

NovaBay Pharmaceuticals, Inc.  
Form S-1/A  
April 18, 2007  
Table of Contents

As filed with the Securities and Exchange Commission on April 18, 2007

Registration No. 333-140714

---

# U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

## AMENDMENT NO. 2

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**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Number)  
**5980 Horton Street, Suite 550**

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

**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)**

---

*Copies to:*

**Chris Barry, Esq.**

**Dorsey & Whitney LLP**

**U.S. Bank Centre**

**1420 Fifth Avenue, Suite 3400**

**Seattle, WA 98101-4010**

**(206) 903-8815**

**Robert Mason, Esq.**

**Fasken Martineau DuMoulin LLP**

**66 Wellington Street West**

**Suite 4200**

**Toronto, Ontario M5K 1N6**

**(416) 366-8381**

**Riccardo A. Leofanti, Esq.**

**Skadden, Arps, Slate, Meagher & Flom LLP**

**222 Bay Street, Suite 1750**

**Toronto, Ontario M5K 1J5**

**(416) 777-4700**

**John Kolada, Esq.**

**Blake, Cassels & Graydon LLP**

**Commerce Court West, Suite 2800**

**Toronto, Ontario M5L 1A9**

**(416) 863-2400**

---

**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. "

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

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

---

<b>Title of Each Class of Securities to be Registered</b>	<b>Proposed Maximum Aggregate Offering Price(1)(2)</b>	<b>Amount of Registration Fee</b>
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.**

---

**Table of Contents**

*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.**

**Table of Contents**

**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**

	<b>Per Share</b>	<b>Total</b>
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.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	8
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	27
<u>USE OF PROCEEDS</u>	28
<u>DIVIDEND POLICY</u>	28
<u>CAPITALIZATION</u>	29
<u>DILUTION</u>	30
<u>SELECTED FINANCIAL DATA</u>	32
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	34
<u>BUSINESS</u>	48
<u>MANAGEMENT</u>	81
<u>RELATED PARTY TRANSACTIONS</u>	95
<u>PRINCIPAL SHAREHOLDERS</u>	96
<u>DESCRIPTION OF CAPITAL STOCK</u>	98
<u>PRIOR SALES OF SHARES</u>	101
<u>SHARES ELIGIBLE FOR FUTURE SALE</u>	102
<u>MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS TO NON-U.S. HOLDERS</u>	106
<u>MATERIAL CANADIAN FEDERAL INCOME TAX CONSIDERATIONS</u>	109
<u>UNDERWRITING</u>	112
<u>NOTICE TO INVESTORS</u>	116
<u>LEGAL MATTERS</u>	117
<u>EXPERTS</u>	117
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	118
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1

---

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.

**Table of Contents**

**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 filed an Investigational New Drug application, or IND, in March 2007 with the U.S. Food and Drug Administration, or FDA, to begin human clinical trials using NVC-422.

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. 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. 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 December 31, 2006 were \$13.1 million.



## **Table of Contents**

### **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.

### **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.

## Table of Contents

*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.

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.

## **Table of Contents**

### **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 April 16, 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\$1.1309.

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.



## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

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.

**Table of Contents****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. Our financial statements have been prepared in accordance with United States GAAP, which differ in certain respects from Canadian GAAP.

	Year Ended December 31,		
	2004	2005	2006
	(in thousands, except share and per share data)		
<b>Statements of Operations Data:</b>			
Revenue	\$	\$	\$ 1,533
Operating Expenses:			
Research and development(1)	1,481	1,952	4,087
General and administrative(1)	1,345	1,617	2,972
Total operating expenses	2,826	3,569	7,059
Interest income (expense) and other, net	22	106	240
Net loss before income taxes	(2,804)	(3,463)	(5,286)
Provision for income taxes			
Net loss	\$ (2,804)	\$ (3,463)	\$ (5,286)
Net loss per share:			
Basic and diluted	\$ (0.32)	\$ (0.36)	\$ (0.46)
Shares used in per share calculations:			
Basic and diluted	8,755,418	9,704,207	11,429,216
Pro forma net loss per share (unaudited):			
Basic and diluted			\$ (0.18)
Shares used in pro forma per share calculations (unaudited):(2)			
Basic and diluted			29,934,926

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

	Year Ended December 31,		
	2004	2005	2006
	(in thousands)		
Research and development	\$ 11	\$ 55	\$ 86
General and administrative		16	281
Total stock-based compensation expense	\$ 11	\$ 71	\$ 367

(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 January 1, 2006, or at the date of the original issuance, if later.

**Table of Contents**

The following table presents a summary of our balance sheet as of December 31, 2006:

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 December 31, 2006	
	Actual	Pro Forma As Adjusted (unaudited)
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 11,086	
Working capital	7,926	
Total assets	11,866	
Deferred revenue - current and non-current	9,167	
Convertible preferred stock	192	
Common stock and additional paid-in capital	14,683	
Total stockholders' equity	1,813	

**Table of Contents**

**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. Through December 31, 2006, we had an accumulated deficit of approximately \$13.1 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 relating to a research and development collaboration, and 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. 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





## **Table of Contents**

clinical trials of our compounds. We have not demonstrated the ability to succeed in achieving clinical endpoints, obtain regulatory approvals, formulate and manufacture products on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability are unlikely to be as accurate as they could be if we had a longer operating history.

***We 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.

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.



## **Table of Contents**

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 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,

## **Table of Contents**

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 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.

## Table of Contents

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 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.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

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

## **Table of Contents**

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 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



## **Table of Contents**

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.

***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



## **Table of Contents**

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 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.

## **Table of Contents**

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.

***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

## **Table of Contents**

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.

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.

## **Table of Contents**

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.

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

## **Table of Contents**

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.

***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,

## **Table of Contents**

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.

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



## **Table of Contents**

***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.

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;

## **Table of Contents**

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.

## Table of Contents

### **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' earnings 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

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

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

## **Table of Contents**

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, 31,849,813 shares of common stock were outstanding as of December 31, 2006, 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 December 31, 2006, 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

## **Table of Contents**

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





**Table of Contents**

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.

**Table of Contents**

**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, plan, 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.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

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.

**Table of Contents**

**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 \$ \_\_\_\_\_ million for the advancement of the clinical development of our Aganocide compounds; and

the remainder of the net proceeds for research and development, working capital and other general corporate 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.

**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.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents, and capitalization at December 31, 2006, 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.

	December 31, 2006		
	Actual	Pro Forma	Pro Forma As Adjusted (unaudited)
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	\$ 11,086	\$ 11,086	\$
Stockholders' equity:			
Convertible preferred stock, \$0.01 par value: 39,000,000 shares authorized, 19,227,195 shares issued and outstanding, actual; no shares authorized, 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; 64,000,000 shares authorized, 31,849,813 shares issued and outstanding, pro forma; 64,000,000 shares authorized, shares issued and outstanding, pro forma as adjusted	126	318	
Additional paid-in capital	14,557	14,557	
Accumulated other comprehensive income	12	12	
Accumulated deficit during development stage	(13,074)	(13,074)	
Total stockholders' equity	1,813	1,813	
Total capitalization	\$ 1,813	\$ 1,813	\$

The above table excludes, as of December 31, 2006:

4,791,259 shares of common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$0.42 per share; and

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

836,000 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.

**Table of Contents****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 December 31, 2006 was \$1.8 million, or \$0.06 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 December 31, 2006 (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 December 31, 2006 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 December 31, 2006	\$ 0.06
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 December 31, 2006 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 December 31, 2006, 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

**Table of Contents**

only and the 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	31,849,813	. %	\$	. %	\$
New shareholders					
<b>Total</b>		100.0%	\$	100.0%	

As of December 31, 2006, there were options outstanding to purchase an aggregate of 4,791,259 shares of our common stock at a weighted average exercise price of \$0.42 per share. The foregoing discussion and tables assume no exercise of any stock options outstanding as of December 31, 2006. 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 \$ .



**Table of Contents****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. Our financial statements have been prepared in accordance with United States GAAP, which differ 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 are not intended to replace the financial statements. See Note 13 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 Period from Jan 1, 2002 to June 30, 2002 (unaudited)		NovaBay Pharmaceuticals, Inc. Year Ended December 31, Period from July 1, 2002 to December 31, 2003      2004      2005      2006			
	(in thousands, except per share data)					
<b>Statements of Operations Data:</b>						
Revenue	\$	\$	\$	\$	\$	\$ 1,533
Operating Expenses:						
Research and development(1)	139	201	270	1,481	1,952	4,087
General and administrative(1)	150	343	683	1,345	1,617	2,972
Total operating expenses	289	544	953	2,826	3,569	7,059
Other income (expense), net	2		(24)	22	106	240
Net loss before income taxes	(287)	(544)	(977)	(2,804)	(3,463)	(5,286)
Provision for income taxes						
Net loss	\$ (287)	\$ (544)	\$ (977)	\$ (2,804)	\$ (3,463)	\$ (5,286)
Net loss per share:						
Basic and diluted	\$ (0.04)	\$ (0.07)	\$ (0.12)	\$ (0.32)	\$ (0.36)	\$ (0.46)
Shares used in per share calculations:						
Basic and diluted	7,634	7,762	8,087	8,755	9,704	11,429
Pro forma net loss per share (unaudited):						
Basic and diluted						\$ (0.18)
Shares used in pro forma per share calculations (unaudited):(2)						
Basic and diluted						29,935

*(footnotes on next page)*

**Table of Contents***(footnotes from prior page)*

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

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

- (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 January 1, 2006, or at the date of the original issuance, if later.

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

**Table of Contents**

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

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

**Overview**

We are a biopharmaceutical company focused on developing innovative product candidates targeting the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid increase in infectious agents that have become resistant to current drugs.

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

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

To date, we have generated no revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock. We have also recently begun to generate revenue through payments for our research and development activities under our agreement with Alcon. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of December 31, 2006, we had an accumulated deficit of \$13.1 million. Our accumulated deficit resulted from research and development expenses and general and administrative expenses. We expect to continue to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

In August 2006, we entered into a Collaboration and License Agreement with Alcon to license to Alcon the exclusive right to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. Under the terms of the agreement, we received an up-front technology access fee of \$10.0 million in September 2006, and we are entitled to receive semi-annual payments to support on-going research and development efforts over the next four years. As product candidates are developed and proceed through clinical trials and FDA approval, we will be entitled to certain milestone payments as well. If the products are commercialized, we will also be entitled to royalties on sales of products containing the Aganocide compounds.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, we may not be able to successfully develop and commercialize any of our product candidates. Any failure to complete the development of our product

**Table of Contents**

candidates in a timely manner would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth in the Risk Factors section of this prospectus.

**Financial Overview*****Research and Development Expense***

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

personnel associated with our research activities;

screening and identification of product candidates;

formulation and synthesis activities;

preclinical studies, including toxicology studies;

clinical trials; and

regulatory affairs.

We expense research and development costs as incurred. Costs incurred for general research and development activities were \$1.3 million, \$1.4 million, \$2.5 million and \$5.7 million for the years ended December 31, 2004, 2005 and 2006 and for the period from inception to December 31, 2006, respectively. Research and development costs incurred to develop NVC-101 and our Aganocide compounds are summarized below.

Development Project	Year Ended December 31,			Inception to Date
	2004	2005	2006	
<b><i>NVC-101</i></b>				
Toxicology/pharmacology	\$ 81,000	\$	\$	\$ 93,000
Clinical trials	75,000	473,000	857,000	1,405,000
Total expenses	\$ 156,000	\$ 473,000	\$ 857,000	\$ 1,498,000
<b><i>Aganocide Compounds</i></b>				
Toxicology/pharmacology	\$	\$ 52,000	\$ 718,000	\$ 770,000
Clinical trials				
Total expenses	\$	\$ 52,000	\$ 718,000	\$ 770,000

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

significant expenses associated with the administration of this trial.

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated

## **Table of Contents**

with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a New Drug Application, or NDA, may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

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

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

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

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

In addition, the completion of clinical trials can be delayed by numerous factors, including delays in identifying and agreeing on acceptable terms with prospective clinical trial sites; slower than expected rates of patient recruitment and enrollment; increases in time required to complete monitoring of patients during or after participation in a trial; and unexpected need for additional patient-related data. The FDA may also require us to conduct additional clinical testing, in which case we would have to expend additional resources as well as time. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Any of these delays, if significant, could impact the timing, approval and commercialization of our product candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our product candidates are safe and effective for indicated uses. Such failure would cause us to abandon a product candidate for some indications and could delay development of other product candidates. If we fail to obtain regulatory approval for any of our product candidates, we will not be able to commercialize our proposed products, and we will not generate product revenues.

### ***General and Administrative Expense***

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, and information technology functions. Other costs include

## **Table of Contents**

facility costs, professional fees for legal and accounting services, insurance, and depreciation expenses. We expect that, after this offering, we will incur significant additional accounting and legal costs related to compliance with securities and other regulations, as well as additional insurance, investor relations and other costs associated with being a public company.

### ***Stock-Based Compensation Expense***

Effective January 1, 2006, we began to measure and recognize compensation expense for all stock-based payments at fair value, in accordance with Statement of Financial Accounting Standard ( SFAS ) No. 123R, Share-Based Payment . Stock-based compensation expense is classified in the statement of operations in the same expense line items as cash compensation. We expect that stock-based compensation expense recognized in the future will be greater than stock-based compensation expense presented in our Notes to Financial Statements on a pro forma basis for 2005, as we are no longer able to apply the minimum value method, which assumes zero volatility, but instead we calculate the fair value of our employee stock options using an estimated volatility rate. Additionally, the stock-based compensation expense recognized in the statement of operations during 2006 does not include any expense for options granted but unvested at December 31, 2005. We expect stock-based compensation expense to increase over the amount recognized during 2006 as more options are granted subject to the SFAS No. 123R guidance.

### ***Other Income, net***

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

### ***Provision for Income Taxes***

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

### ***Critical Accounting Policies and Estimates***

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



## **Table of Contents**

While our significant accounting policies are more fully described in Note 2 to our financial statements, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

### ***Revenue Recognition***

License and collaboration revenue is primarily generated through an agreement with a strategic partner for the development and commercialization of our product candidates. We may enter into additional agreements with other strategic partners as opportunities arise. The terms of such agreements may include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with Emerging Issues Task Force ( EITF ) Issue No. 00-21,

Revenue Arrangements with Multiple Deliverables , we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period. We recognize revenue in accordance with SEC Staff Accounting Bulletin ( SAB ) No. 101, Revenue Recognition in Financial Statements , as amended by SAB No. 104 (together, SAB 104 ). In accordance with SAB 104, revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured.

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

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

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

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

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

## **Table of Contents**

### ***Research and Development Costs***

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

### ***Patent Costs***

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

### ***Stock-Based Compensation***

On January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board (APB) Opinion No. 25 *Accounting for Stock Issued to Employees* and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method. The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified.

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

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

The adoption of SFAS No. 123R had a material effect on our financial position and results of operations. For the year ended December 31, 2006, we recognized an expense of \$313,000 for stock-based compensation related to employee and director stock options. See Note 8 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

### ***Income Taxes***

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

## **Table of Contents**

### **Recently Issued Accounting Pronouncements**

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ). FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. FIN 48 prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently assessing the impact of FIN 48 on our financial position and results of operations.

In September 2006, the SEC issued SAB No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements . SAB No. 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year s financial statements are materially misstated. SAB No. 108 is effective for fiscal years ending on or after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements . SFAS No. 157 establishes a framework for measuring the fair value of assets and liabilities. This framework is intended to provide increased consistency in how fair value determinations are made under various existing accounting standards which permit, or in some cases require, estimates of fair market value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including any financial statements for an interim period within that fiscal year. We are currently assessing the impact of SFAS No. 157 on our financial position and results of operations.

In September 2006, the FASB issued SFAS No. 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans . SFAS No. 158 requires that employers recognize on a prospective basis the funded status of their defined benefit pension and other postretirement benefit plans on their consolidated balance sheet and recognize as a component of other comprehensive income (loss), net of tax, the gains or losses and prior service costs or credits that arise during the period but are not recognized as components of net periodic benefit cost. The adoption of SFAS No. 158 did not have a material impact on our financial position or results of operations.

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

### **Results of Operations**

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

##### *License and Collaboration Revenue*

We recognized license and collaboration revenue of \$1.5 million for the year ended December 31, 2006. License and collaboration revenue consisted of the current period amortization of the upfront technology access fee and amounts received for the funding of research and development activities performed during the year in connection with our collaboration and license agreement with Alcon. The up-front technology access fee is expected to be amortized into revenue on a straight-line basis through August 2010.

## **Table of Contents**

### *Research and Development*

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

We expect that research and development expenses will continue to increase substantially during 2007 and in subsequent years due to our increased focus on developing product candidates, including pursuant to our agreement with Alcon.

### *General and Administrative*

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

We expect that general and administrative expenditures will increase during 2007 and in subsequent years due to increasing payroll, public company expenses, business development costs and expanding operational infrastructure.

