The patent provides coverage for a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. This patent was issued on July 1, 2008 and will expire in 2024.

In July 2008, we completed a successful testing of our formulation of our lead Aganocide compound for dermatological uses, known as AgaDerm in a challenging animal model of dermatophyte infection. The study showedhat the AgaDerm formulation delivered an Aganocide compound effectively when applied on the surface of the skin and enhanced its penetration into hair follicles. The infectious agent was a dermatophyte, Trichophyton mentagrophytes, a parasitic fungus that causes infections of the nails, hair and skin, including ringworm. The Aganocide compound in the AgaDerm formulation was shown to be highly effective not only on the skin surface, but also showed potent ability to kill organisms invading the hair.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods.

In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, long-term service contracts and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this report, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our 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 Emerging Issues Task Force (“EITF”) Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables”, we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our 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. We recognize revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 101, “Revenue Recognition in Financial Statements”, as amended by SAB No. 104 (together, SAB 104). In accordance with SAB 104, 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 collectibility is reasonably assured.

Assuming the elements meet the EITF No. 00-21 criteria for separation and the SAB 104 requirements for recognition, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

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

Funded Research and Development—Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue in accordance with EITF Issue No. 99-19, “Reporting Revenue Gross as a Principal versus Net as an Agent,” 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.

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

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

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services.

Patent Costs

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

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment". SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, 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. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method. The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified. The adoption of SFAS No. 123R had a material effect on our financial position and results of operations. See Note 10 of the Notes to Condensed Consolidated Financial Statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Prior to the adoption of SFAS No. 123R, we valued our stock-based awards using the minimum value method and provided pro-forma information regarding stock-based compensation and net income required by SFAS No. 123. We did not recognize stock-based compensation expense in our statements of operations for option grants to our employees or directors for the periods prior to our adoption of SFAS No. 123R because the exercise price of options granted was generally equal to the fair market value of the underlying common stock on the date of grant.

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in

Conjunction with Selling, Goods or Services", 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.

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Income Taxes

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

Recent Accounting Pronouncements

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities”. SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities by requiring enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities,” and how derivative instruments and related hedged items affect an entity’s operating results, financial position, and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. Early adoption is permitted. We are currently reviewing the provisions of SFAS No. 161 and have not yet adopted the statement. However, as the provisions of SFAS No. 161 are only related to disclosure of derivative and hedging activities, we do not believe the adoption of SFAS No. 161 will have a material impact on our consolidated operating results, financial position, or cash flows.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. The intent of the position is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the intangible asset. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are assessing the potential impact that the adoption of FSP FAS 142-3 may have on its consolidated financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement shall be effective 60 days following the Securities and Exchange Commission’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not believe that implementation of this standard will have a material impact on its consolidated financial position, results of operations or cash flows.

In June 2008, the FASB issued FSP No. EITF 03-6-1, “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities,” (FSP EITF 03-6-1). FSP EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. Management has determined that the adoption of FSP EITF 03-6-1 will not have an impact on the Financial Statements.

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Results of Operations

Three Months Ended September 30, 2008 Compared with the Three Months Ended September 30, 2007

License and Collaboration Revenue

Total license and collaboration revenue was $1.6 million for the three months ended September 30, 2008 and $1.4 million for the three months ended September 30, 2007. License and collaboration revenue consisted of amounts earned under the license and collaboration agreements with Alcon and KCI for amortization of the upfront technology access fees and amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The upfront technology access fee of $10.0 million from Alcon is being amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront technology access fee from KCI of $200,000 is being amortized on a straight-line basis over 18 months through December 2008.

To the extent we earn milestone payments under the Alcon and KCI collaborations, we would expect revenues to increase. However, we cannot predict if and when we will receive any milestones from our collaborations.

