NovaBay Pharmaceuticals, Inc.
Form S-1/A
July 05, 2007
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As filed with the Securities and Exchange Commission on July 5, 2007

Registration No. 333-140714

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 4

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

NOVABAY PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

California	**2834**	**68-0454536**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Number)**	**(I.R.S. Employer Identification No.)**

5980 Horton Street, Suite 550

Emeryville, CA 94608

(510) 899-8800

(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Ramin (Ron) Najafi, Ph.D.

Chairman of the Board, Chief Executive Officer and President

NovaBay Pharmaceuticals, Inc.

5980 Horton Street, Suite 550 Emeryville, CA 94608

(510) 899-8800

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, $0.01 par value	$23,000,000	$2,461(3)

(1) Includes the offering price attributable to shares that the underwriters have the option to purchase solely to cover over-allotments, if any.
(2) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

This Registration Statement contains a prospectus relating to an offering of our common stock in the United States, together with separate prospectus pages relating to an offering of our common stock in Canada. The U.S. prospectus and the Canadian prospectus will be identical in all material respects. The complete U.S. prospectus is included herein and is followed by those pages to be used solely in the Canadian prospectus. Each of the alternative pages for the Canadian prospectus included in this registration statement has been labeled Alternate Page for Canadian Prospectus.

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The information in this prospectus is not complete and may be changed. We cannot sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated , 2007

PROSPECTUS

Shares

Common Stock

This is NovaBay Pharmaceuticals, Inc. s initial public offering in the United States and Canada. NovaBay Pharmaceuticals, Inc. is selling all of the shares of common stock offered by this prospectus.

We expect the public offering price to be between $ and $ per share. Currently, no public market exists for the shares. After pricing the offering, we expect that the common stock will be traded on the American Stock Exchange and on the Toronto Stock Exchange under the symbol NBY.

Investing in our common stock involves risks. See Risk Factors beginning on page 8.

PRICE $ PER SHARE

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions	$	$
Net proceeds, before expenses, to us	$	$

The underwriters may also purchase up to an additional shares from us at the public offering price, less the underwriting discounts and commissions, until 30 days after the date of the closing of this offering to cover over-allotments, if any. The table above provides the maximum amount of underwriting discounts and commissions. Discounts and commissions on the sale of shares to certain investors identified by us will be 0.7% rather than 7%, and to the extent such investors purchase shares in this offering the aggregate underwriting discounts and commissions will be reduced accordingly. In addition, we have agreed to issue to the underwriters broker warrants to purchase up to 7% of the total number of shares sold in this offering, including pursuant to the over-allotment option.

The underwriters expect to deliver the shares on or about , 2007.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Dundee Securities

The date of this prospectus is , 2007.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with additional or different information. If anyone provides you different or inconsistent information, you should not rely on it. We and the underwriters are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers or sales are permitted. The information in this prospectus is only accurate as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since the date of this prospectus.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the following summary together with the more detailed information appearing in this prospectus, including the Risk Factors and our financial statements and related notes included elsewhere in this prospectus, before deciding whether to purchase shares of our common stock. Unless the context otherwise requires, all references in this prospectus to we, our, us, the Company and NovaBay refer to NovaBay Pharmaceuticals, Inc.

Our Company

Overview

We are a biopharmaceutical company focused on developing innovative product candidates targeting 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 increase in infectious agents that have become resistant to current drugs.

We have discovered and are developing a class of antimicrobial compounds, which we have named Aganocide compounds, that we believe could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial infections. Our current development efforts are focused on Aganocide compounds to treat patients with infections of the eye, ear and sinus, to create an improved environment for the healing of wounds and to prevent infections that result from surgical or other hospital procedures, or that can be caused by the use of products, such as contact lens solutions, which can introduce an infection into the body. NVC-422 is our lead compound and forms the basis of all of our Aganocide compounds. Our in-vitro and in-vivo animal tests have demonstrated that NVC-422 kills a wide range of bacteria as well as certain yeasts, fungi and viruses very rapidly, at concentrations that are significantly lower than the concentrations at which it begins to kill human cells. We will need to conduct Phase I, II and III human clinical trials to confirm these results in order to obtain approval of NVC-422 from the U.S. Food and Drug Administration, or FDA. 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. We estimate that the clinical trials will take three to five years to conduct for each indication and will cost between $15 million and $30 million per indication. We filed an Investigational New Drug application, or IND, in March 2007 with the FDA, and began human clinical trials in May 2007.

We are also developing NVC-101 (which we also refer to as NeutroPhase), a solution containing hypochlorous acid, for use in wounds. We have conducted human safety studies under an Institutional Review Board and Phase II studies under an FDA approved IND. We have submitted a 510(k) premarketing application to the FDA to permit the use of NeutroPhase in wound management as a wound cleanser and debriding agent. We have submitted a 510(k) pre-marketing application because we believe that NeutroPhase is substantially equivalent to other approved medical devices. In June 2007, we entered into a license agreement with an affiliate of Kinetic Concepts, Inc., a global medical technology company, to develop, manufacture and commercialize products incorporating NVC-101, as well as other products containing hypochlorous acid as its principal active ingredient, for use in wound care in humans. We have received $200,000 from the Kinetic Concepts affiliate in connection with the license agreement and, if certain milestones are met, we will receive up to an additional $1.25 million. If products covered by the license are commercialized, then we will also receive royalty payments on product sales.

Our current activities are focused on research and development of product candidates that require further development to receive regulatory approval or become commercialized products. The development and commercialization of products based on our compounds will require significantly more research, development and testing as well as governmental approvals. We intend to pursue in-house the development and commercialization of products designed to prevent selected nosocomial infections, or infections that originate

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or occur in a hospital or hospital-like setting, and to partner with leading companies to assist with the development of other products. Since the cost of developing each indication is likely to be in the range of $15 million to $30 million, we will require additional funds to complete the in-house development of multiple indications. In August 2006, we entered into a collaboration and licensing agreement with an affiliate of Alcon, Inc., a leading ophthalmic pharmaceutical company, to develop products incorporating Aganocide compounds for use in the eye, ear and sinus, as well as in contact lens solutions. We received $10.0 million from the Alcon affiliate in September 2006 in connection with the collaboration and licensing agreement. Other than revenues received pursuant to this agreement, and the agreement with the Kinetic Concepts affiliate, we have had no revenues since our inception. We do not expect to have any revenues from sales of our drug products until 2011 or later. Until September 2006, we funded our operations through the proceeds from private placements of our preferred stock and from the exercise of warrants that had been granted to holders of our preferred stock. Our cumulative losses through March 31, 2007 were $14.0 million.

Industry Background

Combating bacterial infections is critical to modern medicine. Since the introduction of penicillin, antibiotics have greatly reduced the risks associated with bacterial infections, made possible the routine use of surgical procedures for non-critical purposes and have increased the probability of success of many modern complex operations. However, the effectiveness of available antibiotics is limited in some cases due to growing bacterial resistance and bacterial biofilm.

Bacteria are becoming resistant to different classes of antibiotics at increasing rates. These increasing levels of resistance are principally the result of repeated exposure of bacteria to non-lethal quantities of antibiotics and the ability of certain bacteria to transmit mutant genes to other bacterial species, thus enabling different species to survive the antibiotic to which the first species was exposed.

Bacterial biofilm may explain other incidences of the ineffectiveness of antibiotics. Many bacteria spend much of their existence within a matrix that they create that has been called biofilm. Encased in biofilm, bacteria are often immune to both antibiotics and white blood cells. Bacterial biofilm is associated with diseases such as sinus infections (sinusitis), ear infections, chronic wounds and infections related to cystic fibrosis. Bacterial biofilms are also frequently found on the surfaces of medical devices, such as catheters and implants, and can cause severe chronic or acute infections.

The method of delivery of most existing anti-infective drugs can also limit their effectiveness in treating bacterial infections. Most infections are localized. However, most current antibiotics used to treat bacterial infections are delivered systemically either orally or through injection or infusion. As a result, the entire body is exposed to the antibiotic in order to treat a local infection. Furthermore, the dosage required to treat a local infection by systemic delivery is substantially higher than would be necessary if delivered locally, resulting in greater risk of toxicity which can cause adverse side effects or other harmful effects on the body.

Increasing bacterial resistance, bacterial biofilm and the limitations of traditional antibiotic therapy are major contributors to the high cost of healthcare. These problems are particularly evident in dealing with nosocomial infections, which originate or occur in a hospital or hospital-like setting, often due to the high prevalence of disease causing organisms, patients reduced immune systems and the exposure of patients to a variety of methods for transmitting infections.

Consequently, we believe a significant market opportunity exists to develop anti-infective products that can be delivered locally in appropriate concentrations to safely kill bacteria quickly and efficiently, whether or not they are within biofilm, and without generating resistance. If developed and approved by regulatory authorities, these products may be able to treat and prevent nosocomial infections, as well as other infections that are currently difficult to treat due to resistant bacteria and biofilm.

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Our Solution

We believe the benefits of our product candidates based upon our antimicrobial compounds may include:

Preventing or Treating Infections Caused by Resistant Bacteria. Our tests indicate that our Aganocide compounds may be effective in destroying certain types of bacteria that have become resistant to existing antibiotics.

Destroying Bacteria Protected by Biofilm. In-vitro experiments indicate that our Aganocide compounds can be effective in destroying bacteria resident in biofilm. However, we have not yet demonstrated that we can destroy bacteria in biofilms in humans.

Killing Numerous Species of Bacteria. We believe that our Aganocide compounds have the potential to be effective against most, if not all, species of bacteria. If we are able to prove this in human clinical trials, it could reduce the need to conduct diagnostic procedures to identify the bacteria causing the infection before commencing treatment.

Treating Certain Infections that May be Viral or Bacterial in Origin. We believe that our Aganocide compounds have the potential to kill not only bacteria but also some viruses, thereby permitting immediate treatment for certain diseases where the causative agent may be a bacterium or a virus. We will need to confirm that the results of preliminary non-human studies are reproducible in human clinical trials.

Reduce Nosocomial (Hospital) Infections. We believe that Aganocide compounds may be able to contribute to preventing the occurrence and the transmission of hospital infections in several ways, including in the prevention of infections associated with the use of certain medical devices, such as invasive catheters, which are a major source of hospital infections. We need to develop appropriate formulations and methods of delivery of Aganocide compounds in order to bring these products to market.

Rapidly Killing Bacteria. Our in-vitro tests indicate that our Aganocide compounds can eliminate certain bacterial colonies in minutes, whereas current therapies may take hours or days at comparable therapeutic concentrations. To be successful in the marketplace, we need to demonstrate that our product candidates can be readily usable and do not disrupt the current practices of medical care.

Reducing Toxicity and Adverse Side Effects. We believe the ability to apply our Aganocide compounds locally and in lower concentrations may reduce the risk of toxicity resulting in adverse side effects. Because Aganocide compounds are small molecules, we believe they are also less likely to elicit an immune response in the body. Although we have demonstrated that systemic absorption of our compounds is very low in animals, we need to confirm this in human studies.

Providing a High Therapeutic Index. The therapeutic index is the ratio of the concentration at which a compound kills normal cells to the concentration at which it kills bacteria. Our in-vitro testing indicates that our Aganocide compounds have a high therapeutic index in that they can kill bacteria when delivered in concentrations far below the level that will harm human cells; however we will need to conduct human clinical trials in order to confirm such safety and efficacy.

Although we have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies, we will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain FDA approval of our compounds. All drug development programs are subject to substantial risk. Often, positive in-vitro or in-vivo animal studies have not been 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. 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 or otherwise delay development of our product candidates.

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We cannot assure you that our product candidates will be safe and effective in large-scale human clinical trials. Furthermore, our compounds are intended to be direct acting and topical in delivery. We have no plans to develop them for use as oral drugs or as drugs requiring delivery by injection into the bloodstream. In order for direct-acting topical drugs to be effective, they must be delivered to the site of infection in a formulation that permits them to be effective. We have not yet demonstrated that formulations of our Aganocide compounds can be effective in humans.