### *Other Income, Net*

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

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

#### *Research and Development*

Research and development expense increased 32% to \$2.0 million for the year ended December 31, 2005 from \$1.5 million for the year ended December 31, 2004. This increase was due in part to an increase in research

## **Table of Contents**

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

### *General and Administrative*

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

### *Other Income, Net*

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

## **Liquidity and Capital Resources**

We have incurred cumulative net losses of \$13.1 million since inception through December 31, 2006. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the private placement of our preferred stock. We raised total net proceeds of \$647,000 through the sale of our Series A Preferred Stock in 2002 and 2003, \$3.0 million through the sale of our Series B Preferred Stock in 2003 and 2004, \$5.4 million through the sale of our Series C Preferred Stock in 2004 and 2005, and \$3.6 million through the sale of our Series D Preferred Stock in 2005 and 2006.

In August 2006, we entered into a Collaboration and License Agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of \$10.0 million in September 2006. This fee is expected to be amortized into revenue on a straight-line basis through August 2010. Additionally, we are entitled to receive semi-annual payments each January and July over the next four years to support on-going research and development efforts. In 2006, we received a payment of \$700,000 for the funding of research and development activities performed through December 31, 2006 which was recognized as revenue during 2006.

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

## **Table of Contents**

### ***Cash and Cash Equivalents***

As of December 31, 2006, we had cash, cash equivalents, and short-term investments of \$11.1 million compared to \$3.2 million at December 31, 2005 and \$4.0 million at December 31, 2004.

### ***Cash Provided by (Used in) Operating Activities***

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

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

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

### ***Cash Used in Investing Activities***

Net cash used in investing activities was \$5.5 million for the year ended December 31, 2006 due to purchases of short-term investments (net of maturities) of \$5.2 million and purchases of property and equipment of \$362,000. Net cash used in investing activities was \$1.1 million for the year ended December 31, 2005 due to the purchases of short-term investments (net of maturities) of \$1.0 million and purchases of property and equipment of \$123,000. For the year ended December 31, 2004, cash used in investing activities of \$161,000 was attributable to purchases of property and equipment.

### ***Cash Provided by Financing Activities***

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

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

We believe that the net proceeds from this offering, together with our cash balance at December 31, 2006, will be sufficient to fund our projected operating requirements through at least the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

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

future clinical trial results;

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

**Table of Contents**

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments;

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

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

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

**Table of Contents****Quarterly Results of Operations**

The following table presents unaudited quarterly results of operations for the eight quarters ended December 31, 2006. This information has been derived from our unaudited financial statements and has been prepared by us on a basis consistent with our audited annual financial statements and includes all adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the information for the periods presented.

	Mar. 31, 2005	June 30, 2005	Sept. 30, 2005	Three Months Ended				Dec. 31, 2006
				Dec. 31, 2005	Mar. 31, 2006	June 30, 2006	Sept. 30, 2006	Dec. 31, 2006
	(unaudited)							
	(in thousands, except per share data)							
<b>Statements of Operations Data:</b>								
Revenue	\$	\$	\$	\$	\$	\$	\$ 208	\$ 1,325
Operating expenses:								
Research and development	536	543	523	350	531	788	1,122	1,646
General and administrative	368	399	390	460	717	714	634	907
Total operating expenses	904	942	913	810	1,248	1,502	1,756	2,553
Other income, net	14	47	17	28	30	9	58	143
Net loss before income taxes	(890)	(895)	(896)	(782)	(1,218)	(1,493)	(1,490)	(1,085)
Provision for income taxes								
Net loss	\$ (890)	\$ (895)	\$ (896)	\$ (782)	\$ (1,218)	\$ (1,493)	\$ (1,490)	\$ (1,085)
Net loss per share:								
Basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.09)	\$ (0.08)	\$ (0.12)	\$ (0.14)	\$ (0.12)	\$ (0.09)
Shares used in per share calculations:								
Basic and diluted	9,077	9,622	10,025	10,072	10,133	10,517	12,469	12,561
Pro forma net loss per share:								
Basic and diluted					\$ (0.04)	\$ (0.05)	\$ (0.05)	\$ (0.03)
Shares used in pro forma per share calculations:								
Basic and diluted					27,684	28,740	31,466	31,788
Stock-based compensation expense included above:								
Research and development	\$ 45	\$ 10	\$	\$	\$ 15	\$ 23	\$ 22	\$ 26
General and administrative				16	21	116	90	54
Total stock-based compensation expense	\$ 45	\$ 10	\$	\$ 16	\$ 36	\$ 139	\$ 112	\$ 80

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

changes in the level of our research and developments activities;

changes in the number of our personnel;



the acquisition or loss of partnering arrangements;

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

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

**Table of Contents**

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

general economic, industry and market conditions.

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

**Net Operating Losses and Tax Credit Carryforwards**

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

**Contractual Obligations**

At December 31, 2006, we did not have any amounts outstanding under debt or credit facilities. In December 2006, we entered into a lease to finance the purchase of laboratory equipment. Under the terms of the arrangement, we will lease \$149,000 of equipment over a 36 month term. The arrangement will be accounted for as a capital lease. At December 31, 2006, we had not yet received the equipment to be leased under this arrangement and therefore, no capital asset or corresponding liability was recorded. The equipment was received in March 2007 at which time we recognized the lease obligation and began making lease payments.

Our contractual obligations as of December 31, 2006 were as follows:

	Payments Due by Period (in thousands)				
	Total	1 year	1-3 Years	3-5 Years	Greater than 5 Years
<b>Contractual Obligations:</b>					
Operating leases	\$ 1,857	\$ 474	\$ 999	\$ 384	\$
Capital lease	136	39	90	7	

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

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

**Inflation**

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

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

**Table of Contents**

**Quantitative and Qualitative Disclosures about Market Risk**

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

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

To date, we have operated exclusively in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations.

## **Table of Contents**

### **BUSINESS**

#### **Overview**

We are a biopharmaceutical company focused on developing innovative product candidates targeting the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid increase in infectious agents that have become resistant to current drugs.

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

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

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

In August 2006, we entered into a collaboration and licensing agreement with an affiliate of Alcon, Inc., a leading ophthalmic pharmaceutical company, to develop products incorporating Aganocide compounds for use in the eye, ear and sinus, as well as in contact lens solutions.

#### **Industry Background**

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

#### ***Bacterial Resistance***

Bacteria are becoming resistant to different classes of existing antibiotics at increasing rates. These increasing levels of resistance are principally the result of repeated exposure of bacteria to non-lethal quantities

## **Table of Contents**

of antibiotics and the ability of certain bacteria to transmit mutant genes to other bacterial species, thus enabling different species of bacteria to survive the antibiotic to which the first species was exposed. The growth of this antibiotic resistance since 1990 has been substantial. The following graph illustrates the growth of resistance in intensive care unit infections in the United States from 1995 to 2004:

### ***Bacterial Biofilm***

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

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

### ***Market Opportunity***

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

many current antibiotics are no longer effective in killing the growing number of resistant types of bacteria;

current antibiotics are generally ineffective in killing bacteria while they reside in biofilm; and

while most infections are localized, most current antibiotics used to treat bacterial infections are delivered systemically either orally or through injection or infusion. As a result, the entire body is exposed to the antibiotic in order to treat a local infection in what may only be in, or on, a small part of the body. Furthermore, the dosage required to treat a local infection by systemic delivery is substantially higher than would be necessary to treat the local infection, resulting in greater risk of toxicity which can cause adverse side effects or other harmful effects on the human body.

## **Table of Contents**

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

a high prevalence of disease-causing organisms,

a high prevalence of patients whose natural defenses (their immune system) are compromised because of illness or drugs,

a high prevalence of patients whose first line of defense against infection (their skin) has been breached due to injury, by surgery or through the use of catheters, and

a high risk of transmission of infection from one patient to another.

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

## **Our Solution**

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

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

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

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

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

*Treat Certain Infections that May be Viral or Bacterial in Origin.* Based on in-vitro and preliminary animal tests, we believe that our Aganocide compounds have the potential to kill not only bacteria, but also some viruses, thereby permitting immediate treatment for certain diseases where the causative agent may be a bacterium or a virus. These results will need to be confirmed in human studies.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

*Reduce Nosocomial (Hospital) Infections.* We believe that Aganocide compounds may be able to contribute to preventing the occurrence and the transmission of hospital infections in several ways. For example, we have identified several applications for use of the Aganocide compounds in the prevention

## Table of Contents

of infections that are associated with the use of invasive catheters, a major source of hospital infections. We need to develop appropriate formulations and methods of delivery in order to bring these product candidates to market.

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

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

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

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

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

We have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies; however, we will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain FDA approval of our compounds. Often, positive in-vitro or in-vivo animal studies are not followed by positive results in human clinical trials, and we may not be able to demonstrate that our products are safe and effective for indicated uses in humans. However, historic data analyzed and published by CMR International, Limited indicates that anti-infective products that enter Phase I clinical trials have a higher probability of being subsequently approved for marketing than drugs in certain other categories. This data shows that anti-infective products entering their Phase I clinical trials have a higher probability of subsequently being approved for marketing than anti-cancer or central nervous system drugs that have successfully completed Phase I and Phase II clinical trials. We believe this is the case because anti-infective drugs are designed not to act upon the human body and its cells, but to act upon microbes. For that same reason, we also believe that animal models of the treatment of infections are more predictive of the treatment of the same infections in humans than is the case in animal models of many other diseases of the human body. The bacteria used in in-vitro and in-vivo tests are the same as those found in human infections. We also believe that the microbiological end-points of clinical trials for



## **Table of Contents**

anti-infective products are clearer (i.e., eradication or substantial reduction in the counts of the number of microbes) than is the case in many other disease categories.

### **Our Strategy**

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

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

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

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

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

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

### **Potential Company Milestones**

Our current plans include the milestones indicated below. These milestones are, in whole or in part, outside our control and are subject to change. There are inherent risks and uncertainties in drug discovery and development, including those factors described in the Risk Factors section of this prospectus. Clinical trials are frequently subject to delays or cancellation because of, among other things, problems with the drug, its formulation, the trial design and the enrollment of patients. This is especially true for Phase I and II clinical trials that are designed to explore the safety and preliminary efficacy of a product at different doses and often in

**Table of Contents**

different formulations. For example, we may learn from our Phase I clinical trials that we require a different formulation which may require us to repeat some animal studies before recommencing Phase I trials; this could postpone the target endpoint significantly. One of the primary goals of Phase II trials is to determine the design, dose and formulation of a drug to be taken into Phase III trials. Because of the high cost of Phase III trials, it may be necessary to repeat a Phase II trial to ensure that these factors have been sufficiently explored to be able to move prudently into a Phase III trial.

	2007	2008
<i>Nasal Decolonization</i>	File IND	Finish Phase II Trials
	Begin Phase I Trials	Begin Phase III Trials
	Complete Phase I Trials	
	Begin Phase II Trials	
<i>Catheter Related Urinary Tract Infections</i>	File IND	Begin Phase I Trials
		Complete Phase I Trials
		Begin Phase II Trials
<i>Partnered Indications</i>	File IND	Begin Phase I
		Complete Phase I
		Begin Phase II
		File IND for second indication
<i>New Partnering Agreements</i>	Enter into one agreement	Enter into one agreement
<b>Our Products and Technology</b>		

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

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

***NVC-101 (NeutroPhase)***

The primary molecule that is created in the oxidative burst is hypochlorous acid. Hypochlorous acid is highly reactive and kills bacteria in seconds. We have explored the properties of hypochlorous acid in a variety of animal models and have established the conditions under which it can be held stable. NVC-101 is our stable formulation of hypochlorous acid. NVC-101 can only exist in a solution. NVC-101 is extremely rapid acting and is very short-lived when applied to tissue. Because of these characteristics, we have decided to focus the development of NVC-101 on rapid cleansing and debridement in wounds, including surgical wounds, chronic wounds (e.g., bed sores and diabetic foot ulcers) and possibly burn wounds where there is a continued risk of surface infection.

***NVC-422***

As the process of the oxidative burst continues, hypochlorous acid reacts with other molecules. Two molecules result from the reaction of hypochlorous acid with taurine: N-chlorotaurine (NCT) and

**Table of Contents**

N,N,-dichlorotaurine (NNDCT). Both NCT and NNDCT are antimicrobial, although NNDCT is significantly more so. However, both of these molecules are chemically unstable.

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

**Other Aganocide Compounds**

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

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

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

*Data from experiments conducted by NovaBay*

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

Although we have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies, we will need to conduct Phase I, II and III human clinical trials to confirm the safety and efficacy of the compounds. In addition, although we believe that in-vitro and in-vivo animal testing of the treatment of infections are far more predictive of the treatment of the same infections in humans than is the case for the treatment of other diseases of the human body, positive in-vitro results are often not followed by positive human tests results, and we cannot assure you that any human clinical trials we conduct will produce the same positive results that we obtained in our in-vitro and in-vivo animal studies.

**Characteristics of the NVC-101 and Aganocide Compounds**

The NVC-101 and Aganocide compounds appear to share many highly desirable characteristics that have been demonstrated in in-vitro and in-vivo animal studies. These characteristics, however, will need to be

**Table of Contents**

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

***Speed of Action***

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

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

Candida albicans 10231	Pseudomonas aeruginosa 27853
Corynebacterium amycolatum 49368	Serratia marcescens 14756
Enterobacter aerogenes 51697	Staphylococcus aureus 29213
Enterococcus faecium 51559 VRE	Staphylococcus aureus 33591, MRSA
Escherichia coli 25922	Staphylococcus epidermidis 12228
Haemophilus influenzae 49144	Staphylococcus haemolyticus 29970
Klebsiella pneumoniae 10031	Staphylococcus hominis 27844
Micrococcus luteus 7468	Staphylococcus saprophyticus 35552
Proteus mirabilis 14153	

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

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

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

**Table of Contents**

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

***Broad Spectrum, Including Against Multi-drug Resistant Species***

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

During a safety study in infected human wounds with NVC-101, there were indications of preliminary efficacy. By preliminary efficacy, we mean that there appears to have been a trend towards more rapid wound-healing when compared to subjects who received treatment with the control substance (saline). However, since this study was neither designed nor conducted with the rigor that is required in order to obtain FDA approval of a product as a drug, it should not be considered as being adequate for submission to the FDA as proof of efficacy. A full Phase I, II and III clinical program would be needed to obtain approval as a drug. The efficacy of NVC-101 was previously demonstrated in animal models of granulating wounds and diabetic wounds. By efficacy in animal models, we mean that animals treated with the test article had significantly lower levels of bacteria at the site of infection than those treated with a control product. Additionally, in the case of wound

**Table of Contents**

model studies, the test product was significantly better than the control product in increasing the speed of healing as measured by the rate of closure of the wound.

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

## **Table of Contents**

Before we can claim that our product candidates are effective against multi-drug resistant bacteria in human infections, we will have to demonstrate such efficacy in Phase I, II and III clinical trials and receive the approval of the FDA or other relevant regulatory authorities.

### ***High Therapeutic Index***

All therapeutic drugs will be toxic at some dose or concentration, resulting in adverse side effects or other harmful effects on the body. In order to assess the relative risk that may be associated with our compounds, we calculate a therapeutic index, which is the ratio of the concentration at which sensitive mammalian cells are killed compared to that at which specific bacteria are killed. A higher ratio is better, because a drug with a high therapeutic index can kill bacteria at concentrations far below those that are likely to harm human cells. Drugs with a low therapeutic index, where the difference between the level at which they are effective and the level at which they harm humans is very small, are difficult to use and require significantly more patient monitoring. Below is a chart comparing the relative safety (as measured by  $CT_{50}$  the concentration at which 50% of a standard mammalian cell line is killed) and efficacy (as measured by MBC the concentration required to kill 99.9% of bacteria in the test) of existing topical anti-bacterial products based upon data generated in experiments conducted in our own laboratories. The levels of safety and efficacy have been standardized by giving Silver Nitrate an Index Value of 1.

The chart below shows how NVC-101 and NVC-422 compare to the products in the previous graph.

## **Table of Contents**

Thus, NVC-101 demonstrates, in these in-vitro studies, greater efficacy than existing anti-bacterial products and NVC-422 has significantly less cell toxicity, which should allow its use in higher concentrations. We believe that this high therapeutic index will permit our product candidates to be used in conditions, such as in chronic wounds or other sensitive tissues, where existing antiseptics should generally not be used.

In addition to in-vitro tests against mammalian cells conducted in-house, we contracted with outside parties to conduct animal toxicity studies on our behalf and at our direction. For NVC-101, these included ocular (eye) toxicity, skin sensitization and toxicity studies on two species of animals with full-thickness wounds. For NVC-422, NovaBay and Alcon have either conducted or contracted for toxicity studies in the eye, ear and nose, as well as systemic studies using intravenous injection. NVC-422 has also been used in pharmacological studies in the bladder. Based on these studies, we believe there should be safe therapeutic doses for NVC-101 and NVC-422 that are several times greater than those required to kill target pathogens.

### ***Efficacy Against Bacterial Biofilm***

In data developed at an independent laboratory on our behalf and at our direction, NVC-422 was demonstrated to be highly effective against well established biofilm grown on urinary tract catheters.