Research and Development

Total research and development expenses decreased by $608,000, to $1.4 million for the three months ended September 30, 2008 compared with $2.0 million for the three months ended September 30, 2007. The decrease was in part due to a decrease of $913,000 in total clinical expenses largely due to the timing of pre-clinical and clinical trials. The total clinical expense includes a decrease of $223,000 in pre-clinical studies costs for nasal studies. The total clinical expense also includes a decrease of $159,000 in pre-clinical studies costs for CAUTI (Catheter Associated Urinary Tract Infection). This also includes a decrease of $335,000 for site investigator fees related to nasal research. The total clinical expenses decrease also includes an overall decrease of $176,604 for contract research organization fees.

Professional services fees related to research and development increased by $15,000 from $85,000 to $100,000 for the three months ended September 30, 2008 compared to the three months ended September 30, 2007. Employee costs related to research and development increased by $158,000, from $890,000 to $1.0 million for the three months ended September 30, 2008 compared to the three months ended September 30, 2007. The increase was due to increased headcount compared to the same period last year.

We expect that research and development expenses will continue to increase substantially for the reminder of 2008 and in future years as we continue to increase our focus on developing product candidates, both independently and in collaboration with Alcon. In particular, we are expecting to incur significant toxicology, clinical, chemistry and manufacturing expenses during 2008 in connection with the pre-surgical nasal preparation and catheter associated urinary tract infections programs.

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General and Administrative

General and administrative expenses increased by $694,000, to $1.7 million for the three months ended September 30, 2008 compared with $1.0 million for the three months ended September 30, 2007. This increase was due in part to an increase of $31,000 in depreciation expense from $48,000 to $79,000. The increase was also in part attributable to a $52,000 increase in office and general expenses from $169,000 to $221,000. The office and general expenses increased primarily due to increased office supplies, rent, and utilities costs.

Professional services fees related to general and administrative expenses increased by $291,000, from $388,000 to $679,000. The increase in professional services fees is primarily caused by increase costs in the following areas: investor relations costs, legal fees related to intellectual property, consultant fees, patent filing fees, and accounting fees. Employee costs related to general and administrative expenses increased by $244,000, from $371,000 to $615,000. The increase was due primarily to increased headcount.

We expect that general and administrative expenses will increase during 2008 and in subsequent years due to increasing public company expenses and 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 public company.

Other Income, Net

Other income, net increased $5,000 to $77,000 for the three months ended September 30, 2008, compared with $72,000 for the three months ended September 30, 2007. This increase was primarily attributable to increased interest income.

We expect that other income, 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.

Nine months ended September 30, 2008 Compared with the Nine months ended September 30, 2007

License and Collaboration Revenue

Total license and collaboration revenue was $4.5 million for the nine months ended September 30, 2008 and $4.4 million for the nine months ended September 30, 2007. License and collaboration revenue consisted of amounts earned under the license and collaboration agreements with Alcon and KCI for amortization of the upfront technology access fees and amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The upfront technology access fee of $10.0 million from Alcon is being amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront technology access fee from KCI of $200,000 is being amortized on a straight-line basis over 18 months through December 2008.

To the extent we earn milestone payments under the Alcon and KCI collaborations, we would expect revenues to increase. However, we cannot predict if and when we will receive any milestones from our collaborations.

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Research and Development

Research and development expenses increased by $683,000 to $6.3 million for the nine months ended September 30, 2008, compared with $5.6 million for the nine months ended September 30, 2007. The increase was due in part to a $455,000 increase in development expenses from $492,000 to $947,000. The increase was also in part due to a $618,000 increase in employee costs related to research and development from $2.6 million to $3.2 million. Employee costs increased due to an increase in headcount.

Professional services expenses related to research and development decreased by $9,000 to $351,000, for the nine months ended September 30, 2008, compared to $360,000 for the nine months ended September 30, 2007. The decrease was primarily attributable to an decrease in consultant expenses related to research and development.