Our Strategy

The key elements of our strategy include:

Developing Product Candidates In-house. We intend to develop our product candidates for selected indications for the prevention and treatment of nosocomial infections in-house, and use qualified clinical research organizations to assist us with the clinical trials. We intend to use the results of early stage clinical trials to establish the priority for development of indications and to abandon an indication where the results are inadequate.

Developing Products through to Proof-of-Concept for Multiple Indications. A major advantage of antimicrobial products is that laboratory and animal models tend to be more predictive of efficacy in humans than is often the case with other classes of drugs. We believe that this enables potential partners to evaluate our compounds much earlier than is normal for drugs in other therapeutic categories.

Licensing Indications through Partnering Arrangements with Leading Companies. We intend to pursue partnering arrangements with leading companies in cases where we expect the likely magnitude, duration and expense of the clinical trial program required to obtain approval will be substantial and beyond our internal resources. Although we have been successful in reaching an agreement with Alcon, we cannot assure you that we can obtain other similar agreements from third parties.

Broadening the Range of Aganocide Compounds. We intend to continue to synthesize further Aganocide compounds, and are currently focusing our efforts on producing additional compounds for certain specific indications in collaboration with Alcon.

Corporate Information

We were incorporated in California in January 2000 as NovaCal Pharmaceuticals, Inc. but did not commence operations until July 1, 2002 when we acquired all of the assets of NovaCal Pharmaceuticals, LLC. In February 2007, we changed our name to NovaBay Pharmaceuticals, Inc. Our principal executive offices are located at 5980 Horton Street, Suite 550, Emeryville, California 94608, and our telephone number is (510) 899-8800. NovaBay , Aganocide , AgaNase and NeutroPhase are our trademarks. All other trademarks and trade names appearing in this prospectus are the property of their respective owners.

Presentation of Financial Information

We present our financial statements in United States dollars, which may be referenced in this prospectus as $, U.S.$, dollars or U.S. dollars . Amounts are stated in U.S. dollars unless otherwise indicated. On June 29, 2007, the noon buying rate in New York for cable transfers payable in Canadian dollars, as certified for customs purposes by the Federal Reserve Bank of New York, was U.S.$1.00 to Cdn$1.0634.

Our financial statements included in this prospectus have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, which differ in certain respects from Canadian generally accepted accounting principles, or Canadian GAAP.

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The Offering

Common stock offered by NovaBay	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	We currently expect to use our net proceeds from this offering as follows: approximately $5 million for the Phase I and II clinical development of NVC-422 in nasal decolonization; approximately $5 million for the pre-clinical, Phase I and initial Phase II studies of NVC-422 in the prevention of catheter associated urinary tract infections; approximately $2 million for pre-clinical studies to select among additional indications to be taken into development; and the remainder of the net proceeds for research and development, working capital and other general purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, services or technologies, or to enter into strategic marketing relationships with third parties. Although we currently anticipate that we will use the net proceeds of this offering as described above, there may be circumstances where, for sound business reasons, a reallocation of funds may be necessary. We may re-allocate the net proceeds from time to time depending upon the ultimate amount of net proceeds raised and upon changes in business conditions prevalent at the time. See Use of Proceeds.
Risk Factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to purchase shares of our common stock.
American Stock Exchange and Toronto Stock Exchange listings	We have applied to list our shares on the American Stock Exchange (AMEX) and the Toronto Stock Exchange (TSX) under the symbol NBY. Any such listing will be subject to the approval of the relevant stock exchange, and any such approval will not be given unless all of the original listing requirements are met.

The number of shares of our common stock to be outstanding following this offering is based on 32,204,813 shares of our common stock outstanding at March 31, 2007, which assumes the conversion of all of our outstanding preferred stock into an aggregate of 19,227,195 shares of common stock upon the completion of this offering, and does not include, as of such date:

- 4.931,924 shares of common stock issuable upon exercise of options outstanding at a weighted average exercise price of $0.49 per share; and
- 394,750 shares of common stock reserved for future grant under our 2005 Stock Option Plan.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

- the underwriters will not exercise their over-allotment option to purchase up to additional shares of common stock;
- no other person will exercise any other outstanding options or warrants;

the initial public offering price will be $ per share, the midpoint of the range set forth on the cover page of this prospectus; and

sales will not be made to those investors for which the underwriters would receive a cash commission equal to 0.7% of the aggregate cash proceeds of such sales.

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Summary Financial Data

The following table summarizes our financial data for the periods presented. You should read this data in conjunction with the information under Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes appearing elsewhere in this prospectus. The summary financial data for the years ended December 31, 2004, 2005, and 2006 are derived from our audited financial statements. We have also included data from our unaudited financial statements for the three months ended March 31, 2006 and 2007. Our financial statements have been prepared in accordance with U.S. GAAP, which differs in certain respects from Canadian GAAP.

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(unaudited)	
Statements of Operations Data:			(in thousands, except share and per share data)		
Revenue	$	$	$ 1,533	$	$ 1,483
Operating Expenses:					
Research and development(1)	1,481	1,952	4,087	531	1,463
General and administrative(1)	1,345	1,617	2,972	717	1,035
Total operating expenses	2,826	3,569	7,059	1,248	2,498
Other income, net	22	106	240	30	122
Net loss before income taxes	(2,804)	(3,463)	(5,286)	(1,218)	(893)
Provision for income taxes					
Net loss	$ (2,804)	$ (3,463)	$ (5,286)	$ (1,218)	$ (893)
Net loss per share:					
Basic and diluted	$ (0.32)	$ (0.36)	$ (0.46)	$ (0.12)	$ (0.07)
Shares used in per share calculations:					
Basic and diluted	8,755,418	9,704,207	11,429,216	10,132,381	12,831,007
Pro forma net loss per share (unaudited):					
Basic and diluted			$ (0.18)		$ (0.03)
Shares used in pro forma per share calculations (unaudited)(2):					
Basic and diluted			29,934,926		32,058,202

(1) Includes stock-based compensation expense as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(unaudited)	
			(in thousands)		
Stock-based compensation expense included above:					
Research and development	$ 11	$ 55	$ 86	$ 15	$ 63
General and administrative		16	281	21	175
Total stock-based compensation expense	$ 11	$ 71	$ 367	$ 36	$ 238

(2) The pro forma weighted average common shares outstanding assumes the conversion of our convertible preferred stock into common stock as though the conversion had occurred on the first day of the fiscal year, or at the date of the original issuance, if later.

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The following table presents a summary of our balance sheet as of March 31, 2007:

on an actual basis, and

on a pro forma as adjusted basis to reflect the conversion into common stock of all outstanding shares of our preferred stock and the sale in this offering of shares of our common stock at an assumed initial public offering price of $ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of March 31, 2007	
	Actual	Pro Forma As Adjusted
	(unaudited) (in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 10,053	
Working capital	5,883	
Total assets	11,483	
Capital lease obligation current and non-current	111	
Deferred revenue current and non-current	9,217	
Convertible preferred stock	192	
Common stock and additional paid-in capital	14,439	
Total stockholders equity	687	

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RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business and operations.

Risks Related to Our Business

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, 2004, 2005, and 2006 we had net losses of approximately $2.8 million, $3.5 million and $5.3 million, respectively, and for the three months ended March 31, 2007 we had a net loss of approximately $0.9 million. Through March 31, 2007, we had an accumulated deficit of approximately $14.0 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 a research and development collaboration. We have incurred substantial research and development expenses, which were approximately $1.5 million, $2.0 million and $4.1 million for the years ended December 31, 2004, 2005 and 2006, respectively, and $1.5 million for the three months ended March 31, 2007. 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, and we expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- seek regulatory clearances and approvals for our product candidates;
- 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.

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,

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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 will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain FDA approval 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 a research and development collaboration. 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 U.S. Food and Drug Administration, or 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 do not expect to 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 received regulatory approval for, nor 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.

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

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

Success in early clinical trials often is not replicated in later studies, and few research and development projects result in commercial products. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would eliminate or adversely impact the timing for revenues from those product candidates. If a clinical study fails to demonstrate the safety and effectiveness of our product candidates, we may abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

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

We 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, or GMP, and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party compliance with these regulations and standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

In addition, if the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we will need to manufacture them in larger quantities. Significant scale-up of manufacturing will require validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product, the regulatory approval or commercial launch of any drugs may be delayed or there may be a shortage in supply and our business may be harmed as a result.

If 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 Manufacturing Ltd. (Alcon), and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the

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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 an affiliate of Kinetic Concepts, Inc. 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). Under the terms of the Alcon agreement, we received a non-refundable technology access fee of $10.0 million and are entitled to certain semi-annual payments for research and development conducted by us under the agreement for four years after the effective date of the agreement, unless Alcon elects to extend this funding term. In addition, if certain milestones are achieved in connection with the development of a product, we are entitled to receive varying milestone payments for the first achievement of each such milestone for a licensed product in each field of use. Under the terms of the agreement with the Kinetic Concepts affiliate (KCI), we received a non-refundable technology access fee of $200,000 and will be entitled to receive additional amounts of up to $1.25 million if certain milestones are met. If products developed under these agreements are commercialized, we will also be entitled to receive royalty payments. 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.

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.

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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 partner with a third party 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. 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 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 and vice president of medical affairs, and other key employees. The efforts of each of these persons is critical to us as we continue to develop our technologies and as we attempt to transition into a company with commercial products. Any of our officers and other key employees may terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our ability to compete effectively, develop our technologies and implement our business strategies.

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

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.

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.

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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.

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.

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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.

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,

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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.

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

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other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

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

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

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

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the United States and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate. We have filed trademark applications for NovaBay and Aganocide in the United States, the European Union, and Japan, and for AgaNase and NeutroPhase in the United States. We have one issued patent and five pending provisional and non-provisional applications in the United States. We also have five pending international applications filed under the Patent Cooperation Treaty, and one issued patent in Mexico, one issued patent in China, and 36 pending foreign national applications in Europe, Argentina, Australia, Brazil, Canada, China, Hong-Kong, Israel, India, Japan, South Korea, Mexico, Singapore, New Zealand and Taiwan. The subject matter of our patents and patent applications cover the following 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. The issued U.S. patent expires in 2020 and 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.

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 in or have sufficient resources to pursue a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. We cannot assure you that these agreements will

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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.

In particular, we operate in the State of California and 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 a patent application with claims directed to the NVC-422 Aganocide compounds and claims directed to the method of using the Aganocide compounds with the United States Patent and Trademark Office, or USPTO, and a related international patent application under the Patent Cooperation Treaty, or PCT. We cannot assure you that any national or regional 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 would be greatly diminished or eliminated.

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.

We have also filed a patent application claiming various derivatives and analogs of NVC-422 Aganocide compounds and their method of use with the USPTO as well as a corresponding PCT application. If our efforts to protect the intellectual property and market position of the NVC-422 Aganocide products and their methods of use do not succeed, our ability to generate revenues from the sale of any such products may be limited or diminished.

However, 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.

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

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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 six 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.

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;

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published studies demonstrating the cost-effectiveness of our products relative to competing products;

availability of reimbursement for our products from government or healthcare payers; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

We currently have no internal sales, marketing or distribution capabilities. In order to commercialize any product candidates approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any products we develop, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

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

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

If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, 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;

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formulating and manufacturing products; and

launching, marketing, distributing and selling products.

Our competitors may:

develop and patent processes or products earlier than we will;

develop and commercialize products that are less expensive or more efficient than any products that we may develop;

obtain regulatory approvals for competing products more rapidly than we will; and

improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

We cannot assure you that our competitors will not succeed in developing technologies and products that are more effective than any developed by us or that would render our technologies and any products we develop obsolete. If we are unable to compete successfully against current or future competitors, we may be unable to obtain market acceptance for any product candidates that we create, which could prevent us from generating revenues or achieving profitability and could cause the market price of our common stock to decline.

Our ability to generate revenues from any products we develop will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from healthcare payers.

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

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

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.

