NovaBay Pharmaceuticals, Inc.
Form S-1/A
May 29, 2007
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As filed with the Securities and Exchange Commission on May 29, 2007

Registration No. 333-140714

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 3

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.

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 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

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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, 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 May 24, 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$1.0841.

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 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 received a non-refundable technology access fee of $10.0 million pursuant to the agreement and are entitled to certain semi-annual payments for research and development conducted by us under the Alcon 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. If products developed under the Alcon agreement are commercialized, we will also be entitled to receive royalty payments, which vary by field of use and whether the product is covered by a valid claim of one of our patents. We cannot assure you that our collaboration with Alcon 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 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.

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

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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.

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

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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.

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

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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.

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.

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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.

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

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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, 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.

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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 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.

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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 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.

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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 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.

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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;
- 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.

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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;

formulating and manufacturing products; and

launching, marketing, distributing and selling products.

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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 some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-looking 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,	
	2002		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				