We expect that research and development expenses will continue to increase substantially in 2008 and in subsequent years as we continue to increase our focus on developing product candidates, both independently and in collaboration with Alcon. In particular, we are expecting to incur significant toxicology, clinical, chemistry and manufacturing expenses during 2008 in connection with the pre-surgical nasal preparation and catheter associated urinary tract infections programs.

General and Administrative

General and administrative expenses increased by $2.0 million, to $5.1 million for the nine months ended September 30, 2008, compared with $3.1 million for the nine months ended September 30, 2007. This increase was primarily due to a $742,000 increase in employee costs from $1.2 million to $2.0 million. Professional services costs increased by $800,000, from $1.1 million to $1.9 million. Investor relations costs increased by $147,000, from $47,000 to $194,000. Office and general expenses increased by $184,000, from $554,000 to $738,000. The bulk of the office expense increase is attributable to increased rent, because we leased additional space during the second and fourth quarters of 2007 to accommodate our increased personnel and expanded laboratory facilities. The increase was also due in part to an increase of $94,000 in depreciation expense from $128,000 to $222,000.

We expect that general and administrative expenses will increase during 2008 and in subsequent years due to increasing public company expenses and 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 public company.

Other Income, Net

Other income, net increased by $27,000 to $334,000 for the nine months ended September 30, 2008, compared with $307,000 for the nine months ended September 30, 2007. This increase was primarily attributable to increased interest income. We expect that other income, 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.

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Liquidity and Capital Resources

We have incurred cumulative net losses of $25.0 million since inception through September 30, 2008. 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. We raised total net proceeds of $647,000 through the sale of our Series A Preferred Stock in 2002 and 2003, $3.0 million through the sale of our Series B Preferred Stock in 2003 and 2004, $5.4 million through the sale of our Series C Preferred Stock in 2004 and 2005, and $3.6 million through the sale of our Series D Preferred Stock in 2005 and 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 2006, we entered into a collaboration and license agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of $10.0 million in September 2006. Additionally, we are entitled to receive semi-annual payments each January and July over the four year term of the agreement to support on-going research and development efforts. In both January and July 2007, we received a payment of $1.4 million to support the performance of research and development activities throughout 2007. The Alcon agreement also provides for milestone payments upon the achievement of specified milestones in each field of use and royalty payments upon the sale of commercialized products.

The aggregate milestone payments payable in connection with the ophthalmic, otic and sinus fields are $19 million, $12 million and $39 million, respectively. As of September 30, 2008, we have not achieved any milestone nor has any product been commercialized to date. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon’s ability to obtain regulatory approval from the FDA and Alcon’s ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.

In June 2007, we entered into a license agreement with KCI. Under the terms of the agreement, we received an upfront technology access fee of $200,000 in June 2007. In addition, we are entitled to receive payments of up to $1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. As of September 30, 2008 we had not earned or received any milestone or royalty payments under the KCI agreement. We cannot control whether or when KCI will launch any products incorporating NeutroPhase, or any other products containing hypochlorous acid as the principal active ingredient, and therefore cannot predict whether 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 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement. As of September 30, 2008, we had an outstanding equipment loan balance of $921,863 carrying a weighted-average interest rate of 10.54%. The principal and interest due under the loan will be repaid in equal monthly installments through May 2011. In January 2008, we borrowed $203,000 under this equipment loan facility at an interest rate of 10.45%. As of September 30, 2008 there was $216,000 available for borrowing under this equipment loan facility.

In March 2008, we amended the Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 with PM Holdings Ltd. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of

$264,000 and the issuance of warrants to purchase 300,000 common shares at an exercise price of $4.00 per share. Under the amended agreement, no further cash or equity amounts are payable during the duration of the agreement through February 2010. We paid the upfront cash amount and issued the warrants during April 2008.

Cash and Cash Equivalents

As of September 30, 2008, we had cash, cash equivalents, and short-term investments of $15.2 million compared to $6.9 million at September 30, 2007.

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Cash Flows

The following table provides information regarding our cash flows and our capital expenditures for the nine months ended September 30, 2008 and 2007.