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Risks Related to This Offering and Ownership of Our Common Stock

Our common stock has not been publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Before this offering, there has been no public market for our common stock. We intend to apply to list our shares on the Toronto Stock Exchange and the American Stock Exchange. Any such listing will be subject to the approval of the relevant stock exchange, and any such approval will not be given unless all of the original listing requirements are met. An active public trading market for our common stock may not develop after completion of this offering or, if developed, may not be sustained. If an active public market does not develop or is not maintained, you may have difficulty selling your shares. The initial public offering price of our shares was determined by negotiations between us and the underwriters for this offering and may not be indicative of the price at which our common stock will trade following the completion of this offering. We cannot assure you that the market price of our common stock will not materially decline below the initial public offering price. The market price for our common stock after this offering will be affected by a number of factors, including:

- 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 market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

The stock prices of many companies in the pharmaceutical and biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. These factors and price fluctuations may also materially and adversely affect the market price of our common stock.

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.

As a public reporting company, we will be required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, or SEC, and Canadian securities regulatory authorities, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Upon approval for listing as a public company on the TSX and on AMEX, we will also be required to comply with marketplace rules and the heightened corporate governance standards of the TSX and 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 new 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

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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.

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.

New investors in our common stock will experience immediate and substantial dilution in the book value of their investment after this offering.

The initial public offering price of our common stock is substantially higher than the book value per share of our common stock. If you purchase common stock in this offering, you will incur immediate dilution of $ in the pro forma net tangible book value per share of common stock, based on an initial public offering price of $ per share. In addition, 32,204,813 shares of common stock were outstanding as of March 31, 2007, which assumes the conversion of all of our outstanding preferred stock into an aggregate of 19,227,195 shares of common stock on the completion of this offering, and an additional shares will be reserved for issuance under our stock option plans as of the date of this prospectus. Investors will incur additional dilution upon the exercise of stock options. For a further description of the effects of dilution in the net tangible book value of our common stock, see Dilution.

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.

After this offering, we will have outstanding shares of common stock based on the number of shares outstanding at . This includes the shares we are selling in this offering, which may be resold in the public market immediately. In addition, shares outstanding as of March 31, 2007, which shares were issued by us prior to , 2005, will be available for immediate sale in the public market as of the date of this prospectus. Following the expiration of, or release from, lock-up agreements with the representatives of the underwriters and applicable Canadian escrow requirements, additional shares will become available for sale in the public market six months after the closing of this offering, 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, additional shares held by our officers and directors will become eligible for sale in the public market over the three to 18 month period following the initial six month lock-up period, as the shares are released from the lock-up agreements with the representatives of the underwriters and applicable Canadian escrow requirements.

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

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

After this offering, our officers and directors collectively will control approximately % of our outstanding common stock, without giving effect to the purchase of shares by any such persons in this offering. Furthermore, our largest shareholder, a family trust established and controlled by Dr. Najafi, our Chairman and

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Chief Executive Officer, will beneficially own % of our outstanding common stock after giving effect to this offering, assuming no additional purchases of shares in this offering by Dr. Najafi, the trust or persons affiliated with them. 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 have broad discretion in the use of proceeds of this offering for working capital and general corporate purposes.

We expect to spend the net proceeds that we will receive from this offering on advancement of the clinical development of our Aganocide compounds, research and development, working capital, general corporate purposes, and potential acquisitions of other complementary businesses, products or technologies. Within those categories, we have not determined the specific allocation of the net proceeds of this offering. Our management will have broad discretion over the use and investment of the net proceeds of this offering within those categories, and accordingly investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management s specific intentions.

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 will 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 NovaBay. 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.

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

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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 the Company s status in the future. If the Company becomes a foreign investment entity within the meaning of the FIE Tax Proposals, there may be certain adverse tax consequences for our Canadian investors. See Material Canadian Federal Income Tax Considerations Foreign Investment Entity Status .

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 prospectus 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on our management s current beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Use of Proceeds, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. In som cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, pla potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-lookin statements include but are not limited to, statements about:

- The efficacy and safety of our product candidates;
- The timing of clinical development of our product candidates;
- The expected characteristics of Aganocide compounds and our ability to demonstrate those characteristics;
- The outcome or success of pre-clinical studies and clinical trials;
- Our expectation regarding federal, state and foreign (including Canadian provincial) regulatory requirements;
- Allocation of resources for the purposes of bringing our proposed products to market;
- The amount of research and development expenses we expect to incur;
- Our ability to develop third-party partnerships;
- Our expectations regarding the use of proceeds from this offering;
- Our plans to in-license products to address new markets;
- Strategies to strengthen our intellectual property protection for our compounds and proposed products; and
- Anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements involve a variety of 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. We discuss many of these risks in this prospectus in greater detail under the heading Risk Factors. Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement for the shares in this offering completely and with the understanding that our actual future results may be materially different from what we expect.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Except as required by law, we assume no obligation to update these 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.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock that we are selling in this offering will be approximately $ million, based on an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses. If the underwriters over-allotment option is exercised in full, we estimate that we will receive net proceeds of approximately $ million, after deducting underwriting discounts and commissions and estimated offering expenses.

We currently expect to use our net proceeds from this offering as follows:

- approximately $5 million for the Phase I and II clinical development of NVC-422 in nasal decolonization;
- approximately $5 million for the pre-clinical, Phase I and initial Phase II studies of NVC-422 in the prevention of catheter associated urinary tract infections;
- approximately $2 million for pre-clinical studies to select among additional indications to be taken into development; and
- the remainder of the net proceeds for research and development, working capital and other general purposes.

We may also use a portion of the net proceeds to acquire or invest in complementary businesses, services or technologies, or to enter into strategic marketing relationships with third parties, but we have no current understandings, commitments or agreements to do so. From time to time, in the ordinary course of business, we expect to evaluate potential acquisitions of or investments in these businesses, services or technologies and strategic relationships.

Although we currently anticipate that we will use the net proceeds of this offering as described above, there may be circumstances where for sound business reasons, a reallocation of funds may be necessary. We may re-allocate the net proceeds from time to time depending upon the ultimate amount of net proceeds raised and upon changes in business conditions prevalent at the time. The timing and amount of our actual expenditures will be based on many factors, including the successful early clinical development of our lead product candidates, cash flows from operations and the anticipated growth of our business. Pending these uses, we intend to invest the net proceeds of this offering primarily in short-term, investment-grade, interest-bearing instruments.

We will require additional funds to complete the nasal decolonization and urinary tract programs to an NDA (New Drug Application) filing with regulatory authorities and for the initiation of at least two additional programs. We estimate that the clinical development of each indication will cost between $15 million and $30 million and will take between three and five years.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate that we will declare or pay any cash dividends on our common stock in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any existing indebtedness and other factors the Board of Directors deems relevant.

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CAPITALIZATION

The following table sets forth our cash, cash equivalents, and capitalization at March 31, 2007, as follows:

- on an actual basis;
- on a pro forma basis after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 19,227,195 shares of our common stock upon the closing of this offering; and
- on a pro forma as adjusted basis after giving effect to (a) the conversion of all outstanding shares of our preferred stock into an aggregate of 19,227,195 shares of our common stock upon the closing of this offering and (b) the issuance of shares of our common stock at an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table in conjunction with the sections titled Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	March 31, 2007		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	$ 10,053	$ 10,053	$
Stockholders equity:			
Convertible preferred stock, $0.01 par value: 39,000,000 shares authorized; 19,227,195 shares issued and outstanding, actual; no shares, issued and outstanding, pro forma and pro forma as adjusted	$ 192	$	$
Common stock, $0.01 par value: 64,000,000 shares authorized; 12,622,618 shares issued and outstanding, actual; 31,849,813 shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	130	322	
Additional paid-in capital	14,309	14,309	
Accumulated other comprehensive income	23	23	
Accumulated deficit during development stage	(13,967)	(13,967)	
Total stockholders equity	687	687	
Total capitalization	$ 687	$ 687	$

The above table excludes, as of March 31, 2007:

- 4,931,924 shares of common stock issuable upon exercise of outstanding options at a weighted average exercise price of $0.49 per share; and
- 394,750 shares of common stock reserved for future grant under our 2005 Stock Option Plan.

For additional information regarding our capital structure, see Management Employee Benefit Plans, Description of Capital Stock and Note 8 to the financial statements.

The pro forma as adjusted information above is illustrative only, and our capitalization following the completion of this offering is subject to adjustment based on the actual initial public offering price of our shares and other terms of this offering to be determined at pricing. Each $1.00 increase (decrease) in the assumed initial offering price per share would increase (decrease) each of cash and cash equivalents, total group equity and total capitalization by approximately $ million.

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DILUTION

Investors participating in this offering will incur immediate, substantial dilution to the extent of the difference between the initial public offering price per share of our common stock and the pro forma net tangible book value per share upon the completion of this offering. Our pro forma net tangible book value as of March 31, 2007 was $0.7 million, or $0.02 per share of common stock. The pro forma net tangible book value per share represents our total tangible assets less total liabilities divided by the number of shares of common stock outstanding as of March 31, 2007 (after giving effect to the conversion of all outstanding shares of preferred stock into shares of common stock upon completion of this offering).

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of shares of common stock in this offering at an assumed initial public offering price of $ per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of March 31, 2007 would have been $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing shareholders and an immediate dilution in net tangible book value of $ per share to purchasers of common stock in this offering, as illustrated in the following table:

Assumed initial public offering price per share		$
Pro forma net tangible book value per share as of March 31, 2007	$ 0.02	
Increase per share attributable to new investors		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors in this offering		$

The pro forma as adjusted information discussed above is illustrative only. Our pro forma net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of our shares and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) total consideration paid by new investors, total consideration paid by all shareholders and the average price per share paid by all shareholders by $ million, $ million and $, respectively, and would increase (decrease) the pro forma as adjusted net tangible book value per share after giving effect to this offering by $ per share and increase (decrease) dilution in pro forma as adjusted net tangible book value per share to new investors in this offering by $ per share, in each case assuming no change in the number of shares sold by us as set forth on the cover page of this prospectus and without deducting underwriting commissions and other estimated expenses of the offering payable by us. Furthermore, upon the completion of this offering, we expect that an additional shares of our common stock will be issuable, subject to vesting, under outstanding stock options. If all of these options were exercised immediately upon the completion of this offering, then based on the assumed initial public offering price in the table above, our pro forma net tangible book value per share as of March 31, 2007 would be $, the increase in our pro forma net tangible book value per share attributable to this offering would be $, our pro forma as adjusted net tangible book value per share after this offering would be $, and the dilution per share to new investors would be $.

The following table presents on a pro forma basis as of March 31, 2007, after giving effect to the conversion of all outstanding shares of preferred stock into common stock upon completion of this offering, the differences between the existing shareholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share, assuming an initial public offering price of $ per share, the midpoint of the estimated range of the initial public offering price set forth on the cover page of this prospectus. The information in the following table is illustrative only and the

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total consideration paid and the average price per share is subject to adjustment based on the actual initial public offering price of our shares of common stock.

	Shares Purchased		Total Consideration		Average Price Per
	Number	Percent	Amount	Percent	Share
Existing shareholders	32,204,813	. %	$	. %	$
New shareholders					
Total		100.0%	$	100.0%	

As of March 31, 2007, there were options outstanding to purchase an aggregate of 4,931,924 shares of our common stock at a weighted average exercise price of $0.49 per share. The foregoing discussion and tables assume no exercise of any stock options outstanding as of March 31, 2007. To the extent that these options are exercised, new investors will experience further dilution. If all of the options outstanding upon the completion of this offering were exercised immediately upon the completion of this offering, the number of shares purchased by existing shareholders and new investors would be , or %, and , or %, respectively; total consideration paid by existing shareholders and new investors would be $, or %, and $, or %, respectively; and the average price per share paid by existing shareholders and new investors would be $, or %, and $, or %, respectively.

If the underwriters exercise their over-allotment option in full, the number of shares held by new investors will increase to , or % of the total shares outstanding after this offering, our pro forma as adjusted net tangible book value per share would continue to be $, and the dilution per share would be $.