#### *Effect of two concentrations of NVC-422 on bacteria in biofilm*

To try to reduce the amount of bacteria and biofilm in urinary tract catheters, saline (salt with water) is typically used to flush the catheter. The chart above shows that compared with this traditional method, NVC-422 is dramatically better in this in-vitro model at killing the bacteria embedded in biofilm on the catheter.

### ***Resistance Not Expected***

We do not expect that our compounds will allow bacteria to generate resistance to their action. A pharmacophore is the essential feature responsible for a drug's biological activity. In our compounds, the pharmacophore is the chlorine ion. This is the same pharmacophore produced by the neutrophil (white blood cell) during what is known as the oxidative burst.

We believe that bacteria have not been able to find a way to survive when under direct attack by the chlorine ion. Furthermore, the developed world's water supply has been protected for over a century through the use of various chemicals incorporating the chlorine ion and no known resistance to the chlorine ion has emerged despite this widespread use.



**Table of Contents*****Aganocide Compounds Are Not Systemic***

Aganocide compounds are intended for localized application targeted at the specific area of infection and not for systemic use. In contrast, most antibiotics need to reach the site of infection through the bloodstream, after direct infusion or after absorption of an oral tablet or capsule. This means that the antibiotic is being distributed throughout the whole body, whether required or not. There are a few conditions, such as bloodstream infections where that is necessary; however, the vast majority of infections are located at a specific site in or on the body, and the use of systemic drugs in these instances only serves to increase the risk of side-effects. In addition, the use of antibiotics throughout the body to target one specific species of bacteria can enable other species to develop resistance to that antibiotic.

***Aganocide Compounds Are Analogs of a Natural Molecule***

NVC-422 is a synthetic analog of a molecule, N-Chlorotaurine, that is produced by white blood cells as part of the innate immune system's defense against invading pathogens. However, unlike NVC-422, N-Chlorotaurine is unstable and undergoes a process of dehydrohalogenation, which means that it cannot be packaged and sold as a finished product ready for use. We have demonstrated the stability of NVC-422 over two years in a pharmaceutical formulation.

**Our Target Markets and Their Development Status**

We believe that the characteristics of our product candidates make them suitable for multiple target markets. The following table summarizes the primary target indications for our current and anticipated development efforts for applications we presently intend to develop with partners and those we intend to develop in-house:

**Target Indications*****Partnering Indications:***

	<b>Status</b>
Conjunctivitis (pink eye)	Licensed to Alcon
Sinus Infections	Licensed to Alcon
Ear Infections	Licensed to Alcon
Contact Lens Solutions	Licensed to Alcon
Woundcare Indications	Proof of Concept complete;
	no partner arrangement currently
Skin Infections (Dermatology)	No partner arrangement currently
Cystic Fibrosis	Initial Test of Concept in progress;
	no partner arrangement currently

***In-House Development:***

Pre-Surgery Nasal Decolonization	IND submission completed Q1 2007
Catheter Associated Urinary Tract Infections	Human Trials expected 2008
Dialysis Access Associated Infections	Human Trials expected 2008
Central Venous Catheter Infections (Prophylaxis)	Proof of Concept trials expected 2008
Ventilator Associated Pneumonia	Test of Concept expected 2008

In the above table, we refer to Test of Concept or Proof of Concept. Test of Concept refers to animal or human studies that we are performing, or intend to perform, in order to confirm that there are grounds for believing that the relevant compound may be effective in a particular indication.

Proof of Concept indicates that the test of concept work has been completed to a point at which we believe that we can present the data to potential outside partners or can make the judgment to embark on development of the indication in-house.

We plan to devote a portion of our future efforts to developing certain indications to a level at which we will have established proof of concept in appropriate animal models (or, if necessary, in humans). Once this has been



## **Table of Contents**

completed, we should then be in a position to decide whether to partner with another company for the development of the indication, continue the development ourselves or terminate it as a potential indication. We may add further indications as we increase our understanding of the properties of the Aganocide compounds.

### ***Conjunctivitis***

Conjunctivitis is the inflammation or infection of the membrane lining the eyelids, commonly known as pink eye. The most frequent cause is a viral (principally adenovirus) infection that is typically very contagious. However, conjunctivitis may also be caused by bacterial infection, among other causes. The specific cause of conjunctivitis, whether viral or bacterial, often cannot be determined without laboratory tests that are normally not conducted. According to the CDC, conjunctivitis was responsible for more than 5,000,000 visits to physicians during 2002.

Despite the availability of a number of different therapies, in many respects the treatment of conjunctivitis is an unmet medical need, as evidenced by the following:

There is currently no product available that addresses viral conjunctivitis.

Primary care physicians are rarely able to distinguish between viral and bacterial conjunctivitis, and microbiological investigations are generally not undertaken in primary care to aid in diagnosis.

The standard of care is to prescribe antibiotics for conjunctivitis, even though the majority of cases will not respond because they are viral in origin.

Conjunctivitis has a significant impact on school and workplace productivity because of the contagious nature of the disease.

### ***Potential Value of Our Approach***

Tests conducted by outside investigators indicate that an Aganocide product candidate may be the first product to address both viruses and bacteria, the two major causes of the disease.

Replacing antibiotics with an Aganocide product in this indication could contribute to a reduction in the growth of bacterial resistance to antibiotics, because much of the use of antibiotics in this indication is inappropriate.

According to a report in the *Wall Street Journal* in February 2007, the U.S. market for ophthalmic antibiotics is approximately \$600 million. Most of these products are being prescribed for conjunctivitis.

### ***Status of Our Program***

In-vivo safety of NVC-422 in the animal eye has been demonstrated.

In-vitro tests have been completed against viruses involved in conjunctivitis.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Additional pre-clinical and clinical development is being conducted by Alcon.

### ***Sinus Infections (Sinusitis)***

Sinusitis, the infection of the sinuses, is a prevalent disease. According to the CDC, 14% of adults have been diagnosed with sinusitis and approximately 31 million people in the United States suffer each year from this condition. According to the Sinus and Allergy Partnership, in one-third of the cases, the infection continues to recur. While the disease is usually bacterial in origin, it also may be viral or fungal. According to studies conducted at the University of West Virginia, published in *Laryngoscope* in 2005, biofilm was found in more than 80% of patient samples where there was a recurrent disease. According to the *American Academy of Family*

## **Table of Contents**

*Physicians*, sinusitis is the third largest market for antibiotics, although studies have shown that antibiotics are largely ineffective at preventing recurrence of this condition.

We believe that this is a significant area of unmet medical need because:

The number of patients with a recurrent form of the disease is substantial.

According to the *New England Journal of Medicine* (1996), \$5 billion was spent in the United States on conventional healthcare costs associated with treating patients with sinusitis.

We believe the current efforts to treat sinusitis are a significant contributor to bacterial resistance because of the inappropriate use of antibiotics.

### *Potential Value of Our Approach*

We have tested an Aganocide compound in an animal model of chronic sinusitis. If the results are replicated in human patients in Phase I, II and III clinical trials and the product is approved by the FDA, it may offer a more effective treatment for sinusitis than existing antibiotics because:

The Aganocide compounds appear to have action against viruses and fungi, in addition to bacteria. Consequently, it may be possible for a single Aganocide product to be used to attack three potential sources of infection in a condition where microbiological diagnosis is difficult.

Based on our studies, Aganocide compounds also appear to be effective against those bacteria that have embedded themselves in biofilm, which may also prevent acute infections from progressing to chronic infections.

We expect the use of an Aganocide compound to reduce the growth of antibiotic resistance because it could reduce the inappropriate use of systemic antibiotics.

Antibiotics generally only provide temporary symptomatic relief against chronic sinusitis, because the microbes resident in biofilm (the underlying cause of chronic sinusitis) tend to survive the antibiotic treatment and later emerge from the biofilm to restart the infection and the subsequent inflammatory response that causes pain.

### *Status of Our Program*

We have conducted preliminary tests on cats suffering from sinusitis with positive efficacy results.

A full pre-clinical and clinical program may be conducted by Alcon.

### ***Ear Infections***

Ear infections fall into one of two categories: (i) Otitis Externa, an inflammation of the outer ear, and (ii) Otitis Media, an infection of the middle ear.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

**Otitis Externa** is an inflammation of the external ear canal that causes pain and may lead to hearing loss. It can become chronic. According to eMedicine (May 2005), approximately 1.2 million people in the United States suffer from Otitis Externa every year, and the CDC estimates that approximately 5.3 million doctor visits per year in the United States are the result of Otitis Externa (2001-2002 data).

We believe that a need exists for more effective treatment of Otitis Externa because:

This disease can be caused by bacterial and fungal infections and current products do not address both causes.

According to the *American Family Physician*, 36% of patients in the United States had to cease work for a median period of four days as a result of Otitis Externa and 21% of those patients required bed-rest because of the pain.

## **Table of Contents**

### *Potential Value of Our Approach*

Our in-vitro studies suggest that our Aganocide compounds are effective against all the causative agents of Otitis Externa, including fungi.

If we can replicate the in-vitro results that we have obtained against bacteria in biofilm in human clinical trials and obtain FDA approval, an Aganocide product could be used to prevent the recurrent form of Otitis Externa by eliminating bacteria resident in biofilm and fungi.

### *Status of Our Program*

We have conducted preliminary studies in dogs with Otitis Externa with indications of efficacy.

This program is now being conducted by Alcon.

**Otitis Media** is an infection of the middle ear, which is particularly prevalent in young children. We believe that an Aganocide product, if approved by the FDA after Phase I, II and III clinical trials, might play a potentially important role in treating this disease. A recently published study in the *Journal of the American Medical Association* has indicated that this disease is associated with biofilm. As a consequence, the CDC is urging more limited use of antibiotics to treat this disease.

### *Potential Value of Our Approach*

Current antibiotics are ineffective against this painful condition.

90% of pre-school children experience at least one incidence of Otitis Media.

30-40% of children have recurrent attacks.

The Aganocide compounds may prevent the recurrent form of Otitis Media by eliminating bacteria resident in biofilm and fungi.

### *Status of Our Program*

The Otitis Media indication has been licensed to Alcon.

### ***Contact Lens Solutions***

We believe there is increasing consumer concern regarding the adequacy of contact lens solutions to provide adequate disinfection of certain microorganisms. We have partnered with Alcon to develop Aganocide compounds for use in disinfecting solutions to offer contact lens users better protection from microorganisms than existing alternatives provide. According to the *Wall Street Journal*, more than 30 million people in the U.S. use contact lenses that require disinfecting solutions.

### *Potential Value of Our Approach*

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

We believe that Aganocide compounds have the potential to protect contact lens users from microorganisms better than existing alternatives because:

Aganocide compounds have a broad spectrum of activity against bacteria, yeasts and fungi.

Aganocide compounds may have the ability to destroy organisms that can form biofilm on contact lenses and in the storage cases in which they are kept.

Infections that result from the failure of contact lens solutions to provide adequate disinfection can be devastating. The *Journal of the American Medical Association* reported in August 2006 that one-third of individuals infected as a result of a disinfection failure require corneal transplants.



## **Table of Contents**

### *Status of Our Program*

We are actively engaged in identifying suitable molecules in our collaboration with Alcon.

Alcon intends to conduct formulation development and testing.

### ***Woundcare Indications***

According to the Agency for Healthcare Research and Quality, five to seven million people in the United States suffer each year from chronic wounds, such as diabetic foot ulcers, venous ulcers and pressure ulcers (bed sores). We believe that there are many more who suffer from wounds in accidents and as a consequence of surgery. According to the Agency for Healthcare Research and Quality, in 2004, burns were noted as a diagnosis in 52,400 hospital stays in the United States.

We believe that this is a significant area of unmet medical need because:

Open wounds are particularly susceptible to infection.

U.S. Public Health Service Guidelines strongly recommend against the use of existing topical disinfectants because they interfere with wound healing.

Chronic wounds are associated with aging, and we expect the number of patients with chronic wounds to increase as a result of a growing aging population in the developed world.

The number of patients with diabetes who will develop diabetic foot ulcers is expected to grow. According to the *New England Journal of Medicine* (January 2007), 312 million people in the world are now considered obese and that, consequently, diabetes is rapidly emerging as a global healthcare problem that threatens to reach pandemic levels. According to eMedicine (updated 2004), 15% of persons with diabetes develop foot ulcers.

### *Potential Value of Our Approach*

There is a need for products that can be used safely to reduce and control the growth of bacteria in chronic wounds.

Our compounds appear to be safe in animal studies of wounds and, in the case of NVC-101, in preliminary human studies on patients with chronic wounds.

Studies, that we supported financially, were conducted by the Institute of Tissue Regeneration, Repair and Rehabilitation, Florida on a wounded rat model. Such studies suggest that:

NVC-422 is effective in reducing infection to levels that are compatible with wound healing.

NVC-422 has a positive impact on the rate at which wounds heal.



**Table of Contents**

*Time taken for wounds to heal when treated with saline and two concentrations of NVC-422*

*Status of Our Program*

We have conducted animal studies for safety and efficacy in this area, which showed the safety and efficacy of NVC-101 and NVC-422 in animal models.

We have conducted animal toxicology studies of NVC-101 in wounds and have submitted the data to the FDA.

We have conducted human safety studies of a formulation of NVC-101 under the approval of the Institutional Review Board at San Francisco Wound Center, with no adverse events attributed to the drug by the investigator.

We have conducted limited exploratory studies of NVC-101 under an IND with no adverse events attributable by the investigators to the product candidate.

We have submitted a 510(k) premarketing application with the FDA to clear NVC-101 as a wound cleansing solution with antimicrobial attributes under the medical device regulations.

We are exploring partnership opportunities with leading companies in the woundcare market.

***Dermatology***

In *The Burden of Skin Diseases* (2005), The Lewin Group reported that, in 2003, the cost of prescription drugs used in dermatological indications, in which we believe our product candidates would have applicability, was \$3.9 billion. According to *Postgraduate Medicine* (1997), some specialists in Europe and New Zealand have called for a moratorium on the use of topical antibiotics to prevent the spread of resistance. This is echoed by the increasing call by public authorities such as the CDC and state consumer education organizations for more restrictive use of antibiotics.

***Potential Value of Our Approach***

The concern regarding resistance to dermatological antibiotics is causing regulatory authorities to pressure doctors to reduce the number of prescriptions of antibiotics in mild indications. This has had a significant impact on the sale of dermatological antibiotics, especially in Europe. We believe that our Aganocide compounds

## **Table of Contents**

may be able to treat many dermatological conditions without contributing to increased bacterial resistance. We believe that the in-vivo work conducted in animals to date indicates that our Aganocide compounds are safe for use in dermatological conditions, because it has been shown to be non-irritating in more sensitive tissues.

### *Status of Our Program*

We are conducting preliminary formulation experiments to create a suitable cream, ointment or gel.

We are exploring partnership opportunities in this market.

### ***Cystic Fibrosis***

Cystic fibrosis is a genetic disorder that causes a build-up of bacterial biofilm in the lungs of those affected. The early death of persons with cystic fibrosis is usually due to infections caused by Pseudomonas bacteria associated with biofilm. The primary antibiotic used to treat this condition is TOBI® -tobramycin. According to Chiron Corporation, sales of TOBI® were \$233 million in 2005. Studies indicate that resistance to tobramycin is becoming a significant problem. Acta Physiologica reported in 2006 that 26 of 29 cystic fibrosis patients in a study developed pseudomonas infections with resistance to inhaled tobramycin and that higher levels of resistance were correlated to significantly greater loss of lung function.

### *Potential Value of Our Approach*

Our in-vitro studies indicate that Aganocide compounds are effective against bacteria in biofilm and, for that reason, we believe that, if a suitable formulation and delivery means can be developed and its safety and efficacy can be demonstrated in Phase I, II and III clinical trials to the satisfaction of the FDA, NVC-422 may be effective against pseudomonas in biofilm in Cystic Fibrosis.

We do not expect that Aganocide compounds, which we believe will be delivered locally by inhalation, will give rise to the problems associated with systemic toxicity relating to current treatments. Our studies in animals indicate that Aganocide compounds are minimally absorbed, if at all.

Unlike current treatments, we do not expect, based on our understanding of the mechanisms of bacterial resistance, that NVC-422 would generate resistance from pseudomonas bacteria.

### *Status of our Program*

We have begun external in-vitro studies and in-vivo studies in animals to see if the Aganocide compounds can play a role in this indication.

We have begun working with external investigators to conduct in-vitro work with sputum from patients with cystic fibrosis.

We are beginning in-vivo studies in a cystic fibrosis animal model.

### ***Pre-Surgery Nasal Decolonization***

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Pre-surgery nasal decolonization involves the treatment of the nasal passages to eliminate potentially harmful bacteria, especially Staph. aureus, prior to surgery in order to reduce the number of surgical site infections. According to the Pennsylvania Health Care Cost Containment Agency, over 1.2% of hospital patients acquired a nosocomial infection in Pennsylvania in 2005. Of those patients that acquired a nosocomial infection 13% died. Of those that did not acquire a nosocomial infection, only 2.3% died. That study indicated that the average additional cost of treating a patient that contracted an infection may have been over \$150,000 per patient.