	Nine Months Ended September 30,	
(in thousands)	2008	2007
Cash used in:		
Operating activities	(7,038)	(3,615)
Investing activities	7,505	(198)
Financing activities	331	(401)
Capital expenditures (included in investing activities above)	(521)	(371)

Our operating activities used cash of $7.0 million and $3.6 million for the nine months ended September 30, 2008 and 2007, respectively. The use of cash in these periods principally resulted from our losses from operations and changes in our working capital accounts.

Our investing activities provided cash of $7.5 million for the nine months ended September 30, 2008. Our investing activities in the nine months ended September 30, 2008 included sales and maturities of marketable securities in our investment portfolio in the amount of $40.1 million, offset by the purchases of marketable securities in the amount of $32.1 million and purchases of property and equipment in the amount of $521,000.

Our investing activities used cash of $198,000 for the nine months ended September 30, 2007. Our investing activities in the nine months ended September 30, 2007 included sales and maturities of marketable securities in our investment portfolio in the amount of $30.2 million, offset by the purchases of marketable securities in the amount of $30.0 million and purchases of property and equipment in the amount of $371,000.

Our financing activities provided cash of $331,000 for the nine months ended September 30, 2008. Our financing activities for the nine months ended September 30, 2008 included $422,000 from borrowings under an equipment loan, offset by $216,000 in principal payments on an equipment loan and $28,000 in payments on capital leases. Our financing activities also included $153,000 in proceeds from the exercise of stock options.

Our financing activities used cash of $401,000 for the nine months ended September 30, 2007. Our financing activities for the nine months ended September 30, 2007 included $494,000 from borrowings under an equipment loan, offset by $46,000 in principal payments on an equipment loan and $22,000 in payments on capital leases. Our financing activities for the nine months ended September 30, 2007 also included $926,000 in initial public offering costs, and $99,000 in proceeds from the exercise of options or warrants.

We believe our cash balance at September 30, 2008 is sufficient to fund our projected operating requirements through at least the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- future clinical trial results;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the 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.

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We do not anticipate that we will generate significant product revenue for a number of years. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances and short-term investments. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience dilution. In addition, debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations for some of our technologies or product candidates that we would otherwise seek to develop on our own. Such collaborations may not be on favorable terms or they may require us to relinquish rights to our technologies or product candidates.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2007 we had net operating loss carryforwards for both federal and state income tax purposes of $10.1 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2014 and 2027. Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

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

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital; assurance of liquidity needs; best available return on invested capital; and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. We do not use derivative financial instruments in our investment portfolio.

To date, we have operated exclusively in the United States and have not had any material exposure to foreign currency rate fluctuations. We have recently formed a wholly-owned subsidiary, which is incorporated under the laws of British Columbia (Canada), which may conduct research and development activities in Canada. To the extent we conduct operations in Canada, fluctuations in the exchange rates of the U.S. and Canadian currencies may affect our operating results.

ITEM 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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

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Changes in Internal Control Over Financial Reporting

During the fiscal quarter covered by this report, there were no changes in our internal control over financial reporting, identified by our Chief Executive Officer or our Chief Financial Officer in connection with the evaluation of the effectiveness of our disclosure controls and procedures, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Legal Proceedings

The Company, on occasion, is involved in legal matters arising in the ordinary course of its business. While management believes that such matters are currently insignificant, there can be no assurance that matters arising in the ordinary course of business for which the Company is or could become involved in litigation will not have a material adverse effect on its business, financial condition or results of operations.

Item 1A. Risk Factors

Our business is subject to a number of risks, some 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.

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. 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.

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We may be unable to raise additional capital on acceptable terms in the future which may in turn limit our ability to develop and commercialize products and technologies.

We expect our capital outlays and operating expenditures to substantially increase over at least the next several years as we expand our product pipeline and increase research and development efforts and clinical and regulatory activities. Conducting clinical trials is very expensive, and we expect that we will need to raise additional capital, through future private or public equity offerings, strategic alliances or debt financing, before we achieve commercialization of any of our Aganocide compounds. In addition, we may require even more significant capital outlays and operating expenditures if we do not continue to partner with third parties to develop and commercialize our products.