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SELECTED FINANCIAL DATA

The selected statement of operations data for the years ended December 31, 2004, 2005 and 2006 and the selected balance sheet data as of December 31, 2005 and 2006 are derived from our audited financial statements, which are included elsewhere in this prospectus. The selected statement of operations data for the year ended December 31, 2003 and for the period from July 1, 2002 to December 31, 2002 and the selected balance sheet data as of December 31, 2002, 2003 and 2004 are derived from our audited financial statements and the related notes which are not included in this prospectus. The selected statement of operations data for the period from January 1, 2002 to June 30, 2002 are derived from the unaudited financial statements of NovaCal Pharmaceuticals, LLC (LLC), our predecessor company. We acquired all of the operating assets of the LLC on July 1, 2002 in a transaction that was accounted for using the purchase method of accounting. The selected statements of operations data for the three months ended March 31, 2006 and 2007 and the selected balance sheet data as of March 31, 2007 have been derived from our unaudited financial statements, which are included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, include all adjustments that management considers necessary for fair presentation of the information for the unaudited periods. Our financial statements have been prepared in accordance with U.S. GAAP, which differs in certain respects from Canadian GAAP. You should read the following selected financial data in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements, related notes and other financial information included in this prospectus. The selected financial data is not intended to replace the financial statements. See Note 12 to our financial statements for an explanation of the method used to determine the number of shares used in computing net loss per share amounts.

	NovaCal Pharmaceuticals, LLC	NovaBay Pharmaceuticals, Inc.						
	Period from Jan 1, 2002 to June 30, 2002	Period from July 1, 2002 to December 31, 2002	Year Ended December 31,				Three Months Ended March 31,	
			2003	2004	2005	2006	2006	2007
	(unaudited)						(unaudited)	
	(in thousands, except per share data)							
Statements of Operations Data:								
Revenue	$	$	$	$	$	$ 1,533	$	$ 1,483
Operating Expenses:								
Research and development(1)	139	201	270	1,481	1,952	4,087	531	1,463
General and administrative(1)	150	343	683	1,345	1,617	2,972	717	1,035
Total operating expenses	289	544	953	2,826	3,569	7,059	1,248	2,498
Other income (expense), net	2		(24)	22	106	240	30	122
Net loss before income taxes	(287)	(544)	(977)	(2,804)	(3,463)	(5,286)	(1,218)	(893)
Provision for income taxes								
Net loss	$ (287)	$ (544)	$ (977)	$ (2,804)	$ (3,463)	$ (5,286)	$ (1,218)	$ (893)
Net loss per share:								
Basic and diluted	$ (0.04)	$ (0.07)	$ (0.12)	$ (0.32)	$ (0.36)	$ (0.46)	$ (0.12)	$ (0.07)
Shares used in per share calculations:								
Basic and diluted	7,634	7,762	8,087	8,755	9,704	11,429	10,133	12,831
Pro forma net loss per share (unaudited):								
Basic and diluted						$ (0.18)		$ (0.03)
Shares used in pro forma per share calculations (unaudited)(2):								

Basic and diluted	29,935	32,058

(footnotes on next page)

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(footnotes from prior page)

(1) Includes stock-based compensation expense as follows:

	NovaCal Pharmaceuticals, LLC		NovaBay Pharmaceuticals, Inc.					
				Year Ended December 31,			Three Months Ended March 31,	
	Period from Jan 1, 2002 to June 30, 2002	Period from July 1, 2002 to December 31, 2002	2003	2004	2005	2006	2006	2007
	(unaudited)		(in thousands, except per share data)				(unaudited)	
Stock-based compensation expense included above:								
Research and development	$	$ 15	$ 2	$ 11	$ 55	$ 86	$ 15	$ 63
General and administrative					16	281	21	175
Total stock-based compensation expense	$	$ 15	$ 2	$ 11	$ 71	$ 367	$ 36	$ 238

(2) The pro forma weighted average common shares outstanding assumes the conversion of our convertible preferred stock into common stock as though the conversion had occurred on the first day of the fiscal year, or at the date of the original issuance, if later.

	NovaBay Pharmaceuticals, Inc. December 31,					March 31,
	2002	2003	2004	2005	2006	2007 (unaudited)
	(in thousands)					
Balance Sheet Data:						
Cash, cash equivalents and short-term investments	$ 159	$ 1,104	$ 4,047	$ 3,212	$ 11,086	$ 10,053
Working capital	(141)	631	3,908	2,985	7,926	5,883
Total assets	339	1,315	4,359	3,562	11,866	11,483
Capital lease obligation current and non-current		30	20			111
Deferred revenue current and non-current					9,167	9,217
Convertible notes payable	235	405				
Convertible preferred stock	27	65	164	175	192	192
Common stock and additional paid-in capital	526	2,258	9,127	10,869	14,683	14,439
Total stockholders equity	9	802	4,093	3,252	1,813	687

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the financial condition and results of our operations should be read in conjunction with the financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section entitled Risk Factors included elsewhere in this prospectus.

Overview

We are a biopharmaceutical company focused on developing innovative product candidates targeting 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 increase in infectious agents that have become resistant to current drugs.

We have discovered and are developing a class of antimicrobial compounds, which we have named Aganocide compounds, that we believe could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial infections. Our antimicrobial compounds are based upon small molecules that are generated by white blood cells that defend the body against invading pathogens. In the body, these compounds are produced on demand and are transient. We have focused our efforts on understanding these molecules and finding ways, primarily by chemical modification, to impart qualities to them to allow them to be developed as therapeutic products.

Our current development efforts are focused on Aganocide compounds to treat patients with infections of the eye, ear and sinus, to create an improved environment for the healing of wounds, whether chronic or acute, and to prevent infections that result from surgical or other hospital procedures, or that can be caused by the use of products, such as contact lens solutions, which can introduce an infection into the body. We operate in one business segment.

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 through payments for our research and development activities under our agreement with Alcon. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of March 31, 2007, we had an accumulated deficit of $14.0 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.

In August 2006, we entered into a collaboration and license agreement with Alcon to license to Alcon the exclusive right to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable technology access fee of $10.0 million upon the effective date of the agreement. 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 us 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

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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.

In June 2007, we entered into a license agreement with an affiliate of Kinetic Concepts, Inc. and granted to the Kinetic Concepts, Inc. affiliate (KCI) 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. Under the terms of the agreement, KCI paid to us a technology access fee of $200,000 and, if certain milestones are met, we are entitled to receive additional amounts of up to $1.25 million. If products covered by the license, including NVC-101, are commercialized, then we will receive royalties based on net revenues from any sales of such products. KCI has the right to terminate the agreement 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 as its principal active ingredient, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days notice.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, we may not be able to successfully develop and commercialize any of our product candidates. Any failure to complete the development of our product candidates in a timely manner would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth in the Risk Factors section of this prospectus.

Financial Overview

Research and Development Expense

Since our inception, we have been focused on drug discovery and development programs. Research and development expense includes our costs for:

personnel associated with our research activities;

screening and identification of product candidates;

formulation and synthesis activities;

preclinical studies, including toxicology studies;

clinical trials; and

regulatory affairs.

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We expense research and development costs as incurred. Costs incurred for general research and development activities were $1.3 million, $1.4 million and $2.5 million for the years ended December 31, 2004, 2005 and 2006, respectively, $1.5 million for the three months ended March 31, 2007 and $7.0 million for the period from inception to March 31, 2007. Research and development costs incurred to develop NVC-101 and our Aganocide compounds are summarized below.

	Year Ended December 31,			Three Months Ended March 31,	Inception to
Development Project	**2004**	**2005**	**2006**	**2007**	**Date**
NVC-101					
Toxicology/pharmacology	$ 81,000	$	$	$	$ 93,000
Clinical trials	75,000	473,000	857,000	53,000	1,458,000
Total expenses	$ 156,000	$ 473,000	$ 857,000	$ 53,000	$ 1,551,000
Aganocide Compounds					
Toxicology/pharmacology	$	$ 52,000	$ 718,000	$ 104,000	$ 874,000
Clinical trials					
Total expenses	$	$ 52,000	$ 718,000	$ 104,000	$ 874,000

We expect that our research and development expenses will increase in future periods as we add personnel, fund studies and trials, and undertake regulatory filings. Additionally, we expect that our capital expenditures for laboratory equipment will increase in the future. Investments in laboratory equipment will increase our depreciation costs and will affect our liquidity by increasing cash used in investing activities. In March 2007, we filed an Investigational New Drug application, or IND, to initiate Phase I human clinical trials associated with our initial Aganocide compound, NVC-422. The FDA recently cleared our IND, and we began Phase I clinical studies in early May 2007.

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a New Drug Application, or NDA, may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

Some of our product candidates may be classified as medical devices rather than drugs. The procedure for obtaining FDA approval for medical devices is different than for drugs, but is likewise rigorous, lengthy and costly.

The successful development of our product candidates is highly uncertain. Satisfaction of all regulatory requirements applicable to our product candidates typically takes many years and requires the expenditure of substantial resources for research and development and testing. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing drugs.

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

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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.

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. The FDA may also require us to conduct additional clinical testing, in which case we would have to expend additional resources as well as time. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. 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 product candidates 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. If we fail to obtain regulatory approval for any of our product candidates, we will not be able to commercialize our proposed products, and we will not generate product revenues.

General and Administrative Expense

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, and information technology functions. Other costs include facility costs, professional fees for legal and accounting services, insurance, and depreciation expenses. We expect that, after this offering, we will incur significant additional accounting and legal costs related to compliance with securities and other regulations, as well as additional insurance, investor relations and other costs associated with being a public company.

Stock-Based Compensation Expense

Effective January 1, 2006, we began to measure and recognize compensation expense at fair value for all stock-based payments, in accordance with Statement of Financial Accounting Standard (SFAS) No. 123R, Share-Based Payment . Stock-based compensation expense is classified in the statements of operations in the same expense line items as cash compensation. We expect that amounts recognized in the future for stock-based compensation will be greater than stock-based compensation expense presented on a pro forma basis in the notes to our financial statements for the periods prior to the adoption of SFAS No. 123R, as we are no longer permitted to apply the minimum value method which assumed zero volatility. Instead, under SFAS No. 123R, we calculate the value of our stock-based payments using a volatility rate based upon the historical volatility of comparable companies from a representative peer group. Additionally, the stock-based compensation expense recognized in the statements of operations during 2006 does not include any expense for options granted but unvested at December 31, 2005. We expect stock-based compensation expense in 2007 and future periods to increase over the amounts recognized during 2006 as more options are granted subject to the SFAS No. 123R guidance. As of March 31, 2007, total unrecognized compensation cost related to unvested stock options granted or modified

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after January 1, 2006 was $562,000. 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 1.9 years.

Other Income, net

Other income, net includes interest income on cash balances and interest expense on outstanding capital leases.

Provision for Income Taxes

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision for income taxes for any of the periods presented. As of December 31, 2006, we had net operating loss and credit carryforwards for both federal and state income tax purposes of $6.4 million. We believe that sufficient uncertainty exists regarding the future realization of deferred tax assets. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. If not utilized, the federal and state net operating loss and credit carryforwards will begin expiring at various dates between 2015 and 2025. Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss and credit carryforwards may be impaired or limited in certain circumstances. Events that could cause limitations in the amount of net operating losses that we may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, that may occur, for example, as a result of this offering aggregated with certain other sales of our stock before or after this offering.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. GAAP. 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 to our financial statements, 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 an agreement with a strategic partner for the development and commercialization of our product candidates. We may enter into additional agreements with other strategic partners as opportunities arise. The terms of such agreements may 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

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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.

Research and Development Costs

We charge research and development costs to expense as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to entities that perform research and clinical trial studies on our behalf.

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

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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.

Prior to the adoption of SFAS No. 123R, we accounted for stock-based compensation awards to employees using the intrinsic value method under the recognition and measurement principles of APB Opinion No. 25. Our application of APB Opinion No. 25 did not result in compensation expense because the exercise price of the stock-based awards was equal to the fair market value of the stock at the grant date.