## **Table of Contents**

According to the Guideline for Prevention of Surgical Site Infection, published by the CDC in 1999, approximately 500,000 patients in the United States suffer from infections contracted during surgery. There are approximately 27,000,000 surgical procedures conducted each year in the United States according to this Guideline. Studies conducted in Germany and reported in January 2001 in the *New England Journal of Medicine* indicate that of 219 patients that developed bloodstream Staph. aureus infections following surgery, the causative agent in 180 of them was the genetically identical strain of Staph. aureus to that which each had in their own nasal passages.

Any form of infection with Staph. aureus results in a prolonged hospital stay, but that stay is even longer when the infection is caused by the resistant strain Methicillin Resistant Staph. aureus or MRSA. According to a study in *Emerging Infectious Diseases* (2004), hospital costs were approximately \$120,000 for those with MRSA surgical site infections, \$75,000 for those with a non-resistant Staph. aureus infection in their surgical site and \$35,000 for those that did not have a surgical site infection.

We believe that this is a significant area of unmet medical need because:

The current means of nasal decolonization is very difficult to integrate into current hospital practice as it involves screening for the Staph. aureus bacteria, isolating patients who are carriers of that bacteria and treating them for approximately five days with nasal mupirocin (Bactroban®) antibiotic.

Resistance to mupirocin, an antibiotic commonly used in nasal decolonization, is rising significantly and therefore treatment of this disease with mupirocin may no longer be tenable in the near future. In a retrospective study at the Mayo Clinic published in the *Journal of Clinical Microbiology* in August 2005, 27% of those patients with MRSA prosthetic joint infections after surgery were mupirocin resistant.

Several European countries have accepted nasal decolonization of patients as a common pre-surgical practice for non-emergency surgery.

### *Potential Value of Our Approach*

AgaNase, our formulation of the Aganocide compound, NVC-422, as a nasal spray or swab, is being developed for nasal decolonization of Staph. aureus.

We believe, based on our in-vitro studies, that NVC-422 is effective against both resistant and non-resistant strains of Staph. aureus.

NVC-422 is highly effective against Staph. aureus, killing that bacteria in under a minute in our tests at doses significantly below the anticipated level at which it will be administered in humans.

We believe that it may be possible to adequately decolonize the nasal passages before any surgery using nasal sprays of AgaNase administered over a one hour period.

### *Status of Our Program*

We have completed all pre-clinical studies and submitted an IND for this indication to the FDA in March 2007.

We have contracted for the conduct of Phase I clinical trials that we expect to begin in the second quarter of 2007.

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

We are preparing for the conduct of Phase II clinical trials that we expect to start in Europe in late 2007 or early 2008.

## **Table of Contents**

### ***Catheter Associated Urinary Tract Infections***

Kalorama International forecasts that the number of urinary tract catheters that will be used worldwide in 2007 is expected to be 207 million. According to the CDC (Emerging Infectious Diseases, 2001) more than 5 million patients use urinary tract catheters in U.S. acute-care hospitals and extended care facilities. The risk of infections with short-term usage of urinary tract catheters is 5% per day according to the CDC. More than 40% of all nosocomial infections occur as a result of the use of urinary tract catheters. According to the CDC, catheter associated urinary tract infections comprise one of the largest institutional reservoirs of nosocomial antibiotic-resistant pathogens. In experiments conducted at the Center for Biofilm Engineering, Montana State University during 2005 and 2006, it was demonstrated in-vitro that NVC-422 can destroy the bacteria resident in biofilm on urinary tract catheters.

#### ***Potential Value of Our Approach***

With bacterial biofilm being a major cause of catheter associated urinary tract infection, we expect that the use of an Aganocide solution could have a significant benefit in preventing these infections.

#### ***Status of our Program***

We have conducted preliminary pharmacology studies in the human bladder with no signs of toxicity at doses significantly above the anticipated level at which the compound will be administered to humans.

Studies at the Center for Biofilm Engineering demonstrated that, in an in-vitro model of urinary tract catheters and artificial urine, a 99.9999% reduction in bacteria resident in biofilm per square centimeter of urinary catheter could be achieved using NVC-422.

We are planning the formal toxicity studies needed to proceed to human trials with the intent of filing an IND for this indication in the fourth quarter of 2007.

We expect to begin human trials in 2008.

### ***Dialysis Access Associated Infections***

According to an article in *Nephrology, Dialysis, Transplantation* (June 2005), 22% of dialysis patients in the United States were hospitalized because of infections related to implanted access lines and 58% of dialysis patients hospitalized for infection had a severe outcome (defined as death, a stay in intensive care unit or prolonged hospitalization). It has been demonstrated through an analysis of several published studies that effective nasal decolonization significantly reduces the rate of infection. In addition, we will be examining the use of a lock solution to protect the dialysis access line from the growth of bacterial biofilm.

#### ***Potential Value of Our Approach***

We expect that the use of either an access lock solution or nasal decolonization containing NVC-422 could contribute to a reduction in the infection rates among the dialysis population. A combination of both approaches might have added benefit.

#### ***Status of our Program***

We are currently planning the toxicity studies that will be required to support the use of an access lock solution.



## **Table of Contents**

### ***Central Venous Catheter (CVC) Infections (Prophylaxis)***

The use of catheters to deliver medications and to readily obtain access to the circulatory system has become the norm in modern hospital care. Unfortunately, they penetrate the primary defense against infection the skin and serve as a conduit for bacteria to invade the human body. According to *Infections in Medicine*, 2004, approximately 5 million CVCs are used in the United States each year. Although intravascular catheters are indispensable in contemporary medical practice, their increased use over the past 20 years has been associated with at least a doubling of resultant CVC-associated blood-stream infections. Each year in the United States, approximately 80,000 CVC-associated bloodstream infections occur in patients in intensive care units and up to 250,000 occur throughout the health care system. These infections are associated with significant morbidity and prolongation of hospital stay. In intensive care units patients, the attributable cost of care is estimated to be from \$34,508 to \$56,000 per episode. These bloodstream infections are serious and are frequently caused by resistant bacteria.

#### *Potential Value of Our Approach*

We are developing a formulation of NVC-422 as a catheter lock solution. A catheter lock solution is injected into the catheter after each delivery of medicine or withdrawal of a blood sample in order to keep the catheter open and filled with solution. Currently, heparin solutions are frequently used for this purpose.

Heparin solutions, while effective at keeping the catheter line open, facilitate the growth of bacteria because heparin is a nutritional product for bacteria. Our tests indicate that the use of an Aganocide solution will eliminate this problem by killing the bacteria.

Bacteria typically form biofilm on the interior surface of the catheter and are very difficult to clear. Frequent replacement of the catheters is expensive and difficult as it requires the use of X-rays to ensure that the catheter is correctly placed. We have demonstrated, in-vitro, that NVC-422 can significantly reduce the number of bacteria present in biofilm on catheters.

#### *Status of Our Program*

We have established in 28 day peripheral intravenous animal toxicity studies the concentration of NVC-422 at which there are no adverse effects in the animal model. We will use that concentration as a guide to appropriate dosing in humans. Before proceeding to file an IND to permit human studies, we will need to conduct further pharmacology and toxicology studies in order to establish the concentration of NVC-422 that is expected to be without toxicity when delivered close to the entrance to the heart.

### ***Ventilator Associated Pneumonia***

Patients who require the assistance of a mechanical ventilator to support their breathing are at a high risk of infection. Biofilm can form in their ventilator breathing tube and can then become an on-going source of infection. Ventilator associated pneumonia accounted for 27% of all infections in hospital intensive care units according to the Guidelines for Preventing Health-Care-Associated Pneumonia, issued by the CDC in 2003.

#### *Potential Value of Our Approach*

Because of the biofilm-related nature of the cause of the infection, we believe that a solution containing an Aganocide compound has the potential to prevent the formation of biofilm and eliminate the reservoir of infection in ventilator tubes.

#### *Status of our Program*

This currently is a conceptual program. We have no data at this time to support safe usage in the lungs, although we expect to be able to evaluate lung toxicity as a result of our cystic fibrosis studies.

## **Table of Contents**

### **Alcon Collaboration Agreement**

In June 2005, we initiated our collaboration with Alcon and its affiliates and agreed to supply compounds and products exclusively to them for use in the eye, ear and sinus. Alcon and its affiliates undertook to evaluate our compounds for use in the eye, ear and sinus and to provide us with reports on their findings. The evaluation process continued and in August 2006, we entered into a License and Collaboration Agreement with Alcon. Under the Alcon agreement, we have 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 (including contact lens solutions), ear and paranasal sinus (excluding the nares).

Pursuant to the Alcon agreement, we received payment from Alcon of a non-refundable technology access fee of \$10.0 million in September 2006. In addition to the technology access fee, we are entitled to payments from Alcon on a semi-annual basis in connection with the 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. The amount of such payments will depend upon the number of persons dedicated by NovaBay to supporting the research program agreed with Alcon. In addition, if certain milestones are achieved in connection with the development of a product, we are entitled to receive certain milestone payments for the first achievement of each such milestone for a licensed product in each field of use (eye, ear or sinus), which vary in amount depending on the field of use and on the type of milestone event achieved. These milestone events relate to the stage of development of the applicable product. The aggregate milestone payments payable in connection with the ophthalmic, otic and sinus fields are \$19 million, \$12 million and \$39 million, respectively. Finally, if products developed under the Alcon agreement are commercialized, we will 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. Alcon is responsible for all the costs that it occurs in developing the products using the Aganocide compounds. We have not achieved any milestones nor has any product been commercialized to date. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized product.

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

Alcon has the right to terminate the Alcon agreement in whole on nine months' prior notice to us or on 135 days notice with respect to specific fields of use where the Coordination Committee (a committee formed under the Alcon agreement and consisting of members from Alcon and NovaBay) determines that it is unlikely that any product will obtain regulatory market approval or be a commercial success in any major market in such field of use.

### **Research and Development**

As of March 31, 2007, we had 24 employees dedicated to research and development. Our research and development expenses consist primarily of personnel-related expenses, laboratory supplies and services provided within our research, development and clinical groups. We expense our research and development expenses as they are incurred. Research and development expenses for 2004, 2005, and 2006 were \$1.5 million, \$2.0 million

## **Table of Contents**

and \$4.1 million, respectively. All of our research and development employees are engaged in drug research and development activities, including those related to the Alcon agreement described above. We expect to incur significant research and development expenses for the foreseeable future.

### **Intellectual Property**

We rely on a combination of patent, trademark, copyright and trade secret laws in the United States and other jurisdictions, as well as confidentiality procedures and contractual provisions, to protect our proprietary technology. We also enter into confidentiality and invention assignment agreements with our employees and consultants and confidentiality agreements with other third parties, and we rigorously control access to our proprietary technology.

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 issued U.S. patent provides coverage for a method of treating burns or promoting wound healing, tissue repair or tissue regeneration using a specific range of formulations of NVC-101. This patent was issued in July 30, 2002 and will expire in 2020. 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 U.S. patent application covering the Aganocide compounds will, if granted, expire in 2024, with additional compounds covered by further patent applications that, if granted, would expire in 2025.

### **Competition**

The market for drugs and medical devices designed to treat or prevent bacterial infections is highly competitive. If developed, our products would compete against a wide variety of existing products, products and technologies that are currently in development, and products and technologies that could be developed and reach the market before or after any products that we develop may be introduced. In particular, we would be competing against existing antibiotics that are sold by many major pharmaceutical companies, or generic equivalents that are being distributed, typically at low prices.

Our potential competitors include large and small pharmaceuticals and medical device companies, such as Pfizer, Inc., Johnson & Johnson, Abbot Grp. Plc., GlaxoSmithKline Plc, Sanofi-Aventis SA, Smith & Nephew Plc, and Novartis AG. Some of these competitors may have far greater resources and experience in the area than we do and may develop and patent processes or products earlier than we are able to, 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 are able to, and improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

These healthcare companies may develop and commercialize competitive products such as:

improved antibiotics that better treat infections and address the shortcomings of current treatments;

biofilm-related products including: products that inhibit the creation of biofilm, such as drugs and catheter-lock solutions; products that destroy biofilm (as opposed to the bacteria within the biofilm); products that are applied to medical devices to inhibit biofilm formation; and products that remove biofilm from medical devices;

## **Table of Contents**

products based on new compounds with attributes similar to Aganocide compounds;

improved antiseptic products with applications similar to certain uses of products that we intend to develop;

products for wound cleansing and debridement (the removal of tissue that is dead or infected) and similar products; and

antimicrobial catheters and dressings that contain silver or other antimicrobial compounds.

According to *Commercial Insights: Antibacterials* (December 2006) published by Datamonitor, there were five new unlaunched antibiotics in Phase III studies or awaiting approval by the FDA. All of these antibiotics are being targeted at hospital acquired infections, especially MRSA. However, they are all products that would be delivered by injection after an infection has been identified. One company is also attempting to extend the use of photodynamic therapy, which is used primarily for periodontal disease, into nasal decolonization of MRSA. The technology requires that the area to be decontaminated should be soaked with a solution and then the solution has to be activated by the use of a laser device, and does not appear to have been readily accepted for use for indications different than its current use. Other companies are believed to be developing compounds that disrupt biofilms or the formation of biofilm. We are aware that one company has announced that it expects to begin Phase I trials in 2010 for the use of a derivative of an existing drug against bacteria in biofilm.

NeutroPhase, if launched for use in wound management, will be competing against multiple products with similar indications for use. However, we believe there is currently no dominant product in this indication.

We believe the principal competitive factors for products in our target markets include their effectiveness in killing bacteria, including bacteria in biofilm, time to kill bacteria, safety, side effects and cost effectiveness. We believe that our compounds may, if approved by the regulatory authorities, have significant advantages over existing compounds and compounds in development of which we are aware, because our Aganocide and NVC- 101 compounds could be used to prevent infections or to treat infections where speed of action, action against bacteria in biofilm, action in topical indications or action against multi-drug resistant bacteria is important.

However, 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.

## **Manufacturing and Supply**

We do not currently operate manufacturing facilities for clinical or commercial production, as we rely on and leverage the manufacturing and distribution infrastructure of third parties. We have no plans to establish our own manufacturing facilities in the future. Third party vendors supply us with the Active Pharmaceutical Ingredient (API) of NVC-422 and the finished clinical trials materials for NVC-101, which are manufactured in compliance with the FDA's Current Good Manufacturing Practice, or CGMP, regulations. We also intend to work with third parties for future clinical trial materials and commercial supplies of NVC-422.

The Alcon Agreement provides for the manufacture by Alcon of finished dosage forms of products incorporating Aganocide compounds for sale under our label in those markets where we have retained marketing rights.

## **Sales and Marketing**

Our lead product candidate, NVC-422, as well as many of the product candidates we expect to develop in the future, are intended to address a variety of different market segments, some of which are large, primary care

## **Table of Contents**

markets. We do not currently have, nor do we intend in the near term to create, a commercialization organization capable of marketing, selling and distributing our targeted product candidates to large, primary care markets. This applies to markets in both the United States and elsewhere. Rather, we intend to establish commercialization partnerships with pharmaceutical, biotechnology or other leading organizations with the experience and resources to bring our products to market. In some cases, we may enter into agreements with these organizations during the development stage of a product candidate to further benefit from their clinical development, regulatory, market research, pre-marketing and other expertise, as is the case with Alcon. As appropriate, we may establish a specialty sales force with expertise in marketing and selling any future approved products to specialty physicians for specific target indications. We may also establish other complementary capabilities related to marketing and selling targeted medicines, particularly where those capabilities may not currently exist at other organizations.

### **Government Regulation**

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in state and local jurisdictions in the U.S. and in other countries. Because our programs involve product candidates that are considered as medical devices and others that are drugs, we intend to submit applications to regulatory agencies for approval or clearance of both medical devices and pharmaceutical product candidates.

#### ***U.S. Government Regulation***

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

Our products may be classified by the FDA as a drug or a medical device depending upon the indications for use or claims. We believe the use of NVC-101 as a solution for cleansing and debriding wounds would be considered as a medical device. Similarly, NVC-422 may be classified as a medical device depending on the indication for use. For example, we believe if the indication is for bladder lavage, 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. In addition, the determination as to whether a particular indication is considered a drug or a device is based in part upon prior precedent.

#### ***Drug Approval Process***

The process required by the FDA before a drug may be marketed in the United States generally involves satisfactorily completing each of the following:

preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;

submission to the FDA of a New Drug Application, or NDA;

## **Table of Contents**

satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third-parties, at which the product is produced to assess compliance with strictly enforced current GMP regulations; and

FDA review and approval of the NDA before any commercial marketing, sale or shipment of the product.

### *Preclinical Studies and IND Application*

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin. Submission of an IND may result in the FDA not allowing the trials to commence or not allowing the trial to commence on the terms originally specified in the IND.