Our future capital requirements will depend on many factors, including:

- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We do not currently have any commitments for future external funding. Additional financing may not be available on favorable terms, or at all. Our ability to obtain additional financing may be negatively affected by the recent volatility in the financial markets and the credit crisis, as well as the general downturn in the economy and decreased consumer confidence. Even if we succeed in selling additional securities to raise funds, our existing shareholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing shareholders. If we raise additional capital through strategic alliance and licensing arrangements, we may have to trade our rights to our technology, intellectual property or products to others on terms that may not be favorable to us. If we raise additional capital through debt financing, the financing may involve covenants that restrict our business activities.

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

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

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

We have incurred net losses since our inception. For the years ended December 31, 2005, 2006 and 2007 we had net losses of approximately $3.5 million, $5.3 million and $5.4 million, respectively. Through September 30, 2008, we had an accumulated deficit of approximately $25 million. To date, we have been, and expect to remain for the foreseeable future, mostly in a research and development stage. Since our inception, we have not generated revenue, except for modest revenue in 2006 and 2007 relating to two research and development collaboration and license agreements. We have incurred substantial research and development expenses, which were approximately $2.0 million, $4.1 million and $7.4 million for the years ended December 31, 2005, 2006 and 2007, respectively. 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, except as may be commercialized under our agreement with KCI, pursuant to which we granted them the exclusive rights to develop, manufacture and commercialize NVC-101, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. We expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will continue to increase substantially in the foreseeable future as we:

- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- develop, formulate, manufacture and commercialize our product candidates either independently or with partners;
- pursue, acquire or in-license additional compounds, products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional qualified personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our product candidates, either independently or with partners, we will not be able to generate such revenues or achieve or maintain profitability in the future. Our failure to achieve and subsequently maintain profitability could have a material adverse impact on the market price of our common stock.

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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.

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. We have conducted limited human studies and will need to conduct Phase I, II and III human clinical trials to confirm the in-vitro and in-vivo results in order to obtain approval from the FDA of our compounds. 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 and will cost between $15 million and $30 million.

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 two 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 other regulatory authorities in the United States and 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 we 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.

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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.

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

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

- the results of preclinical or clinical trials relating to our product candidates;
- the announcement of new products by us or our competitors;
- announcement of partnering arrangements by us or our competitors;
- quarterly variations in our or our competitors' results of operations;
- announcements by us related to litigation;
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning estimates;
- developments in our industry; and
- General, economic and market conditions, including the recent volatility in the financial markets and decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors.

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The volume of trading of our common stock may be low, leaving our common stock open to risk of high volatility.

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

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

As of the closing of our initial public offering, we had 21,254,474 shares of common stock outstanding, of which the 5,000,000 shares we sold in the offering may be resold in the public market immediately. Of the remaining shares, 13,282,199 shares became available for sale in the public market in April 2008, subject in some cases to compliance with the volume and other limitations of Rule 144 and in other cases subject to compliance with applicable Canadian requirements. Thereafter, 2,972,275 additional shares held by certain of our officers and directors will become eligible for sale in the public market over the nine to 24 month period after the closing of the initial public offering, as the shares are released from lock-up agreements with the underwriters and applicable Canadian escrow requirements.

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

We must implement additional and expensive finance and accounting systems, procedures and controls in order to grow our business and organization and to satisfy new reporting requirements, 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 Toronto Stock Exchange, or TSX, and the American Stock Exchange, or AMEX. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, which will be required by 2009, and other requirements of the SEC, Canadian securities regulatory authorities, AMEX and the TSX will increase our costs and require additional management resources. We recently have begun upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of the first Annual Report on Form 10-K for which compliance is required, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed with the SEC and with Canadian securities regulatory authorities. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. We have also entered into a license agreement with KCI pursuant to which we granted to them the exclusive rights to develop, manufacture and commercialize our NVC-101 compound worldwide for use in wound care in humans (other than products or uses intended for the eye, ear or nose). We cannot assure you that our collaboration with Alcon or KCI 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 KCI 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.