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 , using a fair value approach. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

The adoption of SFAS No.123R had a material effect on our financial position and results of operations. See Note 8 to the financial statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Since April 1, 2006, we have granted stock options with exercise prices as follows:

Date of Grant	Number of Options Granted	Weighted Average Exercise Price	Weighted Average Fair Value per Common Share	Weighted Average Intrinsic Value
May-July 2006	1,040,000	$ 0.85	$ 0.85	$
September 2006	78,000	$ 1.00	$ 1.00	$
January 2007 (unaudited)	448,665	$ 1.14	$ 1.14	$

The fair value of the common stock underlying the stock option grants was estimated contemporaneously with the option grants. For the grants from May 2006 through September 2006, this assessment was performed by our board of directors, with input from management. For the options granted in January 2007, we obtained a valuation analysis from Marshall & Stevens, an unrelated valuation specialist. We did not obtain a contemporaneous valuation from an unrelated valuation specialist for the options granted from May 2006 through September 2006 because we believed our estimates of the fair value of our common stock were reasonable and consistent with our understanding of how similarly situated companies in the biopharmaceutical industry were valued. We obtained a valuation from the unrelated valuation specialist in January 2007 in order to enhance the objectivity of our valuation process as we prepared for our initial public offering. We have not granted any stock options since January 2007 and do not expect to grant any options until the completion of this offering. Therefore, we have not performed or obtained any common stock valuations since that date.

Significant Factors, Assumptions, and Methodologies Used in Determining Fair Value

Determining the fair value of our stock requires making complex and subjective judgments. Each of the valuations took into account a number of objective and subjective factors including the following:

- the common stock underlying the option involved illiquid securities in a private company;

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- the prices at which our Series A, Series B, Series C and Series D convertible preferred stock were sold by us primarily to outside investors in arms-length transactions, and the rights, preferences and privileges of the preferred stock relative to the common stock;
- our performance and the status of research and product development efforts;
- developments concerning our third-party collaborations;
- the composition of and additions to the management team;
- our stage of development and business strategy, including our review status with regulatory authorities; and
- the likelihood of achieving a liquidity event for the shares of common stock underlying these stock options, such as an initial public offering, merger or sale of the company, given prevailing market conditions.

We used a market approach to estimate the fair value of our common stock underlying stock options granted from May 2006 through September 2006. The market approach uses direct comparisons to other enterprises to estimate the fair value of the common shares of privately issued securities. The market approach bases the fair value measurement on what other similar enterprises or comparable transactions indicate the value to be.

During April 2006 and September 2006, we initiated discussions with two separate investment banks to evaluate the possibility of an initial public offering. Each investment bank provided us with a preliminary indication of our technology value based upon a set of comparable public companies that had recently completed a financing transaction. In identifying the set of comparable companies, each investment bank considered the industry sector, nature and type of product, stage of clinical studies, size of the offering, and the valuation of the company prior to the financing event. To the estimated technology value indicated by the investment banks, we added our current working capital balance to derive the total estimated enterprise value.

The total estimated enterprise value was allocated to the preferred and common shares using the current-value method. The current-value method considers the liquidation preferences and conversion rights of the preferred stock to estimate the most likely allocation of value. Based on this allocation method and considering all of the objective and subjective factors discussed above, we estimated the fair value of our common stock to be $0.85 per share as of May 2006 and July 2006 and $1.00 per share as of September 2006.

For the stock options granted in January 2007, our board of directors considered the valuation analysis performed by Marshall & Stevens, as well as the objective and subjective factors discussed above, to determine the fair value of our common stock. Marshall & Stevens used an income approach to estimate the fair value of our common stock underlying the options. The income approach involves applying appropriate discount rates to estimated cash flows that are based on forecasts of revenue and costs. The income approach that they used incorporated assumptions regarding clinical success rates, projected costs, projected product sales and a discount rate. Their estimates of clinical success rates and projected product sales were based upon our internal estimates as well as external data regarding historical success rates of similar products. These estimates were consistent with the plans and estimates that we used to manage our business. However, there is inherent uncertainty in making these estimates. The risks associated with achieving our forecasts were assessed in selecting the appropriate discount rates. If different rates had been used, the valuations would have been different.

The total enterprise value estimated using the income approach was allocated to the preferred and common shares using the current-value method. Using these valuation and allocation methods, Marshall & Stevens estimated the fair value of our common stock to be $1.11 per share. Based on the analysis provided by Marshall & Stevens, and after considering all of the objective and subjective factors discussed above, our board of directors determined the fair value of our common stock to be $1.14 per share as of January 2007.

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The foregoing is a summary of the information relating to our determination of the fair value of our common stock solely for purposes of establishing the exercise price of stock options granted since April 1, 2006 while we were a private company. Our determination of the fair value of our common stock in connection with granting stock options may bear no relationship to the price at which our common stock will trade upon completion of this offering.

Significant Factors Contributing to the Difference between Fair Value as of the Date of Each Grant and the Estimated IPO Price

As described above, from May 2006 to January 2007, we granted stock options with exercise prices ranging from $0.85 per share to $1.14 per share. We believe the increase in the fair value of our common stock at each valuation date during the past 15 months, and the continued increase in fair value, as evidenced by the estimated price to the public of $, is primarily attributable to improvements in the objective and subjective factors outlined above, as well as to a number of recent events and developments. In March 2007, we filed an IND to initiate Phase I human clinical trials associated with our initial Aganocide compound. The FDA cleared our IND and we began Phase I clinical trials in May 2007. Additionally, in June 2007, we entered into a collaboration with KCI which is intended to result in the commercialization of NVC-101 within 18 months. If we pursued this strategy independently, we anticipated a minimum of four years to commercialize our NVC-101 compound. In connection with the plans to commercialize NVC-101, we submitted a 510(k) premarketing application to the FDA in April 2007 to permit the use of NVC-101 in wound management. We also hired several key personnel during the second quarter of 2007, including a Vice President of Research in June 2007. Finally, we filed our initial registration statement in February 2007, which was a significant step toward completing our initial public offering, the completion of which is expected to increase the liquidity and marketability of our common stock. Although we believe it is reasonable to expect that the completion of our initial public offering will add value to our common stock because it will have increased liquidity and marketability, the amount of additional value cannot be measured with precision or certainty.

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.

Recently Issued Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. FIN 48 prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. FIN 48 is effective for fiscal years beginning after December 15, 2006. The adoption of FIN 48 did not have a material impact on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements . SFAS No. 157 establishes a framework for measuring the fair value of assets and liabilities. This framework is intended to provide increased consistency in how fair value determinations are made under various existing accounting standards which permit, or in some cases require, estimates of fair market value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application

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is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including any financial statements for an interim period within that fiscal year. We are currently assessing the impact of SFAS No. 157 on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159 The Fair Value Option for Financial Assets and Financial Liabilities . SFAS No. 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact of SFAS No. 159 on our financial position and results of operations.

Results of Operations

Comparison of Three Months Ended March 31, 2006 and March 31, 2007

License and Collaboration Revenue

We recognized license and collaboration revenue of $1.5 million for the three months ended March 31, 2007. License and collaboration revenue consisted entirely of amounts earned under the license and collaboration agreement with Alcon. The revenue recognized for the period ended March 31, 2007 consisted of the current period amortization of the upfront technology access fee and amounts received, or expected to be received, for the funding of research and development activities performed during the period. As the Alcon agreement was effective in August 2006, no such revenue was recognized during the three months ended March 31, 2006.

The up-front technology access fee was initially recorded as deferred revenue and is expected to be amortized into revenue on a straight-line basis through August 2010. During the quarter ended March 31, 2007, we received a payment of $1.4 million to support the performance of research and development activities from January 2007 through June 2007. At March 31, 2007, our deferred revenue balance included $675,000 related to the unearned portion of this payment. This amount will be recognized as revenue during the second quarter of 2007 when the associated research and development activities are performed.

Research and Development

Research and development expenses increased by 176% to $1.5 million for the three months ended March 31, 2007 from $0.5 million for the three months ended March 31, 2006. This increase was due in part to an increase in salary and benefits expense of $404,000, as the number of research and development personnel more than doubled from March 31, 2006 to March 31, 2007. Also, during the three months ended March 31, 2007, laboratory supplies and services expenses increased by $284,000, which was directly related to the increase in research and development personnel and the collaboration with Alcon, which resulted in a higher level of laboratory activities. Additionally, toxicology and pharmacology expenses increased by $92,000 from the first quarter of 2006 to the first quarter of 2007. This increase was primarily due to the initiation of studies for NVC-422 in the second half of 2006 and early 2007 in preparation for the IND filing. The increase in research and development expenses was also attributable to a $48,000 increase in regulatory expenses associated with the IND filing for NVC-422 during the first quarter of 2007. The amortization of stock-based compensation increased by $38,000 from the first quarter of 2006 to the first quarter of 2007 as a result of an increased number of grants becoming subject to the SFAS No. 123R guidance.

We expect that research and development expenses will continue to increase substantially during the remainder of 2007 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 clinical expenses during 2007 in connection with the Phase I clinical studies for NVC-422 which began in May 2007.

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General and Administrative

General and administrative expenses increased by 44% to $1.0 million for the three months ended March 31, 2007 from $0.7 million for the three months ended March 31, 2006. This increase was due in part to an increase in salary and benefits expense of $118,000, as the number of general and administrative personnel more than doubled from March 31, 2006 to March 31, 2007. The increase in general and administrative expenses was also attributable to the issuance of $108,000 in cash and stock to a consultant for investor relations and financial advisory services during the first quarter of 2007. The amortization of stock-based compensation increased by $76,000 from the first quarter of 2006 to the first quarter of 2007 as a result of an increased number of grants becoming subject to the SFAS No. 123R guidance. Rent expense increased by $55,000 during the first quarter of 2007 because we leased additional space in late 2006 to accommodate our increased number of personnel and expanded laboratory facilities. The increase in general and administrative expenses was partially offset by a decrease of $85,000 related to one-time website and communication expenses that we incurred during the first quarter of 2006.

We expect that general and administrative expenses will increase during 2007 and in subsequent years due to increasing payroll, public company expenses, business development costs and 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 to $122,000 for the three months ended March 31, 2007 from $30,000 for the three months ended March 31, 2006. This increase was attributable to increased interest income earned due to higher average cash balances resulting from the $10.0 million payment received in September 2006 and the $1.4 million payment received in January 2007 in connection with the Alcon agreement.

We expect that other income, net will vary based on fluctuations in our cash balances and the interest rate paid on such balances.

Comparison of Years Ended December 31, 2005 and December 31, 2006

License and Collaboration Revenue

We recognized license and collaboration revenue of $1.5 million for the year ended December 31, 2006. License and collaboration revenue consisted of the current period amortization of the upfront technology access fee and amounts received for the funding of research and development activities performed during the year in connection with our collaboration and license agreement with Alcon.

Research and Development

Research and development expenses increased by 109% to $4.1 million for the year ended December 31, 2006 from $2.0 million for the year ended December 31, 2005. This increase was due in part to an increase in salary and benefits expense of $685,000, as the number of research and development personnel more than doubled from December 31, 2005 to December 31, 2006. The increase in research and development expenses was also attributable to a $665,000 increase in toxicology and pharmacology expenses related to the initiation of studies for NVC-422 during the year ended December 31, 2006. Additionally, an increase in expenses related to the NVC-101 clinical studies, which were concluded in late 2006, contributed $384,000 to the increase in research and development expenses. Also, during the year ended December 31, 2006, laboratory supplies and services expenses increased by $318,000, which was directly related to the increase in research and development personnel, which resulted in a higher level of laboratory activities. The increase in research and development expenses for the year ended December 31, 2006 also included amortization of stock-based compensation expense of $85,000 in connection with the adoption of SFAS No. 123R on January 1, 2006. No amounts were recognized for stock-based compensation during the year ended December 31, 2005.