### *Clinical Trials*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. An independent Institutional Review Board, or IRB must also review and approve the clinical trial before it can begin and the IRB must monitor the study until it is completed. The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice requirements and the requirements for informed consent.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

Phase I studies are initially conducted with relatively few subjects to test the drug candidate for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. Such studies are conducted in healthy humans, or, on occasion, in patients.

Phase II studies are generally controlled clinical trials conducted with a relatively small number of subjects to:

evaluate dosage tolerance and appropriate dosage;

identify possible adverse effects and safety risks; and

evaluate, preliminarily, the efficacy of the drug for specific indications in patients with the disease or condition under study.

Phase III studies, commonly referred to as pivotal studies are undertaken with large numbers of patients (several hundred to several thousand) to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

Phase IV post-approval studies, to further assess the drug's safety and effectiveness, are sometimes required by the FDA as a condition of approval.

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Our clinical trials may not proceed in this order for each indication. In addition our Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all.

## **Table of Contents**

### *New Drug Application*

The results of our preclinical testing and clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the product, will be submitted to the FDA in the form of an NDA requesting approval to market the product for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use.

If the NDA submission is accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA or it may require additional clinical data, including additional Phase III clinical trial or trials. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials is not always conclusive and the FDA may interpret data differently than we interpret data. Even after the FDA initially approves an NDA, the FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the drug reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, risk minimization action plans, and surveillance programs to monitor the effect of approved products, which have been commercialized. The FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-marketing programs.

Certain changes to an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Before approving an application, the FDA will inspect the facility or the facilities, including third-party facilities where the drug is manufactured, for compliance with current good manufacturing practice, or CGMPs. The FDA may also inspect the clinical sites at which the trials were conducted to assess their compliance with good clinical practice requirements. If the FDA concludes that the application demonstrates that the product is safe and effective for the proposed indication, and that the manufacturing process and the manufacturing facilities meet CGMPs, the FDA will issue an approval letter. If the FDA concludes that the application, manufacturing process or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide to not approve the application.

### *Post Approval*

If regulatory approval of a product or new indication for an existing product is obtained, we will be required to comply with a number of post-approval requirements. We will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling requirements. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including CGMP regulations, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, we and our third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with CGMP regulations and other regulatory requirements.



## **Table of Contents**

### ***Medical Devices***

We expect some of our products to be regulated as medical devices. Unless an exception applies, each medical device we wish to commercialize in the United States will require either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval.

#### *510(k)*

When a 510(k) clearance is required, we must submit a premarket notification demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution. The evidence required to prove substantial equivalence varies with the risk posed by the device and its complexity. By regulation, the FDA is required to complete its review of a 510(k) within 90 days of submission of the notification. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous pre-marketing requirements, known as pre-market approval (see discussion below).

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, will require a new 510(k) clearance or could require a Pre-Market Approval application, or PMA approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or a PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

#### *Pre-Market Approval*

If an applicant is unable to demonstrate that a product candidate is substantially equivalent to a marketed device, the FDA will require the submission and approval of a PMA application before marketing of the product. The FDA will approve a PMA only if the applicant provides the FDA with a reasonable assurance that the product is safe and effective when used in accordance with its proposed labeling. The PMA review process includes analysis of manufacturing processes, inspection of manufacturing facilities, and a comprehensive review of pre-market data.

A PMA application must be supported by extensive data, including data from preclinical studies and human clinical trials, and must contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling.

After the FDA determines that a PMA application is sufficiently complete to permit a substantive review, the FDA will file the application and begin an in-depth review. The FDA, by statute, has 180 days to review a PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the

## **Table of Contents**

approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the FDA's Quality System Regulations. New PMA applications or supplemental PMA applications are required for significant modifications to the manufacturing process, labeling, intended use and design of a device that is approved through the pre-market approval process. Pre-market approval supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

### *Clinical Trials*

A clinical trial is almost always required to support a PMA application and, to a much lesser extent, to support a 510(k) pre-market notification. When FDA approval of a device requires human clinical trials, and if the clinical trial presents a significant risk to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the IRB, overseeing the clinical trial. If the product is deemed a non-significant risk device, FDA approval is not required, but informed consent and approval from the IRB overseeing the clinical trial is required. Clinical trials are subject to extensive recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB at the relevant clinical trials site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice, or GCP, requirements. The applicant, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. The results of clinical testing may not be sufficient to obtain approval of a product.

### *Our Device Candidates*

In April 2007, we submitted a 510(k) premarket notification for NeutroPhase for wound irrigation and other possible uses. In addition, we believe any medical device coated with NVC-422 or any other Aganocide compound will be regulated as a class III device and will require a PMA submission. We also believe that certain uses of a solution containing NVC-422 may be classified as a medical device.

### ***Continuing Food and Drug Administration Regulation of Medical Devices***

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

the FDA's Quality Systems Regulations, or QSRs, which require manufacturers to follow stringent design, testing, production, control, labeling, packaging, storage, shipping, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations which impose restrictions on labeling and promotional activities, and FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses;

post-market surveillance requirements which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

the FDA Medical Device Reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

notices of correction or removal, and recall regulations.



## **Table of Contents**

In addition, we will be required to register our facility and list our products with the FDA, and we will be subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services to determine compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors. We have never undergone a regulatory inspection and cannot assure you we will pass such an inspection in the future.

### ***Promotional Issues***

Physicians may prescribe legally available drugs or devices for an indication that has not been approved by the FDA a so-called off-label use. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA and other governmental agencies do, however, restrict communications on the subject of off-label use by a manufacturer or those acting on behalf of a manufacturer. Companies may not promote FDA-approved drugs or devices for off-label uses. The FDA and other governmental agencies actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained.

### ***International Regulation***

In addition to being subject to the laws and regulations in the United States, we will be subject to a variety of laws and regulations in those other countries in which we seek to study and commercialize products. European and Canadian regulatory requirements and approval processes are similar in principle to those in the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of the European Union, European countries, Canada and other countries before we can commence clinical trials or marketing of the product in those respective countries. The approval process may be longer or shorter than that required for FDA approval. The requirements governing pricing, reimbursement, clinical trials, and to a lesser extent, product licensing vary from country to country.

In the European Union, there are two ways that a company can obtain multi-state marketing authorization for a pharmaceutical product. The first route is the centralized procedure. This procedure is compulsory for certain pharmaceutical products, in particular pharmaceutical products derived from biotechnology, but is also available for pharmaceutical products containing a new active substance or whose applications constitute a significant innovation. Under this procedure the applicant nominates a rapporteur, who is the co-coordinator for the evaluation of an application for marketing authorization, and co-rapporteur. A marketing authorization granted under the centralized procedure is valid in all Member States of the European Union. The second route to obtain marketing authorization in the European Union is the mutual recognition procedure. Application is made in all the Member States in which the marketing of the product is sought but the applicant chooses one Member State to act as the reference Member State and to prepare an assessment report. Within 90 days of receipt of such report, each Member State applied to may object to the approval if it believes the product raises a potential serious risk to public health. If the Member States do not reach an agreement on whether the approval should be granted or rejected, the matter is referred to the European Union relevant authority whose opinion is then forwarded to the European Commission. The European Commission makes the ultimate decision, which in most cases follows the European Union relevant authority's opinion.

To obtain marketing approval in Canada, we must provide Canada's Therapeutic Products Directorate with clinical data that demonstrates safety and efficacy for the new indications in humans. The data is provided in a new drug submission or in a supplemental new drug submission. We cannot market an Aganocide product for new indications in Canada until a supplemental new drug submission is approved by the Therapeutic Products Directorate. If the Therapeutic Products Directorate approves a supplemental new drug submission, the Therapeutic Products Directorate issues a marketing approval, known as a notice of compliance, for the new indications.

## **Table of Contents**

### ***Third Party Reimbursement and Pricing Controls***

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Aganocide products from which we may receive revenue in the future may not be considered cost-effective, and reimbursement may not be available or sufficient to allow these products to be sold on a competitive and profitable basis.

In many foreign markets, including Canada and the countries in the European Union, pricing of some pharmaceutical products, in particular reimbursed products, is subject to governmental control. In the European Union, a product must receive specific country pricing approval in order to be reimbursed in that country. The pricing approval in the Member States of the European Union can take many months, and, in certain circumstances, sometimes years, to obtain. In Canada, pricing of patented medicines must be approved by the Patented Medicine Prices Review Board. In addition, the provincial governments have the authority to assess the reimbursement status, if any, and the price at which they will reimburse newly approved drugs, pharmaceutical products and pharmaceutical product indications. Obtaining price approval from the Patented Medicine Prices Review Board and reimbursement status and price level from provincial governments can take six to twelve months or longer after the receipt of the notice of compliance.

In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. The adoption of such proposals could harm our business and financial condition.

### ***Anti-Kickback and False Claims Laws***

In the United States, we are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. The federal Anti-Kickback Law makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, offer, receive or pay any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, order or prescription of a particular drug or device, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. The federal government has issued regulations, commonly known as safe harbors that set forth certain provisions which, if fully met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Law. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Law, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Law will be pursued. Violations of the law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Law. Some of these state prohibitions apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs. Due to the breadth of these laws, it is possible that our future sales and marketing practices or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us.

False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for payment to third party payors (including Medicare and Medicaid) claims for reimbursed items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of Medicaid rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products, will be subject to scrutiny under these laws. In addition, pharmaceutical companies have been prosecuted under the federal False

## **Table of Contents**

Claims Act in connection with their off-label promotion of drugs. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals (known as relators or, more commonly, as whistleblowers) may share in the amounts paid by the entity to the government in fines or settlement.

Penalties for a violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim. In addition, certain states have enacted laws modeled after the federal False Claims Act. If the U.S. government were to allege that we were or our partners were, or convict us or our partners of, violating these false claims laws, we could be harmed, and suffer a decline in our stock price.

## **Employees**

As of March 31, 2007, we had 32 full-time employees, including 14 with doctoral degrees. Of our full time workforce, 24 employees are engaged in research and development, and 8 in finance and administration. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## **Facilities**

Our principal executive offices and our research and development and administrative operations are located in an approximately 11,000 square foot research, development, and administrative facility located in Emeryville, California and in an adjacent facility consisting of approximately 2,600 square feet that we recently leased to accommodate our operations. We have leased our primary facility until October 31, 2009 and the adjacent facility until December 31, 2011. We may seek to expand our facilities to meet our operational requirements within the next twelve months.

## **Legal Proceedings**

We are currently not a party to, nor is our property the subject matter of, any pending or, to our knowledge, contemplated material legal proceedings. From time to time, we may become party to litigation and subject to claims arising in the ordinary course of our business.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table provides information with respect to our directors and executive officers as of March 31, 2007.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>	<b>Municipality of Residence</b>
Ramin ( Ron ) Najafi, Ph.D.	48	Chairman of the Board, Chief Executive Officer and President	Novato, CA; Marin County
John ( Jack ) O Reilly	64	Senior Vice President, Corporate Development, Chief Financial Officer, Treasurer and Director	Palo Alto, CA; Santa Clara County
Behzad Khosrovi, Ph.D.	63	Vice President, Research and Development	El Cerrito, CA; Contra Costa County
Colin Scott, MB, Ch.B.	55	Vice President, Clinical Research and Development	Discovery Bay, CA; Contra Costa County
Charles J. Cashion(1)*	56	Director	San Diego, CA; San Diego County
Anthony Dailley, D.D.S.(2)*	51	Director	Mill Valley, CA; Marin County
Paul E. Freiman(1)(2)(3)*	72	Director	San Francisco, CA; San Francisco County
T. Alex McPherson, M.D., Ph.D.(2)(3)*	68	Director	Edmonton, Alberta, Canada
Robert R. Tufts	73	Director	San Francisco, CA; San Francisco County
Tony Wicks(1)(2)(3)*	68	Director	Novato, CA; Marin County

\* Independent director, as defined in the AMEX Company Guide

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating/Corporate Governance Committee

**Ramin ( Ron ) Najafi, Ph.D.** has served as our Chairman of the Board and President since July 2002, and as our Chief Executive Officer since November 2004. Prior to joining us, from January 2000 to June 2002, Dr. Najafi served in various management positions with NovaCal Pharmaceuticals, LLC ( NovaCal LLC ), including as Chairman of the Board from January 2000 to June 2002, as President and Chief Scientific Officer from February 2002 to June 2002, and as Chief Executive Officer from January 2000 to February 2002. We acquired all of the assets of NovaCal LLC in July 2002. From 1996 to December 2000, Dr. Najafi was the President and Chief Executive Officer of California Pacific Labs, Inc., a chemical laboratory supplies company. Dr. Najafi's prior experience also includes serving as a scientist at Aldrich Chemical, Rhone Poulenc Rorer (now Sanofi-Aventis), and at Applied Biosystems (a division of PerkinElmer, Inc.). Dr. Najafi received a B.S. and M.S. degree in Chemistry from the University of San Francisco and a Ph.D. in Organic Chemistry from the University of California at Davis.

**John ( Jack ) O Reilly** has served as a director since July 2002 and as our Senior Vice President, Corporate Development, Chief Financial Officer and Treasurer since November 2004. Mr. O Reilly also served as our Chief Executive Officer from July 2002 to October 2004. From February 2002 to June 2002, Mr. O Reilly was a director and the Chief Executive Officer of NovaCal LLC. From 2000 to January 2002, he was the Executive Chairman of Xomol Inc., a healthcare information technology company. Mr. O Reilly's prior experience also includes several positions at Syntex Corporation, where he served as the Senior Director of Corporate Development, Finance Director of the Pharmaceutical Group and CFO of operating units in France

## Table of Contents

and Switzerland, as the President of Vectorpharma International, Inc., a drug delivery company which was sold to Recordati S.p.A., a multinational European pharmaceutical company, and as the Chief Executive Officer of Spectra Biomedical, Inc., a clinical genetics company sold to GlaxoSmithKline. Mr. O'Reilly received a B.A. in history from Oxford University and an M.B.A. from Stanford University.

**Behzad Khosrovi, Ph.D.** has served as our Vice President, Research & Development since November 2003. From 1998 to November 2003, Dr. Khosrovi was a consultant in the biotechnology industry, generally working with start-up companies in the San Francisco Bay Area. Dr. Khosrovi's prior experience also includes serving as the Vice President of Development at Neurobiological Technologies, Inc. from 1992 to 1998 and at Cetus Corporation from 1976 to 1990. Dr. Khosrovi received an M.A. in natural science from Cambridge University and a Ph.D. in applied microbiology and biochemical engineering from Manchester University.

**Colin Scott, MB, Ch.B.** has served as our Vice President, Clinical Research and Development since January 2006. Prior to joining us, from October 2004 to December 2005, Dr. Scott was the Vice President, Drug Development for GlycoMimetics, a biotech company that specializes in the modification of carbohydrate/protein interactions. From June 2004 to September 2004, Dr. Scott was a consultant to several biopharmaceutical companies. From September 2002 to May 2004, Dr. Scott served as the Vice President, Clinical and Regulatory at Arriva Pharmaceuticals, Inc., a biopharmaceutical company focused on the development of anti-inflammatory therapies for respiratory indications. From March 2001 to May 2002, he served as the Vice President, Clinical of Emisphere Technologies, Inc., a biopharmaceutical company focused on developing oral forms of injectable drugs. Dr. Scott received a medical degree in pulmonology and infectious diseases from Glasgow University in Scotland.

**Charles J. Cashion** has served as a director since November 2005. Mr. Cashion currently serves as the Senior Vice President, Finance and Chief Financial Officer of Conatus Pharmaceuticals Inc., a biotechnology start-up company focused in the areas of inflammation and liver disease, which he co-founded with other senior management of Idun Pharmaceuticals, Inc. following the sale of Idun to Pfizer, Inc. in July 2005. From 2001 to July 2005, Mr. Cashion was the Executive Vice President, Chief Financial Officer and Secretary of Idun. Mr. Cashion's prior experience also includes serving as the Senior Vice President, Chief Financial Officer and Secretary of Quidel Corporation, a publicly owned, medical diagnostics company, and as the Senior Vice President, Finance, Chief Financial Officer, Secretary, and Treasurer of The Immune Response Corporation, a publicly owned biopharmaceutical company. Mr. Cashion received his B.S. in accounting and an M.B.A. in finance from Northern Illinois University.

**Anthony Dailley, D.D.S.** has served as a director since May 2002. Dr. Dailley is one of our founders and has been involved in a number of start-up companies, including serving as a director of NovaCal LLC from January 2000 to May 2002. Dr. Dailley currently serves as the President of Breathcare, a specialty dental practice which he founded in 2000. From 1995 to 2000, he was the Treasurer and a member of the board of directors of Indicator Technologies, Inc., a medical device company in California. From 1985 to 1987, he was a co-owner of 1-800-DENTIST, a dentist referral service which he co-founded. Dr. Dailley also held a teaching position at the University of the Pacific School of Dentistry for a number of years. Dr. Dailley received his B.S. in cell and molecular biology from San Francisco State University and his dental degree from the University of the Pacific School of Dentistry in San Francisco.