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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 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.

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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.

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

As of September 30, 2008, our officers and directors collectively controlled approximately 18.1% of our outstanding common stock (and approximately 23.3% of our common stock when including options held by them which were exercisable as of or within 60 days of September 30, 2008). Furthermore, as of September 30, 2008, our largest shareholder, a family trust established and controlled by Dr. Ramin Najafi, our Chairman and Chief Executive Officer, beneficially owned 14.5% of our outstanding common stock. As a result, Dr. Najafi can significantly influence the management and affairs of our company and most matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other shareholders.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

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

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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.

It may be difficult to recruit and retain independent members for our Board of Directors.

The burdens being placed on the members of a board of directors by applicable laws and regulations are making it increasingly difficult to recruit qualified candidates to be members of a board of directors of a public company. These same burdens may make it increasingly difficult to retain members of our Board of Directors. If we are unable to maintain a Board of Directors in which our shareholders have confidence, this could have an adverse impact on shareholder confidence and on the price of our stock.

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.

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

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

Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time-consuming. Furthermore, if participating patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies.

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

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

- unexpected need for additional patient-related data.

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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 indication of 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 or by the Center for Drug Evaluation and Research and the same physical product may be regulated by one such agency for one indication and the other agency for another indication. Our products may be classified by the FDA as a drug or a medical device depending upon the 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 would be considered as a medical device. In addition, 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.

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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 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 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 regulated 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.

If we receive regulatory approval for drug products that we develop, we and our collaborators will also 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 potential drug products.

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Any regulatory approvals that we receive for drug products that we develop may also be subject to limitations on the indicated uses for which the drug 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.

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.

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.

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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.

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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. We have registered the NovaBay trademark and design in the United States, and the Aganocide trademark in the United States, the European Community and Japan. We have allowed trademark applications in the United States for AgaNase, NeutroPhase, and NovaBay. We have registered the NovaBay trademark in Australia, the AgaNase trademark in Australia, the European Community, South Korea and Japan, the NeutroPhase trademark in Australia, Ireland and the United Kingdom, and have applications for these same trademarks pending in a number of other foreign countries.

We have two issued patents, one allowed patent application and six pending applications in the United States. We also have two pending international applications filed under the Patent Cooperation Treaty, one issued patent each in China, Hong Kong, Israel, India, Mexico, and South Korea, and 46 pending foreign national applications in Europe, Argentina, Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, South Korea, Mexico, Singapore, New Zealand, Taiwan and South Africa.

The subject matter of our patents and patent applications cover three key areas: methods relating to the manufacture and use of NVC-101, composition of matter of the Aganocide compounds and their compositions, and methods of treatment utilizing the Aganocide compounds.

Our first issued patent in the U.S. provides coverage for a method of treating burns or promoting wound healing, tissue repair or tissue regeneration using a specific range of formulations of NVC-101. This patent was issued on July 30, 2002 and will expire in 2020. The second issued patent in the U.S. provides coverage for a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. This patent was issued on July 1, 2008 and will expire in 2024.

The allowed application claims the composition of matter for NVC-422 and other Aganocide compounds. Once issued, it is expected to expire in 2026.

NovaBay aggressively protects and enforces its patent rights worldwide. However, certain risks remain. We cannot assure you that patents will issue from any of our applications or, for those patents 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. In addition, we cannot assure you 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, we cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will 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.

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We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. We cannot assure you that these agreements will be enforceable, will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and proprietary know-how will not otherwise 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 we are unable to protect the intellectual property and market exclusivity of Aganocide compounds and products, thereby enabling other parties to commercialize competing products, our ability to generate revenues from the sale of our products may be limited or diminished.