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General and Administrative

General and administrative expenses increased 84% to $3.0 million for the year ended December 31, 2006 from $1.6 million for the year ended December 31, 2005. This increase was due in part to an increase in salary and benefits expense of $410,000, as the number of general and administrative personnel doubled from December 31, 2005 to December 31, 2006. The increase in general and administrative expenses was also attributable to a $272,000 increase in expenditures for audit and legal services, in large part due to the completion of a multi-year audit in the first quarter of 2006 and the current year audit at the end of 2006. No audit fees were recorded during 2005. Also, increased patent activity pertaining to NVC-422 and its analogs contributed $130,000 to the increase in general and administrative expenses during the year ended December 31, 2006. This increase also included amortization of stock-based compensation expense of $227,000 in connection with the adoption of SFAS No. 123R on January 1, 2006. No amounts were recognized for stock-based compensation during the year ended December 31, 2005. We also incurred additional expenses of $73,000 during the year ended December 31, 2006 to develop our website and other communication capabilities. Rent expense increased by $47,000 during 2006 as we leased additional space to accommodate our increased number of personnel and expanded laboratory facilities.

Other Income, Net

Other income, net increased to $240,000 for the year ended December 31, 2006 from $106,000 for the year ended December 31, 2005. The increase was primarily due to increased interest income earned as a result of higher average cash balances due to the $10.0 million Alcon payment received in September 2006.

Comparison of Years Ended December 31, 2004 and December 31, 2005

Research and Development

Research and development expense increased 32% to $2.0 million for the year ended December 31, 2005 from $1.5 million for the year ended December 31, 2004. This increase was due in part to an increase in research and development salary and benefits expense of $400,000, as the staffing levels continued to grow from December 31, 2004 to December 31, 2005. Research and development expense also increased due to a $398,000 increase in clinical expenses related to the NVC-101 studies initiated during that time period. These increases during the year ended December 31, 2005 were partially offset by a $301,000 decrease in laboratory supplies and service expenses. In 2004 we increased our laboratory activity significantly in connection with the increase in the number of our research and development personnel. These expenses began to stabilize in 2005 as the number of our research and development personnel grew at a slower rate.

General and Administrative

General and administrative costs increased 20% to $1.6 million for the year ended December 31, 2005 from $1.3 million for the year ended December 31, 2004. This increase was partially due to an increase of $90,000 in expenditures related to accounting and information technology services as we expanded our finance and administrative departments. Also, increased patent activity pertaining to NVC-422 and its analogs contributed $131,000 to the increase in general and administrative expense during the year ended December 31, 2005. Additionally, rent expense for the year ended December 31, 2005 increased by $53,000 from December 31, 2004, reflecting the move to a new corporate headquarters during July 2004. As a result, rent expense for the year ended December 31, 2004 only reflected five months rent at the higher rate as compared to a full twelve months rent during the year ended December 31, 2005. These increases were partially offset by a decrease of $119,000 in investment banking fees. In 2004, we engaged an investment bank to explore potential financing options, none of which we ultimately pursued. No such fees were recognized during the year ended December 31, 2005.

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Other Income, Net

Other income, net increased to $106,000 for the year ended December 31, 2005 from $22,000 for the year ended December 31, 2004. The increase was primarily due to increased interest income earned as a result of higher average cash balances and higher yields during the period.

Liquidity and Capital Resources

We have incurred cumulative net losses of $14.0 million since inception through March 31, 2007. 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 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 next four years to support on-going research and development efforts. In 2006, we received a payment of $700,000 for the funding of research and development activities performed through December 31, 2006. During January 2007, we received a payment of $1.4 million to support the performance of research and development activities from January 2007 through June 2007. We expect to receive an additional payment of $1.4 million in July 2007 to support the research and development activities to be performed from July 2007 through December 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. 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.

During April 2007, we entered into a Master Security Agreement to establish a $1.0 million equipment loan facility with General Electric Capital Corporation. The purpose of the loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan will be secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate of 5.94% over the three year Treasury rate in effect at the time of funding.

On May 22, 2007, we borrowed $494,000 under the equipment loan facility. The principal and interest due under the loan will be repaid in equal monthly installments through September 2010 at an interest rate of 10.65%. As of the date of this prospectus, we had an outstanding loan balance of $479,000 under the facility.

Cash and Cash Equivalents

As of March 31, 2007, we had cash, cash equivalents, and short-term investments of $10.1 million compared to $11.1 million at December 31, 2006 and $3.2 million at December 31, 2005.

Cash Provided by (Used in) Operating Activities

For the three months ended March 31, 2007, cash used in operating activities of $320,000 was attributable primarily to our net loss of $893,000 and a $281,000 increase in prepaid expenses and other assets. Prepaid

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expenses and other assets increased due to an advance payment made to a vendor for our NVC-422 clinical study and due to the recognition of a receivable for amounts due from Alcon for reimbursable expenses. These amounts were offset by a $582,000 increase in accounts payable and accrued liabilities, primarily due to costs incurred in connection with the initial public offering that were accrued during the period but not paid until after March 31, 2007.

For the year ended December 31, 2006, cash provided by operating activities of $4.7 million was attributable primarily to an increase in deferred revenue related to the $10.0 million upfront technology access fee received from Alcon and an increase in accounts payable and accrued liabilities reflecting amounts that were expensed during the period but not paid until after December 31, 2006. This amount was offset by our net loss of $5.3 million, excluding the amounts recognized for stock-based compensation and depreciation, which are non-cash expenses.

For the year ended December 31, 2005, cash used in operating activities of $3.2 million was attributable primarily to our net loss of $3.5 million, excluding the amounts recognized for stock-based compensation and depreciation, which are non-cash expenses.

For the year ended December 31, 2004, cash used in operating activities of $2.5 million was attributable primarily to our net loss of $2.8 million, excluding the amounts recognized for losses on disposals of property and equipment and depreciation, which are non-cash expenses. This amount was partially offset by an increase of $193,000 in accounts payable and accrued liabilities, primarily due to research and development costs that were expensed during 2004 but were not paid until 2005.

Cash Provided by (Used in) Investing Activities

For the three months ended March 31, 2007, cash used in investing activities of $235,000 was attributable to purchases of property and equipment of $287,000 offset by net sales or maturities of short-term investments of $52,000. Net cash used in investing activities was $5.5 million for the year ended December 31, 2006 due to purchases of short-term investments (net of maturities) of $5.2 million and purchases of property and equipment of $362,000. Net cash used in investing activities was $1.1 million for the year ended December 31, 2005 due to the purchases of short-term investments (net of maturities) of $1.0 million and purchases of property and equipment of $123,000. For the year ended December 31, 2004, cash used in investing activities of $161,000 was attributable to purchases of property and equipment.

Cash Provided by (Used in) Financing Activities

Net cash used in financing activities of $487,000 was primarily attributable to costs incurred in connection with our initial public offering of $532,000 offset by $50,000 in proceeds from option exercises.

Net cash provided by financing activities of $3.5 million for the year ended December 31, 2006 was attributable to sales of preferred stock of $2.6 million and proceeds from option and warrant exercises of $1.0 million, partially offset by $93,000 of costs incurred in preparation for our initial public offering.

Net cash provided by financing activities for the years ended December 31, 2005 and 2004 was $2.5 million and $5.6 million, respectively. Net cash provided by financing activities in both years was primarily related to the sales of preferred stock.

We believe that the net proceeds from this offering, together with our cash balance at March 31, 2007 will be 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;

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future clinical trial results;

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

the cost and timing of regulatory approvals;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technological and market developments;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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Quarterly Results of Operations

The following table presents unaudited quarterly results of operations for the eight quarters ended March 31, 2007. This information has been derived from our unaudited financial statements and has been prepared by us on a basis consistent with our audited annual financial statements and includes all adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the information for the periods presented.

	Three Months Ended							
	June 30, 2005	Sept. 30, 2005	Dec. 31, 2005	Mar. 31, 2006	June 30, 2006	Sept. 30, 2006	Dec. 31, 2006	Mar. 31, 2007
	(unaudited)							
	(in thousands, except per share data)							
Statements of Operations Data:								
Revenue	$	$	$	$	$	$ 208	$ 1,325	$ 1,483
Operating expenses:								
Research and development	543	523	350	531	788	1,122	1,646	1,463
General and administrative	399	390	460	717	714	634	907	1,035
Total operating expenses	942	913	810	1,248	1,502	1,756	2,553	2,498
Interest income and other, net	47	17	28	30	9	58	143	122
Net loss before income taxes	(895)	(896)	(782)	(1,218)	(1,493)	(1,490)	(1,085)	(893)
Provision for income taxes								
Net loss	$ (895)	$ (896)	$ (782)	$ (1,218)	$ (1,493)	$ (1,490)	$ (1,085)	$ (893)
Net loss per share:								
Basic and diluted	$ (0.09)	$ (0.09)	$ (0.08)	$ (0.12)	$ (0.14)	$ (0.12)	$ (0.09)	$ (0.07)
Shares used in per share calculations:								
Basic and diluted	9,622	10,025	10,072	10,133	10,517	12,469	12,561	12,831
Pro forma net loss per share:								
Basic and diluted				$ (0.04)	$ (0.05)	$ (0.05)	$ (0.03)	$ (0.03)
Shares used in pro forma per share calculations:								
Basic and diluted				27,684	28,740	31,466	31,788	32,058
Stock-based compensation expense included above:								
Research and development	$ 10	$	$	$ 15	$ 23	$ 22	$ 26	$ 63
General and administrative			16	21	116	90	54	175
Total stock-based compensation expense	$ 10	$	$ 16	$ 36	$ 139	$ 112	$ 80	$ 238

Our operating results have varied and will continue to vary in the future from quarter to quarter depending upon our level of business activities. Factors affecting our quarterly operating results include, but are not limited to:

- changes in the level of our research and developments activities;
- changes in the number of our personnel;

the acquisition or loss of partnering arrangements;

the achievement of milestones or other events requiring payments to us under partnering agreements;

the timing and success of development efforts for our product candidates;

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- the amount and timing of expenditures to expand our operations; and

- general economic, industry and market conditions.

Our operating results are difficult to forecast and will fluctuate, and we believe that quarter-to-quarter comparison of our operating results will not necessarily be meaningful. As a result, you should not rely upon them as an indication of our future performance.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2006 we had net operating loss and credit carryforwards for both federal and state income tax purposes of $6.4 million. If not utilized, the federal and state net operating loss and credit carryforwards will begin expiring at various dates between 2015 and 2025. Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss and credit carryforwards may be impaired or limited in certain circumstances. Events that could cause limitations in the amount of net operating losses that we may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, that may occur, for example, as a result of this offering aggregated with certain other sales of our stock before or after this offering.

Contractual Obligations

At March 31, 2007, we did not have any amounts outstanding under debt or credit facilities.

Our contractual obligations as of March 31, 2007 were as follows:

	Payments Due by Period (in thousands)			
		Less than		
Contractual Obligations:	**Total**	**1 year**	**1-3 Years**	**3-5 Years**
Operating leases	$ 1,857	$ 530	$ 936	$ 391
Capital lease	130	44	86	

Our commitments under the operating leases shown above consist of payments relating to four leases for laboratory and office space in one office building in Emeryville, California. These leases have a range of expiration dates beginning on October 31, 2009 and ending on December 31, 2011.

Our commitment under the capital lease shown above consists of the total payments due under one lease of laboratory equipment. This amount includes $19,000 of interest payments over the 36 month term of the lease.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future. There can be no assurances, however, that our business will not be affected by inflation.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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.

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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 portfolio of cash equivalents, short-term marketable securities and restricted cash in a variety of securities, including money market mutual funds, Treasury bills, Treasury notes and commercial papers. 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. Accordingly, we do not have any material exposure to foreign currency rate fluctuations.

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BUSINESS

Overview

We are a biopharmaceutical company focused on developing innovative product candidates targeting 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 increase in infectious agents that have become resistant to current drugs.

We have discovered and are developing a class of antimicrobial compounds, which we have named Aganocide compounds, that we believe could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial infections. Our current development efforts are focused on Aganocide compounds to treat patients with infections of the eye, ear and sinus, to create an improved environment for the healing of wounds, whether chronic or acute, and to prevent infections that result from surgical or other hospital procedures or that can be caused by the use of products, such as contact lens solutions, which can introduce an infection into the body.