**Paul E. Freiman** has served as a director since May 2002. He also served as a director of NovaCal LLC from May 2001 to May 2002. Since May 1997, Mr. Freiman has been the President and Chief Executive Officer of Neurobiological Technologies, Inc., a biotechnology company focused on acquiring and developing central nervous system related drug candidates. He has also served as a member of the board of directors of Neurobiological Technologies since April 1997. Mr. Freiman's prior experience includes serving as the former chairman and chief executive officer of Syntex Corporation, which was sold to The Roche Group for \$5.3 billion during his tenure. Mr. Freiman currently serves as Chairman of Penwest Pharmaceutical Co., and serves on the boards of Calypte Biomedical Corporation, NeoPharm, Inc., Otsuka America Pharmaceuticals, Inc., and SciGen.



## **Table of Contents**

Ltd. Mr. Freiman received a B.S. degree in pharmacy from Fordham University and an honorary doctorate from the Arnold & Marie Schwartz College of Pharmacy.

**T. Alex McPherson, M.D., Ph.D.** has served as a director since July 2006. Dr. McPherson was President and Chief Executive Officer of Biomira, Inc., a biotechnology company specializing in the development of products for the treatment of cancer, from 1991 until his retirement in May 2006. He is a Fellow of the Australasian, Canadian and American Colleges of Physicians and is a past President of both the Alberta and Canadian Medical Associations. Dr. McPherson is currently a Professor Emeritus in the Faculty of Medicine of the University of Alberta, and was Deputy Minister of the Alberta Ministry of Hospitals and Medical Care, and was Deputy Commissioner and Executive Director of the Premier's Commission on Future Health Care for Albertans (The Rainbow Report). Dr. McPherson received his M.D. in medicine from the University of Alberta and his Ph.D. from the University of Melbourne.

**Robert R. Tufts** has served as a director since May 2002. He also served as a director of NovaCal LLC from February 2001 to May 2002. Mr. Tufts is a founding law partner of Tufts Stephenson & Kasper, LLP, which he founded in April 1999, and was formerly a partner with Jackson Tufts Cole and Black, LLP for over 35 years. He specializes in corporate representation for start-up and emerging businesses, business financings, mergers and acquisitions, and in corporate taxation. Mr. Tufts received his B.A. in history from New York University and received his law degree from Harvard Law School.

**Tony Wicks** has served as a director since May 2002. He also served as a director of NovaCal LLC from March 2001 to May 2002. Since 1995, Mr. Wicks has been pursuing private investments, venture work and participating in property investments. Prior to that, from 1986 to 1995, Mr. Wicks was the Chief Executive Officer of American Resource Corporation Inc., a public company in the mining industry with activities in North & South America. Prior to that, he served as the Chief Executive Officer of several public and private companies in Europe and the U.S. and was directly involved in company start-up operations, and with public listings. Mr. Wicks received his H.N.C. in electrical engineering from Essex Polytechnic.

## **Classified Board of Directors**

Our Board of Directors currently consists of eight members. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal. Effective upon the closing of this offering, we will divide the terms of office of the directors into three classes:

Class I, whose term will expire at the annual meeting of shareholders to be held in 2008;

Class II, whose term will expire at the annual meeting of shareholders to be held in 2009; and

Class III, whose term will expire at the annual meeting of shareholders to be held in 2010.

Upon the closing of this offering, Class I shall consist of Messrs. Dailley, O'Reilly and Tufts; Class II shall consist of Messrs. McPherson, Wicks and Cashion; and Class III shall consist of Messrs. Freiman and Najafi. At each annual meeting of shareholders after the initial classification, the successors to directors whose terms will then expire serve from the time of election and qualification until the third annual meeting following their election and until their successors are duly elected and qualified. A resolution of the Board of Directors or affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of our outstanding voting stock may change the authorized number of our directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. This classification of the Board of Directors may have the effect of delaying or preventing changes in control or management of our company.

## **Table of Contents**

### **Board Committees**

Our Board of Directors has an Audit Committee, a Compensation Committee and a Nominating/Corporate Governance Committee.

*Audit Committee.* Our Audit Committee consists of Messrs. Cashion, Freiman and Wicks. All members of the Audit Committee are independent directors, as defined in the AMEX Company Guide. Mr. Cashion is the chairman of the committee and qualifies as an audit committee financial expert within the meaning of Item 407(d)(5) of Regulation S-K under the Securities Exchange Act of 1934, as amended. The functions of this committee include:

meeting with our management periodically to consider the adequacy of our internal controls and the objectivity of our financial reporting;

meeting with our independent auditors and with internal financial personnel regarding these matters;

pre-approving audit and non-audit services to be rendered by our independent auditors;

recommending to our Board of Directors the engagement of our independent auditors and oversight of the work of our independent auditors;

reviewing our financial statements and periodic reports and discussing the statements and reports with our management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls and auditing matters;

reviewing our financing plans and reporting recommendations to our full Board of Directors for approval and to authorize action; and

administering and discussing with management and our independent auditors our Code of Ethics.

Both our independent auditors and internal financial personnel regularly meet privately with the Audit Committee and have unrestricted access to this committee.

*Compensation Committee.* Our Compensation Committee currently consists of Messrs. Wicks, Dailley, Freiman and McPherson. Mr. Wicks is the chairman of the committee and all members of the Compensation Committee are independent directors, as defined in the AMEX Company Guide. The functions of this committee include:

reviewing and, as it deems appropriate, recommending to our Board of Directors, policies, practices and procedures relating to the compensation of our directors, officers and other managerial employees and the establishment and administration of our employee benefit plans;

exercising authority under our employee benefit plans;

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

reviewing and approving executive officer and director indemnification and insurance matters; and

advising and consulting with our officers regarding managerial personnel and development.

*Nominating/Corporate Governance Committee.* Our Nominating/Corporate Governance Committee is comprised of Messrs. McPherson, Freiman and Wicks. Mr. McPherson is the chairman of the committee and all members of the Nominating/Corporate Governance Committee are independent directors, as defined in the AMEX Company Guide. The functions of this committee include:

identifying qualified candidates to become members of our Board of Directors;

selecting nominees for election of directors at the next annual meeting of shareholders (or special meeting of shareholders at which directors are to be elected);

## **Table of Contents**

selecting candidates to fill vacancies of our Board of Directors;

developing and recommending to our Board of Directors our corporate governance guidelines; and

overseeing the evaluation of our Board of Directors.

### **Corporate Cease Trade Orders and Bankruptcies**

To our knowledge, after due inquiry, none of our directors or officers or any shareholder holding sufficient securities of NovaBay to affect materially the control of NovaBay, is, or has been within the ten years before the date of this prospectus, a director or officer of any other company that, while such person was acting in that capacity, was the subject of a cease trade or similar order, or an order that denied such company access to any statutory exemptions under Canadian securities legislation, for a period of more than 30 consecutive days, or became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold the assets of that company.

### **Penalties and Sanctions**

To our knowledge, after due inquiry, none of our directors or officers or any shareholder holding sufficient securities of NovaBay to affect materially the control of NovaBay has been subject to any penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority or has entered into a settlement agreement with a Canadian securities regulatory authority or been subject to any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **Personal Bankruptcies**

To our knowledge, after due inquiry, none of our directors or officers, other than Colin Scott, or any shareholder holding sufficient securities of NovaBay to affect materially the control of NovaBay or a personal holding company of any such persons has, within the ten years before the date of this prospectus, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director or officer or shareholder.

### **Conflicts of Interest**

NovaBay's directors and officers are required by law to act honestly and in good faith with a view to the best interests of NovaBay. To the best of our knowledge, there are no known existing or potential conflicts of interest among NovaBay, our directors, officers or other members of management of NovaBay as a result of their outside business interests as of the date hereof. However, certain of our directors and officers and other members of our management serve as directors, officers, and members of management of other public companies. Accordingly, conflicts of interest may arise between their duties to us and their duties as directors, officers or members of management of such other public companies or in generally acting on behalf of NovaBay.

The directors and officers of NovaBay have been advised of their obligations to act at all times in good faith in the interest of NovaBay and to disclose any conflicts to NovaBay if and when they arise. Persons considering the purchase of shares of our common stock pursuant to the offering under this prospectus must appreciate that they will be required to rely on the judgment and good faith of these persons in resolving any such conflicts of interest that may arise.

**Table of Contents**

**Indebtedness of Directors and Executive Officers**

As of the date of this prospectus, no amount was owed to us by any of our directors or executive officers.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our Compensation Committee has been at any time one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers on our Board of Directors or Compensation Committee.

**Scientific Advisory Board**

The members of our Scientific Advisory Board, none of whom are our officers or employees of NovaBay, provide advice, assistance and consultation in their fields to our Vice-President of Research and Development and our Chief Executive Officer. We have entered into scientific advisory board agreements with our advisory board members. We consider our advisory board members to be opinion leaders in their respective fields. At least once a year, the Scientific Advisory Board will meet to review our current and planned scientific activities and will, through an independent member of the Board of Directors, provide the Board of Directors with an independent assessment of those activities.

As of March 31, 2007, our Scientific Advisory Board consisted of the following members:

<b>Name</b>	<b>Title</b>	<b>Affiliation</b>
Bernard Churchill, M.D.	Professor of Urology & Chief, Division of Pediatric Urology	David Geffen School of Medicine at University of California, Los Angeles
William Costerton, Ph.D.	Director of Biofilm Engineering	University of Southern California
Frederick Hawthorne, Ph.D.	Co-Director, International Institute for Nano and Molecular Medicine	University of Missouri-Columbia
Larry Truesdale, Ph.D.	Director of Combinatorial Chemistry	Pfizer, Inc.
Roger Whiting, Ph.D.	President and Chief Scientific Officer	Roxro Pharma, Inc.

**Compensation Discussion and Analysis**

The primary objective of our compensation policies and programs with respect to executive compensation is to serve our shareholders by attracting, retaining and motivating talented and qualified individuals to manage and lead our business. We focus on providing a competitive compensation package which provides significant short and long-term incentives for the achievement of measurable corporate and individual performance objectives. Decisions regarding executive compensation are ultimately determined by our Compensation Committee, who review a number of factors in their decisions, including recommendations of management. Future decisions regarding executive compensation will continue to be the responsibility of our Compensation Committee.

In 2006, we paid our senior management through a mix of base salary, bonus and equity compensation at levels that we believed were comparable to executives of companies of similar size and stage of development. As a private company, our compensation plans were generally developed by our management and approved by our Board and Compensation Committee on an individual basis, utilizing a number of factors including publicly available data and our general business conditions and objectives. We expect that in the future, we may engage the services of compensation consultants to review our policies and procedures with respect to executive

## **Table of Contents**

compensation, or conduct annual benchmark reviews of our executive compensation or subscribe to various surveys or reports to assist us in setting appropriate levels of compensation for our executives.

### ***Elements of Executive Compensation***

#### ***Base Salary***

We seek to provide our senior management with a level of base salary in the form of cash compensation appropriate to their roles and responsibilities. Base salaries for our executives are established based on the executive's qualifications, experience, scope of responsibilities, future potential and past performance, as well as the salaries paid by other companies for similar positions. Base salaries are reviewed annually and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

#### ***Incentive Cash Bonuses***

Our practice is to award incentive cash bonuses to our executive officers based upon their individual performance as well as business and strategic objectives of the Company. In 2006, bonuses were awarded to our executive officers primarily based on their contributions to achieving specific development and other business goals. The Compensation Committee expects to adopt formal processes for incentive cash bonuses in 2007 and beyond, and intends to utilize incentive cash bonuses to reward executives for achieving financial and operational goals and for achieving individual performance objectives.

#### ***Long-Term Equity Compensation***

We believe that long-term performance is achieved through an ownership culture that encourages long-term performance by our executive officers through the use of stock-based awards. We have established equity incentive plans to provide our employees, including our executive officers, with incentives to help align those employees' interests with the interests of shareholders. We normally grant our executive officers stock options upon their commencement of employment with us, which generally vest over a four year period, to provide a long-term incentive to such officers, provide them with an opportunity to obtain an ownership interest in our company and further align their interests with the interests of our shareholders. In 2006, we granted Colin Scott, one of our executive officers, an option to acquire 200,000 shares of our common stock. The Compensation Committee believes that the use of stock and stock-based awards promotes our overall executive compensation objectives and expects that equity incentives will continue to be a significant source of compensation for our executives.

Historically, we have issued stock options, which may be exercised prior to vesting and converted into restricted stock. The stock options that we grant generally vest as to 25% of the shares underlying the grant on the first anniversary of the grant date, with the remainder vesting in 12 equal quarterly installments thereafter over the three year period beginning on the first anniversary of the date of grant. In addition, these stock options generally will have a maximum term of ten years. We have not had a formalized policy as to the amount or timing of grants to executive officers. The Compensation Committee expects any future grants will be made on a structured and systematic basis, based on a number of factors, including individual performance, benchmark data, our strategic goals and our financial condition.

#### ***Other Compensation***

Our executive officers are eligible to receive the same benefits, including non-cash group life and health benefits, that are available to all employees. Certain additional benefits may be provided to our executives such as a car allowance, but each on a case-by-case basis.

**Table of Contents****Summary Compensation Table**

The following table shows information regarding the compensation earned during the fiscal years ended December 31, 2004, 2005 and 2006 by our Chief Executive Officer, Chief Financial Officer and our two other executive officers who were serving in such capacities during fiscal years 2004, 2005 and 2006. The officers listed below are collectively referred to as the Named Executive Officers in this prospectus.

Name	Year	Salary	Bonus	Options Awards(1)	All Other Compensation(2)	Total
Ramin ( Ron ) Najafi, Ph.D. Chairman of the Board, CEO and President	2006	\$ 240,000	\$ 48,000	\$	\$ 25,691	\$ 313,691
	2005	200,000				200,000
	2004	200,000				200,000
John ( Jack ) O Reilly Sr. VP, Corporate Development and CFO	2006	198,500	33,750		14,482	246,732
	2005	152,000				152,000
	2004	198,200				198,200
Behzad Khosrovi, Ph.D. VP, Research and Development	2006	172,200	31,219		12,202	215,621
	2005	150,000				150,000
	2004	154,800				154,800
Colin Scott, MB, ChB VP, Clinical Research and Development(3)	2006	195,800	20,000	25,721		241,521
	2005					
	2004					

- (1) Valuation of awards based on the recognized expense for fiscal year 2006, determined pursuant to SFAS No. 123R utilizing assumptions discussed in Note 8 to our financial statements. No expense was recognized in fiscal years 2004 or 2005 in accordance with the prospective application transition method prescribed by SFAS No. 123R.
- (2) These amounts represent cash compensation for accrued and unused vacation leave entitlements.
- (3) Mr. Scott was not employed by us prior to fiscal year 2006.

**Grants of Plan-Based Awards**

Executive officers were awarded incentive stock options, to the extent permissible under the Internal Revenue Code. The exercise price per share of each option granted to our Named Executive Officers was determined in good faith by our Board of Directors to be equal to the fair market value of our common stock on the date of the grant. All options were granted under our 2002 Stock Option Plan and 2005 Stock Option Plan and are immediately exercisable. Except as otherwise noted below, the stock options vest as to 25% of the shares underlying the grant on the first anniversary of the grant date, with the remainder vesting in 12 equal quarterly installments thereafter over the three year period following the first anniversary of the date of grant. For a further description of our 2002 Stock Option Plan and 2005 Stock Option Plan, see Employee Benefit Plans.

**Table of Contents**

The following table presents information concerning grants of plan-based awards to each of the Named Executive Officers during fiscal years 2004, 2005 and 2006.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	% of Total Options Granted in Year	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards(1)	Expiration Date
Ramin ( Ron ) Najafi, Ph.D. Chairman of the Board, CEO and President				\$	\$	
John ( Jack ) O Reilly Sr. VP, Corporate Development and CFO						
Behzad Khosrovi, Ph.D. VP, Research and Development	1/29/04	400,000(2)	31%	0.15		1/29/14
Colin Scott, MB, ChB VP, Clinical Research and Development	1/17/06	200,000(3)	12%	0.60	83,279	1/17/16

- (1) Valuation of awards granted in fiscal year 2006 is based on the grant date fair value of the awards, determined pursuant to SFAS No. 123R utilizing assumptions discussed in Note 8 to our financial statements. No grant date fair value is provided for awards granted in fiscal years 2004 and 2005 in accordance with the prospective application transition method prescribed by SFAS No. 123R.
- (2) In January 2004, Dr. Khosrovi was granted an option to purchase an aggregate of 400,000 shares of our common stock. 50,000 shares subject to such option were fully vested as of the date of grant. The remaining shares vest in accordance with the following schedule: (i) 100,000 shares vest upon our first IND for the NVC-101 product if filed before December 1, 2013; (ii) 50,000 shares vest upon completion of our Phase I and II clinical trials for the NVC-101 product if completed before December 1, 2013; and (iii) the remaining 200,000 shares vest in four equal quarterly installments over the one year period commencing with the end of the calendar quarter following completion of our Phase I and II clinical trials for the NVC-101 product. As of December 31, 2006, the option was vested with respect to 200,000 shares.
- (3) In January 2006, Mr. Scott was granted an option to purchase an aggregate of 200,000 shares of our common stock. The option vests in equal quarterly installments over four years on the first day of each quarter, provided that Mr. Scott continues to provide services to us. As of December 31, 2006, the option was vested with respect to 50,000 shares.