We have filed patent applications with claims directed to the Aganocide compounds and claims directed to the method of using the Aganocide compounds with the United States Patent and Trademark Office, or USPTO, and related international patent applications in Argentina, Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore and Taiwan. The first of these patents has issued in the U.S. However, we cannot assure you that any additional patents will eventually be issued from the U.S. or international patent applications. Should we be unable to obtain patents with sufficiently broad scope to protect our proprietary rights, the interest of potential partners for the development and commercialization of our Aganocide products could be greatly diminished.

If no such patents are issued or if they are issued but are later found invalid or unenforceable or are not of sufficient scope, or after such patents expire in a given jurisdiction, our competitors may produce generic products and make them available at a cost that is cheaper than the price at which we, or our commercial partners, would offer to sell any Aganocide products we develop.

Also, 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.

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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.

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.

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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 any 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.

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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, 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 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.

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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.

A significant terrorist attack or threat of such attack may adversely impact our ability to obtain financing.

A major terrorist attack, the threat of such attack or other unforeseen events beyond our control, may occur at a time when we need to raise additional financing. Closure or severe perturbation of the financial markets as a result of such events may make such financing impossible or unattractive and our plans may be seriously disrupted. As a consequence, the progress of the company towards revenues or profits could be significantly impaired.

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

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

- a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and

- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

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

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

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

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

Although we believe that we are not currently a “foreign investment entity” within the meaning of the FIE Tax Proposals (as defined in “Material Canadian Federal Income Tax Considerations—Foreign Investment Entity Status”), no assurances can be given in this regard or as to our status in the future. If we become a “foreign investment entity” within the meaning of the FIE Tax Proposals, there may be certain adverse tax consequences for our Canadian investors.

Because we are a California corporation and the majority of our directors and officers are resident in the United States, it may be difficult for investors in Canada to enforce against us certain civil liabilities and judgments based solely upon the securities laws of Canada.

We are organized under the laws of California and our principal executive offices are located in California. A majority of the directors and officers and the experts named in this report reside principally in the United States and all or a substantial portion of their assets and all or a substantial portion of our assets are located in the United States. Consequently, it may be difficult for shareholders to effect service of process within Canada upon us or our directors, officers or experts who are residents of the United States. Furthermore, it may not be possible to enforce against us or such directors, officers or experts, in the United States, judgments obtained in Canadian courts, including judgments based upon the civil liability provisions of applicable Canadian securities law.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sales of Unregistered Securities

The following is a summary of our recent transactions involving sales of our securities that were not registered under the Securities Act of 1933, as amended (the “Securities Act”):

(1) In April 2008, we issued a two year warrant and a four year warrant to purchase an aggregate of 300,000 of common stock to PM Holdings Ltd. as part of our consideration for the revision of the agreement dated February 13, 2007 with PM Holdings. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of $264,000 and the issuance of warrants to purchase 300,000 of common stocks at an exercise price of $4.00 per share.

(2) In July 2008, we issued total of 15,000 shares of common stock to the principals of The Investor Relations Group as compensation for services rendered to us.

Purchases of Equity Securities by the Issuer and Affiliated Purchaser

We did not repurchase any of our outstanding equity securities during the fiscal quarter covered by this report.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Other Information

None

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ITEM 6. Exhibits

The following exhibits are filed or furnished herewith or are incorporated herein by reference to the location indicated.

Exhibit No.	Description	Location
3.1	Amended and Restated Articles of Incorporation of Registrant	Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007
3.2	Amended and Restated Bylaws of Registrant	Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007
10.1	Amended Lease Agreement	Filed herewith
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of the principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of the principal financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

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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 14, 2008

NOVABAY PHARMACEUTICALS, INC.

/s/ Ramin Najafi

Ramin (“Ron”) Najafi
President and Chief Executive Officer
(duly authorized officer)

Date: November 14, 2008

/s/ Thomas J. Paulson

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

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