Our antimicrobial compounds are based upon small molecules that are generated by white blood cells that defend the body against invading pathogens. In the body, these compounds are produced on demand and are transient. We have two primary compounds: NVC-101 and NVC-422. NVC-101, which we also refer to as NeutroPhase, is a solution containing hypochlorous acid, a small molecule that is the same as that which is naturally generated when a white blood cell defends the body against bacteria. NVC-422 is an analog of another molecule produced by a white blood cell and is now our lead compound, forming the basis of all of our Aganocide compounds. NVC-422 s primary advantage is that it kills a wide range of bacteria as well as certain yeasts, fungi and viruses, very rapidly, and we have demonstrated through in-vitro experiments that NVC-422 kills these pathogens at concentrations that are significantly lower than the concentrations at which it begins to harm human cells.

The development and commercialization of products based on our Aganocide compounds will require significantly more research, development and testing as well as governmental approvals. We intend to pursue the in-house development and commercialization of products designed to prevent selected nosocomial (hospital or institutional) infections and to partner with leading companies to assist us with the development of other products, where the expertise of the partner would help maximize the value of the particular product through development and/or commercialization.

In August 2006, we entered into a collaboration and licensing agreement with an affiliate of Alcon, Inc., a leading ophthalmic pharmaceutical company, to develop products incorporating Aganocide compounds for use in the eye, ear and sinus, as well as in contact lens solutions. In June 2007, we entered into a license agreement with an affiliate of Kinetic Concepts, Inc., a global medical technology company with leadership positions in advanced wound care and therapeutic surfaces, 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.

Industry Background

Combating bacterial infections is critical to modern medicine. Until the advent of antibiotics, led by the introduction of penicillin in the 1940s, infections were a routine cause of death. Since that time, antibiotics have greatly reduced the risks associated with bacterial infections, have made possible the routine use of surgical procedures for non-critical purposes and have increased the probability of success of many modern complex operations. As a result, most people in the developed world now tend to believe that bacterial infections can be readily treated with a course of antibiotic therapy; however, recent developments relating to bacterial resistance and bacterial biofilm are calling this into question.

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Bacterial Resistance

Bacteria are becoming resistant to different classes of existing antibiotics at increasing rates. These increasing levels of resistance are principally the result of repeated exposure of bacteria to non-lethal quantities of antibiotics and the ability of certain bacteria to transmit mutant genes to other bacterial species, thus enabling different species of bacteria to survive the antibiotic to which the first species was exposed. The growth of this antibiotic resistance since 1990 has been substantial. The following graph illustrates the growth of resistance in intensive care unit infections in the United States from 1995 to 2004:

Bacterial Biofilm

Many bacteria spend much of their existence within a matrix that they create, called biofilm. Biofilm consists of mucopolysaccharide (or slime-like) structures produced by microorganisms as a defense mechanism against their environment. Encased in biofilm, bacteria can survive for prolonged periods by assuming a dormant state. When bacteria are in a dormant state, they are largely immune to antibiotics, which are generally only effective against bacteria during specific non-dormant stages in their life cycle. When bacteria are protected by biofilm, antibiotics frequently provide only temporary relief and bacteria can eventually emerge from their biofilm to reinfect the patient. In biofilm, bacteria are also largely protected from white blood cells that normally kill most pathogens that enter the body. White blood cells combat bacteria by engulfing them, which they are unable to do once bacteria have created biofilm. Furthermore, many commonly used antiseptics are neutralized by biofilm.

According to the Center for Integrative Biology and Infectious Diseases of the National Institutes of Health (2007), biofilms account for 80% of the microbial infections in humans. Bacterial biofilm is associated with diseases such as sinus infections (sinusitis), ear infections, chronic wounds and infections related to cystic fibrosis. Bacterial biofilms are also frequently found on the surfaces of medical devices, such as catheters and implants, and can cause severe chronic or acute infections.

Market Opportunity

Limitations of Existing Anti-Infective Drugs. Many anti-infective drugs have limitations in their efficacy and application that may inhibit their effectiveness in treating many bacterial infections. These limitations include:

- many current antibiotics are no longer effective in killing the growing number of resistant types of bacteria;
- current antibiotics are generally ineffective in killing bacteria while they reside in biofilm; and
- while most infections are localized, most current antibiotics used to treat bacterial infections are delivered systemically either orally or through injection or infusion. As a result, the entire body is

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exposed to the antibiotic in order to treat a local infection in what may only be in, or on, a small part of the body. Furthermore, the dosage required to treat a local infection by systemic delivery is substantially higher than would be necessary to treat the local infection, resulting in greater risk of toxicity which can cause adverse side effects or other harmful effects on the human body.

Hospital Infections. Increasing bacterial resistance, bacterial biofilm and the limitations of traditional antibiotic therapy are major contributors to the high cost of healthcare throughout the world. These problems are particularly evident in dealing with so-called nosocomial infections. These are infections that originate or occur in a hospital or hospital-like setting. According to the Pennsylvania Healthcare Cost Containment Council, in Pennsylvania hospitals alone, hospital-acquired infections led to approximately $2.9 billion of added costs in 2005 and, more significantly, almost 14% of those that acquired such infections died. Nosocomial infections result from a combination of four factors:

- a high prevalence of disease-causing organisms,
- a high prevalence of patients whose natural defenses (their immune system) are compromised because of illness or drugs,
- a high prevalence of patients whose first line of defense against infection (their skin) has been breached due to injury, by surgery or through the use of catheters, and
- a high risk of transmission of infection from one patient to another.

According to *Emerging Infectious Diseases*, a journal published by the Centers for Disease Control and Prevention (CDC) in 2001, each year there are 2,000,000 healthcare associated infections in the United States, which result in 90,000 deaths.

Our Solution

We have developed a class of antimicrobial compounds that we believe form a platform on which to create several products to address the differing needs in the treatment and prevention of bacterial infections. We believe that our Aganocide compounds can be highly effective in their antimicrobial activity, without causing harm to the body s own cells, at doses that are likely to be used in therapy.

We believe the benefits of product candidates based upon our antimicrobial compounds will include:

Prevent or Treat Infections Caused by Resistant Bacteria. Our in-vitro and preliminary in-vivo animal tests indicate that our Aganocide compounds may be effective in destroying certain types of bacteria that have become resistant to existing antibiotics.

Destroy Bacteria Protected by Biofilm. We believe that effective treatment of several types of infections such as sinus infections, ear infections and bladder infections require products that can destroy bacteria even when resident in biofilm. In-vitro experiments indicate that our Aganocide compounds can be effective in destroying bacteria resident in biofilm. Although we have demonstrated that our Aganocide compounds can kill bacteria in biofilms grown in devices in laboratories, we need to show that our Aganocide compounds can kill bacteria in biofilm when those devices, such as catheters, are used in humans.

Allow for Treatment Without the Need to Identify the Causative Bacterium and its Susceptibility. We believe that our Aganocide compounds have the potential to be effective against most, if not all, species of bacteria, whether resistant or susceptible to current antibiotics. If we are able to prove this in human clinical trials, the use of an Aganocide product could eliminate the need to conduct diagnostic procedures to identify the bacteria causing the infection before commencing treatment.

Treat Certain Infections that May be Viral or Bacterial in Origin. Based on in-vitro and preliminary animal tests, we believe that our Aganocide compounds have the potential to kill not only bacteria, but

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also some viruses, thereby permitting immediate treatment for certain diseases where the causative agent may be a bacterium or a virus. These results will need to be confirmed in human studies.

Reduce Nosocomial (Hospital) Infections. We believe that Aganocide compounds may be able to contribute to preventing the occurrence and the transmission of hospital infections in several ways. For example, we have identified several applications for use of the Aganocide compounds in the prevention of infections that are associated with the use of invasive catheters, a major source of hospital infections. We need to develop appropriate formulations and methods of delivery in order to bring these product candidates to market.

Rapidly Killing Bacteria. Our tests indicate that our Aganocide compounds eliminate certain bacteria in minutes, whereas current therapies may take hours or days at analogous therapeutic concentrations. As a result, we believe that our product candidates could contribute to significant improvements in a variety of clinical procedures, including eliminating the need for days of clinical isolation currently necessary to allow some antibiotic therapies to run their course. To be successful in the marketplace, we need to demonstrate that our product candidates can be readily usable and do not disrupt the current practices of medical care.

Reduce Toxicity and Adverse Side Effects. Aganocide compounds are intended for localized application targeted at the specific area of infection and not for systemic use. Consequently, we believe that there may be a significant reduction in the risk of toxicity resulting in adverse side effects, as compared to the risks associated with systemic antibiotics. Although we have demonstrated that systemic absorption of our compounds is very low in animals, we need to confirm this in human studies.

High Therapeutic Index. The therapeutic index, as used to assess our compounds, is the ratio of the concentration at which a compound harms normal cells to the concentration at which it kills bacteria. Our in-vitro and in-vivo animal testing indicates that Aganocide compounds have a high therapeutic index, meaning that they can kill bacteria when delivered in concentrations far below the level that are likely to harm mammalian cells. We therefore expect products containing Aganocide compounds to enable more effective and safer treatment of diseases than other antimicrobial products, which may be effective in killing bacteria but which have greater risks of adverse side effects and other harmful effects on the body. We need to confirm these results in human clinical trials.

Resistance Unlikely. We believe that the development of resistance by bacteria to the Aganocide compounds is less likely than is the case with existing antibiotics because Aganocide compounds are analogs of the molecules used by the human immune system. The microbiocidal activity of NVC-101 and our Aganocide compounds is based on the use of active chlorine. Similar forms of active chlorine have been used to protect drinking water supplies throughout the world since the nineteenth century and no known resistance has been established.

Small Molecules Unlikely to Produce an Immune Reaction. The Aganocide compounds are small molecules. Unlike peptides and proteins, these molecules are of a size that is unlikely to generate an antibody response by the human body. Generally, only large molecules, infectious agents, or insoluble foreign matter will elicit an immune response in the body, however we need to conduct Phase I, II and III human clinical trials in order to confirm this.

We have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies; however, we will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain FDA approval 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. However, historic data analyzed and published by CMR International, Limited indicates that anti-infective products that enter Phase I clinical trials have a higher probability of being subsequently approved for marketing than drugs in certain other categories. We believe this is the case because anti-infective drugs are designed not to act upon the human body and its cells, but to act upon microbes. For that same reason, we also believe that animal models of the treatment of infections are more predictive of the

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treatment of the same infections in humans than is the case in animal models of many other diseases of the human body. The bacteria used in in-vitro and in-vivo tests are the same as those found in human infections. We also believe that the microbiological end-points of clinical trials for anti-infective products are clearer (i.e., eradication or substantial reduction in the counts of the number of microbes) than is the case in many other disease categories. While our compounds are anti-infective, they kill bacteria by a different mechanism than the compounds that have been included in the CMR International report and, therefore, the historically higher probability of success of anti-infective products may not necessarily apply in the case of our Aganocide compounds.

Our Strategy

Our objective is to develop and commercialize NVC-101 and Aganocide-based products through both internal development efforts and partnerships with leading companies for certain applications. The key elements of our strategy include:

Developing Product Candidates In-house. We intend to develop our product candidates for selected indications for the prevention and treatment of nosocomial infections in-house and use qualified clinical research organizations to assist us with the clinical trials. The initial indications that we intend to develop are nasal decolonization (the treatment of nasal passages to eliminate harmful bacteria prior to surgery) and the prevention of infections associated with urinary tract catheters. However, we may reprioritize our efforts or abandon an indication based on results of our initial human trials.

Developing Products through to Proof-of-Concept for Multiple Indications. A major advantage of antimicrobial products is that success with laboratory and animal models tends to be much more predictive of eventual regulatory approval than is often the case with other classes of drugs. Reliable pre-clinical data often can be generated much faster and less expensively than having to achieve proof-of-concept (i.e., demonstration of safety and efficacy) through Phase II clinical trials. We believe this enables potential partners to evaluate our compounds much earlier than might otherwise be the case for drugs in other therapeutic categories.