**Table of Contents****Outstanding Equity Awards at Fiscal Year-End**

The following table presents the outstanding equity awards held by each of the Named Executive Officers as of the fiscal year ended December 31, 2006.

Name	Number of Securities Underlying Unexercised Options(#) Exercisable	Number of Securities Underlying Unexercised Options(#) Unexercisable	Option Awards		Option Exercise Price (\$)	Option Expiration Date
			Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Value of Unexercised In-the-Money Options(1)		
Ramin ( Ron ) Najafi, Ph.D. Chairman of the Board, CEO and President					\$	\$
John ( Jack ) O Reilly Sr. VP, Corporate Development and CFO	600,000(2) 106,383(3)		100,000(2)		0.10 0.47	2/21/12 1/22/09
Behzad Khosrovi, Ph.D. VP, Research and Development	200,000(4)		200,000(4)		0.15	1/29/14
Colin Scott, MB, ChB VP, Clinical Research and Development	200,000(5)				0.60	1/17/16

- (1) The value of unexercised in-the-money options listed above have been calculated on the basis of the assumed initial public offering price of \$ , less the applicable exercise price per share, multiplied by the number of shares underlying such options.
- (2) In May 2002, Mr. O Reilly was granted an option to purchase an aggregate of 700,000 shares of our common stock. 100,000 shares subject to such option were fully vested as of the date of grant. The remaining 600,000 shares vest in equal 100,000 share increments upon NovaBay's achieving each of the following: (i) raising an initial \$1,000,000 of capital in an equity financing; (ii) filing an IND; (iii) raising a second \$1,000,000 of capital in an equity financing; (iv) receiving clearance for the filed IND; (v) entering into a significant partnership agreement with another company for the development or exploitation of NovaBay products or intellectual property; and (vi) entering into a second significant partnership agreement with another company for the development or exploitation of NovaBay products or intellectual property before January 2010. As of December 31, 2006, the option was vested with respect to 600,000 shares and 100,000 shares were subject to vesting conditions.
- (3) The option was fully vested as to all shares upon the date of grant.
- (4) In January 2004, Dr. Khosrovi was granted an option to purchase an aggregate of 400,000 shares of our common stock. 50,000 shares subject to such option were fully vested as of the date of grant. The remaining shares vest in accordance with the following schedule: (i) 100,000 shares vest upon our first IND for the NVC-101 product if filed before December 1, 2013; (ii) 50,000 shares vest upon completion of our Phase I and II clinical trials for the NVC-101 product if completed before December 1, 2013; and (iii) the remaining 200,000 shares vest in four equal quarterly installments over the one year period commencing with the end of the calendar quarter following completion of our Phase I and II clinical trials for the NVC-101 product. As of December 31, 2006, the option was vested with respect to 200,000 shares.
- (5) In January 2006, Mr. Scott was granted an option to purchase an aggregate of 200,000 shares of our common stock. The option vests in equal quarterly installments over four years on the first day of each quarter, provided that Mr. Scott continues to provide services to us. As of December 31, 2006, the option was vested with respect to 50,000 shares.



**Table of Contents****Option Exercises and Stock Vested**

None of the Named Executive Officers exercised any options to purchase our common stock or became vested in restricted stock during the year ended December 31, 2006.

**Pension Benefits**

We do not have any qualified or non-qualified defined benefit plans.

**Non-Qualified Deferred Compensation**

We do not have any non-qualified defined contribution plans or other deferred compensation plans.

**Employment Contracts and Termination of Employment and Change of Control Arrangements**

We intend to enter into an employment agreement with each of our Named Executive Officers prior to the completion of this offering.

Mr. O Reilly was granted a stock option in May 2002 to purchase up to 700,000 shares of our common stock at an exercise price of \$0.10 per share. Mr. Scott was granted a stock option in January 2006 to purchase up to 200,000 shares of our common stock at an exercise price of \$0.60 per share. Upon a change in control of NovaBay, all unvested shares subject to the foregoing options will immediately vest and will remain exercisable until the expiration of the applicable option.

Mr. Khosrovi, our Vice President of Research and Development, was granted a stock option in January 2004 to purchase up to 400,000 shares of our common stock at an exercise price of \$0.15 per share. Upon a change in control of NovaBay, all unvested option shares will immediately vest and will remain exercisable until the expiration of such option. The option will also vest in full upon the completion of this offering.

**Director Compensation**

The compensation and benefits for services as a member of our Board of Directors is determined by our Board of Directors. Directors employed by us are not compensated for service on the Board or any committee of the Board; however, we reimburse directors for any out-of-pocket expenses in connection with attending meetings of our Board of Directors and committees of our Board of Directors. We currently do not pay our directors cash fees for their service as a member of the Board of Directors or service on any committee of the Board of Directors.

Our non-employee directors did not receive any cash compensation for their service as a director in 2006.

The compensation received during 2006 by each director who is not a Named Executive Officer is set forth below.

Name	Option Awards(1) (\$)	Total (\$)
Charles J. Cashion	\$ 48,453	\$ 48,453
Anthony Dailley	36,809	36,809
Paul E. Freiman	26,254	26,254
T. Alex McPherson	33,592	33,592
Robert R. Tufts	37,284	37,284
Tony Wicks	37,284	37,284

- (1) Valuation of awards based on the recognized expense for the fiscal year 2006, determined pursuant to SFAS No. 123R utilizing assumptions discussed in Note 8 to our financial statements. The grant date fair values of the options were as follows: \$56,938 for each of Messrs. Wicks, Tufts, Dailley and Freiman, and \$90,554 and \$90,316 for Messrs. McPherson and Cashion, respectively.

## **Table of Contents**

### **Employee Benefit Plans**

#### ***2002 Stock Option Plan***

Our 2002 Stock Option Plan (the 2002 Plan ) was adopted by our Board of Directors in May 2002 and approved by our shareholders in October 2002. A total of 4,500,000 shares of our common stock have been reserved for issuance under the 2002 Plan. Under the 2002 Plan, we are authorized to grant to officers and other employees options to purchase shares of our common stock intended to qualify as incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code ) and are authorized to grant to directors, officers, employees, consultants or independent contractors options that do not qualify as incentive stock options under the Internal Revenue Code. All options granted under the 2002 Plan have terms not exceeding 10 years and generally are immediately exercisable but vest over time. No director, employee, consultant or independent contractor may be granted options to acquire more than 400,000 shares of our common stock in any calendar year under the 2002 Plan. Options granted under the 2002 Plan are not transferable by the recipient except by will or by the laws of descent and distribution. As of December 31, 2006, options to purchase an aggregate of 2,852,716 shares of our common stock were outstanding under the 2002 Plan at a weighted average exercise price of \$0.23 per share. Our Board of Directors has determined that no further option grants will be made under the 2002 Plan, but all outstanding options under the 2002 Plan will continue to be governed by the terms and conditions of the 2002 Plan.

#### ***2005 Stock Option Plan***

Our 2005 Stock Option Plan (the 2005 Plan ) was adopted by our Board of Directors and approved by our shareholders in May 2005. A total of 2,470,000 shares of our common stock have been reserved for issuance under the 2005 plan. Under the 2005 Plan, we are authorized to grant to officers and other employees options to purchase shares of our common stock intended to qualify as incentive stock options, as defined under Section 422 of the Internal Revenue Code, and are authorized to grant to directors, officers employees, consultants or independent contractors options that do not qualify as incentive stock options under the Internal Revenue Code. All options granted under the 2005 Plan have terms not exceeding 10 years and generally are immediately exercisable but vest over time. No one director, employee, consultant or independent contractor may be granted options to acquire more than 750,000 shares of our common stock in any calendar year under the 2005 Plan. Options granted under the 2005 Plan are not transferable by the recipient except by will or by the laws of descent and distribution. As of December 31, 2006, options to purchase an aggregate of 1,634,000 shares of our common stock were outstanding under the 2005 Plan at a weighted average exercise price of \$0.77 per share, and 836,000 additional shares of common stock were reserved for future grant or issuance under the 2005 Plan. No further option grants will be made under the 2005 Plan after the date of this prospectus. Although no further options will be granted under the 2005 Plan, all outstanding options under the 2005 Plan will continue to be governed by the terms and conditions of the 2005 Plan.

#### ***401(k) Plan***

We maintain a tax-qualified retirement plan that provides eligible employees of our Company with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to defer up to the applicable annual Internal Revenue Code limits. The 401(k) plan permits us to make matching contributions and profit sharing contributions to eligible participants, although such contributions are not required. Pre-tax contributions are allocated to each participant s individual account and are then invested in selected investment alternatives according to the participants directions. Employee contributions are 100% vested at all times. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on these contributions are not taxable to the employees until distributed from the 401(k) plan and all contributions are deductible by us when made.

**Table of Contents****Options Held by Officers, Directors, Employees and Consultants**

The following table presents summarized information pertaining to options outstanding as of the date of this prospectus.

Group	Number of Persons Holding Options	Number of Options	Exercise Price	Market Value on Date of Grant(1)	Expiration Dates
Current and former executive officers	3	700,000	\$ 0.10	\$ 0.10	February 21, 2012
		400,000	\$ 0.15	\$ 0.15	January 29, 2014
		106,383	\$ 0.47	\$ 0.15	January 22, 2009
		200,000	\$ 0.60	\$ 0.60	January 17, 2016
Current and former directors who are not executive officers	6	120,000	\$ 0.10	\$ 0.10	Various(2)
		120,000	\$ 0.15	\$ 0.15	December 15, 2013
		395,000	\$ 0.28	\$ 0.28	April 30, 2014
		709,000	\$ 0.85	\$ 0.85	Various(3)
All other current and former employees	29	150,000	\$ 0.10	\$ 0.10	Various(4)
		100,000	\$ 0.15	\$ 0.15	Various(5)
		25,000	\$ 0.28	\$ 0.28	Various(6)
		217,000	\$ 0.60	\$ 0.60	Various(7)
		290,000	\$ 0.85	\$ 0.85	Various(8)
		78,000	\$ 1.00	\$ 1.00	September 14, 2016
Consultants	38	257,333	\$ 0.10	\$ 0.10	Various(9)
		135,000	\$ 0.15	\$ 0.15	Various(10)
		54,000	\$ 0.28	\$ 0.28	Various(11)
		112,000	\$ 0.60	\$ 0.60	Various(12)
		278,918	\$ 0.85	\$ 0.85	March 31, 2015(13)
		25,625	\$ 0.94	\$ 0.94	March 31, 2015(13)
		7,415	\$ 1.14	\$ 1.14	December 31, 2007(13)
		90,000	\$ 1.14	\$ 1.14	January 17, 2017

(1) Because there was no market for our shares, the fair value was determined by our Board of Directors.

(2) From December 31, 2011 to March 18, 2012

(3) From May 24, 2016 to July 10, 2016

(4) From September 1, 2012 to April 15, 2013

(5) From January 29, 2014 to January 31, 2014

(6) From December 12, 2014 to March 31, 2015

(7) From October 30, 2015 to January 17, 2016

(8) From May 24, 2016 to July 18, 2016

(9) From December 31, 2011 to June 30, 2012

(10) From December 31, 2011 to January 30, 2014

(11) From January 6, 2015 to May 12, 2015

(12) From May 12, 2015 to January 17, 2016

(13) Options issued outside of the 2002 and 2005 Plans

**Limitation on Liability and Indemnification Matters**

As allowed by the California Corporations Code, our amended and restated articles of incorporation eliminate the liability of each of our directors for monetary damages to the fullest extent permissible under

**Table of Contents**

California law. Our amended and restated articles of incorporation and our amended and restated bylaws further provide for indemnification of our officers and directors to the maximum extent permitted by California law, and also permit the indemnification of other corporate agents at the discretion of our Board of Directors. We also maintain insurance policies which insure our officers and directors against certain liabilities.

We have entered into agreements to indemnify our directors and certain of our officers in addition to the indemnification provided for in the amended and restated articles of incorporation and amended and restated bylaws. These agreements will, among other things, indemnify our directors and some of our officers for certain expenses (including attorneys fees), judgments, fines and settlement amounts incurred by such persons in any action or proceeding, including any action by or in our right, on account of services by such persons as a director or officer of NovaBay or as a director or officer of any of our subsidiaries, or as a director or officer of any other company or enterprise that persons provide services to at our request.

There is no pending litigation or proceeding naming any of our directors or officers for which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

**Table of Contents**

**RELATED PARTY TRANSACTIONS**

Since December 31, 2003, there has not been any transaction, nor is there any proposed transaction, to which we were or will be a party, in which the amount involved exceeded or will exceed \$120,000 or which had or will have a material affect on us, and in which any director, executive officer, holder of more than 5% of any class of our voting securities or any associate, affiliate or member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than the compensation agreements and other agreements and transactions which are described in Management and the transactions described below.

**Policies and Procedures**

Pursuant to the written charter of our Audit Committee, our Audit Committee of the Board of Directors is responsible for reviewing and approving, prior to our entry into any such transaction, all related party transactions and potential conflict of interest situations involving a principal shareholder, a member of the board of directors or senior management. In addition, our Code of Ethics and Business Conduct requires that our officers and employees use good judgment to adhere to high ethical standards with respect to situations that create an actual or potential conflict between such person's personal interests and the interests of the company.

**Transactions with Related Parties**

We have entered into, or intend to enter into, indemnification agreements with each of our current directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under California law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers.

**Table of Contents****PRINCIPAL SHAREHOLDERS**

The following table indicates information as of March 31, 2007 regarding the ownership of our common stock by:

each person who is known by us to own more than 5% of our shares of common stock;

each Named Executive Officer;

each of our directors; and

all of our directors and executive officers as a group.

The number of shares beneficially owned and the percentage of shares beneficially owned are based on 32,204,813 shares of common stock outstanding as of March 31, 2007, which assumes the conversion of all of our outstanding preferred stock into 19,227,195 shares of common stock upon the completion of this offering, and \_\_\_\_\_ shares of common stock outstanding upon consummation of this offering. Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission. Shares subject to options that are exercisable within 60 days following March 31, 2007 are deemed to be outstanding and beneficially owned by the optionee for the purpose of computing share and percentage ownership of that optionee, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Except as indicated in the footnotes to this table, and as affected by applicable community property laws, all persons listed are the shareholders of record and have sole voting and investment power for all shares shown as beneficially owned by them.

Name and Address of Beneficial Owners (1)	Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned	
		Prior to Offering	After Offering
Ramin ( Ron ) Najafi, Ph.D.(2)	6,249,000	19.4%	. %
John ( Jack ) O Reilly(3)	806,383	2.4	
Behzad Khosrovi, Ph.D.(4)	670,000	2.1	
Colin Scott, MB, ChB(3)	200,000	*	
Charles J. Cashion(3)	164,000	*	
Anthony Dailley, DDS(5)	613,208	1.9	
Paul E. Freiman(6)	330,000	1.0	
T. Alex McPherson, MD, Ph.D.(7)	159,666	*	
Robert R. Tufts(8)	455,000	1.4	
Tony Wicks(9)	469,929	1.4	
All directors and executive officers as a group (10 persons)(10)	10,117,186	28.9%	. %

\* Less than one percent

- (1) The address for each of the persons listed is c/o NovaBay Pharmaceuticals, Inc., 5980 Horton Street, Suite 500, Emeryville, California 94608.
- (2) Consists of 6,249,000 shares of common stock held by the Najafi Family Trust dated September 13, 2006, of which Dr. Najafi and his spouse are the trustees.
- (3) Consists solely of shares issuable upon exercise of outstanding options which are currently exercisable.
- (4) Includes 400,000 shares issuable upon exercise of outstanding options which are currently exercisable.
- (5) Includes (i) 200,847 shares held by the Anthony and Terry Dailley Trust, of which Mr. Dailley and his spouse are trustees, (ii) 14,361 shares held by the Anthony Dailley DDS Profit Sharing Plan, of which Mr. Dailley is the trustee, and (iii) 248,000 shares issuable upon exercise of outstanding options which are currently exercisable.
- (6) Includes 280,000 shares issuable upon exercise of outstanding options which are currently exercisable.





**Table of Contents**

- (7) Includes 143,000 shares issuable upon exercise of outstanding options which are currently exercisable.
- (8) Consists of (i) 254,000 shares held by a trust established by Mr. Tufts, of which Mr. Tufts and his spouse are trustees, and (ii) 201,000 shares issuable upon exercise of outstanding options which are currently exercisable.
- (9) Consists of (i) 161,929 shares held by the Wicks Revocable Trust, of which Mr. Wicks and his spouse are trustees, and (ii) 308,000 shares issuable upon exercise of outstanding options which are currently exercisable.
- (10) Includes 2,750,383 shares of common stock issuable upon exercise of outstanding options which are currently exercisable.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

The following description of our securities and provisions of our amended and restated articles of incorporation and amended and restated bylaws is only a summary. You should also refer to the copies of our amended and restated articles and bylaws which have been filed with the Securities and Exchange Commission as exhibits to our registration statement. The description of common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering in accordance with the terms of the amended and restated articles of incorporation that will be adopted by us immediately prior to the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 65,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share.