Licensing Indications through Partnering Arrangements with Leading Companies. We intend to pursue partnering arrangements with leading companies in cases where we expect the likely magnitude, duration and expense of the clinical trial program required to obtain regulatory approval will be substantial and beyond our internal resources. In such cases, licensing the indications to leading companies in each field-of-use will enable us to take advantage of the partners resources and expertise in development, commercialization and sales and marketing of the resulting products. We may also pursue the formation of a joint venture where there are multiple opportunities in one therapy area.

Broadening the Range of Aganocide Compounds. We intend to continue to synthesize further Aganocide compounds. We are currently focusing our efforts on producing additional compounds for certain specific indications in collaboration with Alcon. We may continue to test new Aganocide compounds for other potential uses.

Provide Cost-Effective Solutions to the Problem of Hospital Infections. We expect to be able to provide products that will be cost-effective for hospitals to use to prevent and treat hospital infections that, according to *Clinical Pulmonary Medicine* (2002), cost between $5 and $10 billion per year in the United States, with much of that cost being a charge to the hospital. We expect that our product candidates, if successful, will enable savings to be made that would be significantly greater than the cost of the products, based upon our expectations of the cost of manufacture. In the complex hospital environment, we will need to clearly demonstrate the cost effectiveness of our products on the basis of well-designed pharmaco-economic trials.

Potential Company Milestones

Our current plans include the milestones indicated below. These milestones are, in whole or in part, outside our control and are subject to change. There are inherent risks and uncertainties in drug discovery and

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development, including those factors described in the Risk Factors section of this prospectus. The filing of an Investigational New Drug application (IND) requires substantial pre-clinical work in order to demonstrate to the FDA that the potential use of the drug in clinical trials for the intended indication is appropriate and likely to be safe. Clinical trials are frequently subject to delays or cancellation because of, among other things, problems with the drug, its formulation, the trial design and the enrollment of patients. This is especially true for Phase I and II clinical trials that are designed to explore the safety and preliminary efficacy of a product at different doses and often in different formulations. For example, we may learn from our Phase I clinical trials that we require a different formulation which may require us to repeat some animal studies before recommencing Phase I trials; this could postpone the target endpoint significantly. One of the primary goals of Phase II trials is to determine the design, dose and formulation of a drug to be taken into Phase III trials. Because of the high cost of Phase III trials, it may be necessary to repeat a Phase II trial to ensure that these factors have been sufficiently explored to be able to move prudently into a Phase III trial.

	2007	**2008**
Nasal Decolonization	File IND	Finish Phase II Trials
	Begin Phase I Trials	Begin Phase III Trials
	Complete Phase I Trials	
	Begin Phase II Trials	
Catheter Related Urinary Tract Infections	File IND	Begin Phase I Trials
		Complete Phase I Trials
		Begin Phase II Trials
Partnered Indications	File IND	Begin Phase I
		Complete Phase I
		Begin Phase II
		File IND for second indication
New Partnering Agreements	Enter into one agreement	Enter into one agreement

We expect the clinical development for each indication to take between three and five years to complete from the time of filing an IND, but such trials may take longer because of unforeseen issues that may require resolution before a trial can be completed.

Our Products and Technology

We have developed two primary compounds, NVC-101 (also referred to as NeutroPhase) and NVC-422, that we intend to use in the development of products to treat various bacterial infections. NVC-422 is our lead compound in a new class of antimicrobial compounds that we call the Aganocide compounds.

We developed our Aganocide compounds through research and development based on the human body s natural immune system and the molecules involved in combating infections. The body s primary defense against infection is the anatomic barrier of the skin and mucous membranes. Once pathogens penetrate the primary defense, the next line of defense is provided by the white blood cells. The most numerous of the white blood cells is the neutrophil. When it encounters bacteria or other pathogens, the neutrophil engulfs it and generates a series of small molecules with which to destroy it. The process in which these molecules are created is called the oxidative burst . These molecules typically have a very short life as they are created on demand to accomplish a specific task. We have focused our efforts on understanding these molecules and finding ways, primarily by chemical modification, to impart qualities to them to allow them to be developed as therapeutic products.

NVC-101 (NeutroPhase)

The primary molecule that is created in the oxidative burst is hypochlorous acid. Hypochlorous acid is highly reactive and kills bacteria in seconds. We have explored the properties of hypochlorous acid in a variety of animal models and have established the conditions under which it can be held stable. NVC-101 is our stable

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formulation of hypochlorous acid. NVC-101 can only exist in a solution. NVC-101 is extremely rapid acting and is very short-lived when applied to tissue. Because of these characteristics, we have decided to focus the development of NVC-101 on rapid cleansing and debridement in wounds, including surgical wounds, chronic wounds (e.g., bed sores and diabetic foot ulcers) and possibly burn wounds where there is a continued risk of surface infection.

NVC-422

As the process of the oxidative burst continues, hypochlorous acid reacts with other molecules. Two molecules result from the reaction of hypochlorous acid with taurine: N-chlorotaurine (NCT) and N,N,-dichlorotaurine (NNDCT). Both NCT and NNDCT are antimicrobial, although NNDCT is significantly more so. However, both of these molecules are chemically unstable.

We have succeeded in creating stable analogs of these molecules, one of which is our NVC-422 compound. NVC-422 is our lead compound and it has a number of advantages. It kills a very wide range of pathogens, including not only bacteria, but also yeasts, fungi and some viruses. NVC-422 can kill pathogens very rapidly and can do so at concentrations significantly lower than the concentrations at which it begins to harm human cells.

Other Aganocide Compounds

In our research, we are also testing the antimicrobial and safety profiles in cell assays of additional compounds that have similar conceptual structures to NVC-422, but which may have different characteristics such as the ability to penetrate different tissues and the speed at which they kill pathogens. To date, we have created several other molecules that have similar antimicrobial properties to NVC-422. The additional Aganocide compounds that we are researching are shown in the following table (along with NVC-422), together with their therapeutic index, which is a measure of the relationship between safety and efficacy, based on our in-vitro tests. We measure safety by testing different concentrations of the compound against a standard mammalian cell type to find the concentration at which the compound kills 50% of the cells. We measure efficacy by testing different concentrations of the compound against standard bacterial strains to identify the level at which it kills more than 99.99% of those strains.

The therapeutic index of the following Aganocide compounds is the ratio of the concentration at which the compound harms mammalian cells to that at which it kills the specified bacteria in in-vitro tests. A high therapeutic index suggests better therapeutic activity.

	Escherichia coli	**Psedomonas aeruginosa**	**Staph. aureus**
NVC-422	6,000	6,300	2,900
NVC-521	2,000	1,000	500
NVC-524	2,300	4,900	2,400
NVC-530	4,600	5,100	1,200
NVC-539	1,100	1,000	500
NVC-546	2,100	4,400	2,100
NVC-570	38	150	38

Data from experiments conducted by NovaBay

We are also currently exploring the other properties of these compounds (such as stability, ability to penetrate into tissue, duration of action, etc.). In our collaboration with Alcon, we are creating a significant number of additional compounds of this type to optimize their efficacy in the different target indications.

Although we have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies, we will need to conduct Phase I, II and III human clinical trials to confirm the safety and efficacy of the

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compounds. In addition, although we believe that in-vitro and in-vivo animal testing of the treatment of infections are far more predictive of the treatment of the same infections in humans than is the case for the treatment of other diseases of the human body, positive in-vitro results are often not followed by positive human tests results, and we cannot assure you that any human clinical trials we conduct will produce the same positive results that we obtained in our in-vitro and in-vivo animal studies.

Characteristics of the NVC-101 and Aganocide Compounds

The NVC-101 and Aganocide compounds appear to share many highly desirable characteristics that have been demonstrated in in-vitro and in-vivo animal studies. These characteristics, however, will need to be confirmed in Phase I, II and III clinical trials before they can be approved by the FDA. Because the bacteria that we have used in our tests are the same as those found in human infections, the primary focus of our clinical trials will be to confirm that our formulations can effectively deliver the compounds to the site of the infection, without causing adverse side effects. It is possible however, that the positive results achieved in in-vitro or in-vivo animal studies will not be followed by positive results in human clinical trials.

Speed of Action

Unlike most antibiotics, which can take many hours to kill certain kinds of bacteria, NVC-101 and the Aganocide compounds, even at small doses, can kill bacteria in minutes. By increasing the concentration to doses that would be typically used in humans, we believe that the time to kill many types of bacteria should be a minute or less. The speed of action of a product may be important in many instances, because (a) a topical product may be rapidly removed from the area of application (e.g., by blinking in the case of ophthalmic formulations) or (b) it is infeasible to hold a product in place for a sustained period of time (e.g., in a flush solution to eliminate bacteria from biofilm in urinary tract catheters).

We submitted an Investigational New Drug Application (IND) for NVC-101 for use in infected chronic venous leg ulcer wounds, that was cleared by the FDA in 2004. The IND included the results of in-vitro and in-vivo animal tests that were either conducted in at least triplicate by NovaBay or were conducted by independent outside laboratories on our behalf and at our direction. These tests demonstrated that, at concentrations that are approximately 40 to 500-fold less than the intended concentration for use in humans, NVC-101 killed the following microbes in one minute or less:

Candida albicans 10231	Pseudomonas aeruginosa 27853
Corynebacterium amycolatum 49368	Serratia marcescens 14756
Enterobacter aerogenes 51697	Staphylococcus aureus 29213
Enterococcus faecium 51559 VRE	Staphylococcus aureus 33591, MRSA
Escherichia coli 25922	Staphylococcus epidermidis 12228
Haemophilus influenzae 49144	Staphylococcus haemolyticus 29970
Klebsiella pneumoniae 10031	Staphylococcus hominis 27844
Micrococcus luteus 7468	Staphylococcus saprophyticus 35552
Proteus mirabilis14153	

The numbers shown in this table are the strain identification numbers of ATCC, an organization that provides standard biological materials to the industry and academia.

We believe that all these microbes are amongst those that may be found in a chronic wound, as well as in many other infectious conditions.

In our IND for NVC-422, we submitted data on its speed of action, including the time needed to kill the microbe with the minimum concentration at which the target organism is killed (MBC). This is a more demanding test than that undertaken with NVC-101 because in some cases the concentration used was as low as 0.003% of the expected concentration to be used in humans.

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The graphs below further illustrate the rapidity of action of NVC-422 at higher concentrations.

Broad Spectrum, Including Against Multi-drug Resistant Species

NVC-101 and our Aganocide compounds have killed, in-vitro, all bacteria and yeasts against which they have been tested. They were highly effective against two of the primary multi-drug resistant bacteria, Methicillin-Resistant Staphylococcus aureus (MRSA) and Vancomycin-Resistant Enterococcus (VRE). NVC-101 has been shown in in-vitro experiments to be highly effective against multiple strains of anthrax *(Bacillus anthracis)*, in both their vegetative and spore forms.

During a safety study in infected human wounds with NVC-101, conducted at a major wound care center with the approval of its Institutional Review Board, there were indications of preliminary efficacy. By preliminary efficacy, we mean that there appears to have been a trend towards more rapid wound-healing when compared to subjects who received treatment with the control substance (saline). However, since this study was not designed to obtain FDA approval of a product as a drug, it should not be considered as being adequate for submission to the FDA as proof of efficacy. A full Phase I, II and III clinical program would be needed to obtain approval as a drug. The efficacy of NVC-101 was previously demonstrated in animal models of granulating wounds and diabetic wounds. By efficacy in animal models, we mean that animals treated with the test article had significantly lower levels of bacteria at the site of infection than those treated with a control product. Additionally, in the case of wound model studies, the test product was significantly better than the control product in increasing the speed of healing as measured by the rate of closure of the wound.

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In-vivo, NVC-422 has demonstrated efficacy in infected animal models of chronic wounds, eye infections and ear infections. The following tables show the activity of NVC-422 against multi-drug resistant strains of bacteria recovered from recent nosocomial infections in animal tests. They indicate the MIC (Minimum Inhibitory Concentration) required for different antibiotics against which they were tested. They compare the concentration of the antibiotic or NVC-422 required to kill a standard strain against the concentration to kill the resistant strain.