**Common Stock**

Currently, we are authorized to issue 64,000,000 shares of common stock. At December 31, 2006, 12,622,618 shares of common stock were deemed outstanding and held of record by 203 holders. Under our amended and restated articles of incorporation and amended and restated bylaws, holders of common stock do not have cumulative voting rights. The shares of common stock offered by this prospectus, when issued, will be fully paid and non-assessable and will not be subject to any redemption or sinking fund provisions. Holders of common stock do not have any preemptive, subscription or conversion rights.

Holders of common stock are entitled to receive dividends declared by the Board of Directors out of legally available funds, subject to the rights of preferred shareholders, if any, and the terms of any existing or future agreements between us and our lenders. We presently intend to retain future earnings, if any, for use in the operation and expansion of our business. We do not anticipate paying cash dividends in the foreseeable future. See Dividend Policy. In the event of our liquidation, dissolution or winding up, common shareholders are entitled to share ratably in all assets legally available for distribution after payment of all debts and other liabilities, and subject to the prior rights of any holders of outstanding shares of preferred stock, if any.

**Preferred Stock**

Currently, we are authorized to issue 4,000,000 shares of Series A Preferred Stock, 7,000,000 shares of Series B Preferred Stock, 8,000,000 shares of Series C Preferred Stock and 20,000,000 shares of Series D Preferred Stock. As of December 31, 2006, there were 3,215,032 shares of Series A Preferred Stock held by 75 shareholders of record, 6,864,410 shares of Series B Preferred Stock held by 139 shareholders of record, 6,666,659 shares of Series C Preferred Stock held by 172 shareholders of record and 2,481,094 shares of Series D Preferred Stock held by 115 shareholders of record. Upon consummation of this offering, each share of Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock will convert into one share of our common stock such that all of our outstanding preferred stock will convert into an aggregate of 19,227,195 shares of our common stock.

Upon the closing of this offering, the Board of Directors will be authorized to issue from time to time up to an aggregate of 5,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each of these series, including the dividend rights, dividend rates, conversion rights, voting rights, term of redemption, including sinking fund provisions, redemption price or prices, liquidation preferences and the number of shares constituting any series or designations of a series without further vote or action by the shareholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of us without further action by the shareholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control. We currently have no plans to issue any shares of preferred stock.

---

## **Table of Contents**

We believe that the ability to issue preferred stock without the expense and delay of a special shareholders' meeting will provide us with increased flexibility in structuring possible future financings and acquisitions, and in meeting other corporate needs that might arise. This also permits the Board of Directors to issue preferred stock containing terms which could impede the completion of a takeover attempt, subject to limitations imposed by applicable securities laws. The Board of Directors will make any determination to issue these shares based on its judgment as to the best interests of NovaBay and our shareholders at the time of issuance. This could discourage an acquisition attempt or other transaction which shareholders might believe to be in their best interests or in which they might receive a premium for their stock over the then market price of the stock.

### **Anti-Takeover Provisions**

*California Law.* We are subject to the provisions of Section 1203 of the California Corporations Code, which includes provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of NovaBay. First, if an interested person makes an offer to purchase the shares of some or all of our existing shareholders, we must obtain an affirmative opinion in writing as to the fairness of the offering price prior to completing the transaction. California law considers a person to be an interested person if the person directly or indirectly controls our company, if the person is directly or indirectly controlled by one of our officers or directors, or if the person is an entity in which one of our officers or directors holds a material financial interest. If after receiving an offer from such an interested person, we receive a subsequent offer from a neutral third party, then we must notify our shareholders of this offer and afford each of them the opportunity to withdraw their consent to the interested person's offer. Section 1203 and other 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 are also subject to other provisions of the California Corporations Code, which include voting requirements that may also have the effect of deterring hostile takeovers, disposing of our assets or delaying or preventing changes in control or management of NovaBay. Under Section 1101, if a single entity or constituent corporation owns more than 50% but less than 90% of the outstanding shares of any series of our capital stock and attempts to merge our Company into itself or other constituent corporation, the Company's non-redeemable securities may only be exchanged for non-redeemable securities of the surviving entity unless all of our shareholders consent to the transaction or the terms of the transaction are approved and determined fair by the California Commissioner of Corporations. Likewise, Section 1001(d) of the California Corporations Code imposes similar restrictions on the disposition of the Company's assets to affiliated entities. Under Section 1001(d), any proposed sale or disposition of all or substantially all of our assets to any other corporation that we are controlled by or under common control with must be consented to by our shareholders holding at least 90% of the outstanding shares of our capital stock or approved and determined fair by the California Commissioner of Corporations. Sections 1101 and 1001 could make it significantly more difficult for a third-party to acquire control of our Company by preventing a possible acquirer from cashing out minority shareholders or selling substantially all of our assets to a related party and therefore could discourage a hostile bid, or delay, prevent or deter entirely 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.

*Articles of Incorporation and Bylaws.* Provisions of our amended and restated articles of incorporation and amended and restated bylaws may also make it more difficult to acquire control of us. These provisions could deprive shareholders of the opportunity to realize a premium on the shares of common stock owned by them. In addition, these provisions may adversely affect the prevailing market price of the stock and are intended to:

enhance the likelihood of continuity and stability in the composition of the Board and in the policies formulated by the Board;

discourage transactions which may involve an actual or threatened change in control of us;

**Table of Contents**

discourage tactics that may be used in proxy fights;

encourage persons seeking to acquire control of us to consult first with the Board of Directors to negotiate the terms of any proposed business combination or offer; and

reduce our vulnerability to an unsolicited proposal for a takeover that does not contemplate the acquisition of all of our outstanding shares or that is otherwise unfair to our shareholders.

*Classified Board of Directors; Removal; Filling Vacancies and Amendment.* Upon the closing of this offering, our amended and restated articles of incorporation and amended and restated bylaws will provide for the Board to be divided into three classes of directors serving staggered, three-year terms. The classification of the Board has the effect of requiring at least two annual shareholder meetings, instead of one, to replace a majority of the members of the Board. Subject to the rights of the holders of any outstanding series of preferred stock, the amended and restated bylaws will authorize the Board to fill vacancies, including newly created directorships and those resulting from removal by a vote of the shareholders. Accordingly, this provision could prevent a shareholder from obtaining majority representation on the Board by enlarging the Board of Directors and filling the new directorships with its own nominees.

*Special Shareholder Meetings.* Our amended and restated bylaws will provide that special meetings of shareholders for any purpose or purposes may only be called by the Chairman of the Board, the president, a majority of our Board or by shareholders holding in the aggregate no less than 10% of our common stock. Special meetings called by a shareholder shall be subject to certain advance notice and information content requirements. A special meeting of the shareholders may not be held absent a written request complying with these advance notice requirements and containing the specified informational content. The request shall state the purpose or purposes of the proposed meeting. This limitation on the right of shareholders to call a special meeting could make it more difficult for shareholders to initiate actions that are opposed by the Board of Directors. These actions could include the removal of an incumbent director or the election of a shareholder nominee as a director. They could also include the implementation of a rule requiring shareholder ratification of specific defensive strategies that have been adopted by the Board of Directors with respect to unsolicited takeover bids. In addition, the limited ability of the shareholders to call a special meeting of shareholders may make it more difficult to change the existing Board and management.

*Written Consent; Special Meetings of Shareholders.* The amended and restated articles of incorporation and amended and restated bylaws will prohibit the taking of shareholder action by written consent without a meeting unless such action has been previously approved by the Board of Directors. These provisions will make it more difficult for shareholders to take action opposed by the Board of Directors.

*Amendment of Provisions in Our Amended and Restated Articles of Incorporation.* Our amended and restated articles of incorporation will generally require the affirmative vote of the holders of at least two-thirds of the outstanding voting stock in order to amend any provisions of the articles of incorporation concerning:

the authority of shareholders to act by written consent; and

enlarging or reducing the authorized number of directors or fixing the exact number of directors.

These voting requirements will make it more difficult for minority shareholders to make changes in the articles of incorporation that could be designed to facilitate the exercise of control over us.

*Amendment of Provisions in Our Amended and Restated Bylaws.* Our amended and restated bylaws will generally require the affirmative vote of the holders of at least two-thirds of the outstanding voting stock in order to amend any provisions of the amended and restated bylaws concerning:

the removal or appointment of directors;

the authority of shareholders to act by written consent;

**Table of Contents**

procedure and content of shareholder proposals concerning business to be conducted at a meeting of shareholders;

director nominations by shareholders; and

enlarging or reducing the authorized number of directors or fixing the exact number of directors.

These voting requirements will make it more difficult for minority shareholders to make changes in the bylaws that could be designed to facilitate the exercise of control over us.

**Options**

As of December 31, 2006, options to purchase a total of 4,791,259 shares of common stock were outstanding, and up to 836,000 additional shares of common stock were reserved for future issuance under our 2005 Plan. For a more complete discussion of our stock option plans, please see Management Employee Benefit Plans.

**Registration Rights**

No holders of our common stock are entitled to registration rights with respect to their shares. In connection with this offering, however, we have agreed to issue to the underwriters broker warrants to purchase an amount of our common stock equal to up to 7% of the number of shares sold pursuant to this offering (including the over-allotment option) at an exercise price equal to the public offering price of the shares sold in this offering. These warrants will have certain rights of registration in the United States of the common stock issuable upon exercise of the warrants, beginning one year from the date of this prospectus.

**Transfer Agent and Registrar**

Computershare Shareholder Services, Inc., located in Providence, Rhode Island, Providence County, is the transfer agent and registrar for our common stock in the United States and Computershare Investor Services, Inc., located in Toronto, Ontario, Canada, is the co-transfer agent and registrar for our common stock in Canada.

**PRIOR SALES OF SHARES**

The following table summarizes all issuances of shares of common stock by NovaBay during the 12 month period preceding the date of this prospectus.

<b>Date of Issuance or Sale</b>	<b>Description of Transaction</b>	<b>Aggregate Number and Type of Shares Issued</b>	<b>Price Per Common Share</b>
February 2007	Compensation for services rendered	70,000 shares of common stock	N/A
June 2006 to December 2006	Compensation for services rendered	66,754 shares of common stock	N/A
January 2006 to June 2006	Exercise of warrants	2,297,169 shares of common stock	\$0.40 to \$0.60
January 2006 to September 2006	Private placement	1,738,873 shares of Series D Preferred Stock (which will convert into 1,738,873 shares of common stock upon completion of	\$1.50

this offering)



**Table of Contents****SHARES ELIGIBLE FOR FUTURE SALE**

Prior to the offering, there has been no public market for our common stock, and there can be no assurance that a significant public market for our common stock will develop or be sustained after the offering. Any future sale of a substantial amount of our common stock in the public market after this offering, or the perception that such sales may occur, could adversely affect the prevailing market price of our common stock. Furthermore, because some of our shares will not be available for sale after this offering due to the contractual and legal restrictions on resale described below, the sale of a substantial amount of our common stock in the public market after these restrictions lapse could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

**U.S. Resale Restrictions**

Upon completion of the offering, we will have \_\_\_\_\_ shares of common stock outstanding assuming no exercise of any options after December 31, 2006 and assuming no exercise of the underwriters' over-allotment option or broker warrants. All of the shares sold by us in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the "Securities Act"), except for shares held by persons who may be deemed our affiliates, as that term is defined under Rule 144 of the Securities Act.

In addition, \_\_\_\_\_ shares outstanding as of December 31, 2006, which shares were issued by us prior to \_\_\_\_\_, 2005, will be available for immediate sale in the U.S. 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 the release from applicable escrow requirements, \_\_\_\_\_ additional shares will become available for sale in the public market 6 months after the closing of this offering, subject in some cases to compliance with the volume and other limitations of Rule 144. Thereafter, \_\_\_\_\_ additional shares held by our officers and directors will become eligible for sale in the public market over the subsequent three to 18 month period, as the shares are released from the lock-up agreements with the representatives of the underwriters and the release from applicable escrow requirements. Please see "Shares Eligible for Future Sale - Lock-Ups" below.

For the reasons set forth below, we expect that the following shares will be eligible for sale in the U.S. public market at the following times:

<b>Date</b>	<b>Approximate Number of Shares Eligible for Sale in U.S. Public Market</b>	<b>Comment</b>
Upon effectiveness		Freely tradable shares sold in this offering; shares saleable under Rule 144(k)
3 months after the date of the prospectus		Shares released under lock-up agreements and applicable escrow requirements; shares saleable under Rule 144, 144(k) or 701
6 months after the date of the prospectus		Shares released under lock-up agreements and applicable escrow requirements; shares saleable under Rule 144, 144(k) or 701
9 months after the date of the prospectus		Shares released under lock-up agreements; shares saleable under Rule 144 or 701
12 months after the date of the prospectus		Shares released under lock-up agreements and applicable escrow requirements; shares saleable under Rule 144 or 701
18 months after the date of the prospectus		Shares released under lock-up agreements and applicable escrow requirements; shares saleable under Rule 144 or 701
24 months after the date of the prospectus		Shares released under lock-up agreements; shares saleable under Rule 144 or 701



## **Table of Contents**

### ***Rule 144***

#### ***General***

In general, under Rule 144 as currently in effect, a person, including an affiliate, who has beneficially owned our shares for at least one year is entitled to sell, within any three-month period commencing 90 days after the date of this prospectus, a number of such shares that does not exceed the greater of:

1% of the then outstanding shares of our common stock; or

the average weekly trading volume of our common stock during the four calendar weeks preceding such sale, subject to the filing of a Form 144 with the SEC by such person with respect to the sale.

Sales under Rule 144 are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us. However, these shares would remain subject to lock-up and escrow arrangements and would only become eligible for sale when the lock-up and escrow periods expire. Persons who are not our affiliates may be exempt from these restrictions under Rule 144(k) discussed below.

#### ***Rule 144(k)***

A person who is not deemed to have been an affiliate of ours at any time during the 90 days immediately preceding the sale and who has beneficially owned his or her shares for at least two years is entitled to sell his or her shares under Rule 144(k) without regard to the limitations described above. Persons deemed to be affiliates must always sell under the limitations imposed by Rule 144, even after the applicable holding periods have been satisfied. However, if these shares are subject to lock-up or escrow arrangements, such shares would only become eligible for sale when the lock-up and escrow periods expire.

### ***Rule 701***

Any employee or consultant who purchased his or her shares under a written compensatory plan or contract is entitled to rely on the resale provisions of Rule 701, which permits non-affiliates to sell their Rule 701 shares without having to comply with the public information, holding period, volume limitation or notice provisions of Rule 144 and permits affiliates to sell their Rule 701 shares without having to comply with the Rule 144 holding period restrictions, in each case commencing 90 days after the date of this prospectus. As of December 31, 2006, the holders of options to purchase approximately \_\_\_\_\_ shares of common stock, which options were issued pursuant to Rule 701, will be eligible to sell their shares, upon exercise of such options and subject to the vesting thereof, upon the expiration of the 180-day lock-up period required by the stock option plan pursuant to which the options were granted.

#### ***Sale of Shares***

We are unable to estimate the actual number of shares that will be sold pursuant to Rule 144 or Rule 701, since this will depend on the market price of our common stock, the personal circumstances of the sellers and other factors. Such future sales or the availability for sale of substantial amounts of our common stock in the public market could adversely affect prevailing market prices of our common stock and could impair our ability to raise capital through future sales of our securities.

We intend to file a registration statement on Form S-8 under the Securities Act as soon as practicable after the completion of the offering to register \_\_\_\_\_ shares of common stock subject to outstanding stock options or reserved for issuance under our stock plans. This registration will permit the resale of these shares by non-affiliates in the public market without restriction under the Securities Act, upon completion of the lock-up and escrow periods described above. Shares registered under the Form S-8 registration statement held by affiliates will be subject to Rule 144 volume limitations. See Management Compensation Discussion and Analysis and Management Employee Benefit Plans.

See also Risk Factors 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 .



---

## **Table of Contents**

### **Additional Canadian Resale Restrictions**

Under the securities laws of the provinces of Canada in which shares of our common stock are being offered pursuant to this prospectus, a person who owns our common shares, or securities convertible into our common shares (other than options granted to our directors, officers, employees and consultants), issued by us more than four months prior to the date of this prospectus will generally be able to freely sell those common shares, or the common shares issued upon the conversion of such convertible securities, in Canada following the date of this prospectus. To the extent that such common shares or convertible securities were issued by us during the four months preceding the date of this prospectus, those common shares, or the common shares issued upon the conversion of those convertible securities, may not be resold, except under a prospectus or an exemption from the prospectus requirement, until four months have passed since the date of distribution of those securities by us, at which time such a person will generally be able to freely sell those common shares in Canada. Any of our directors, officers, employees and consultants who purchase common shares from us either directly or pursuant to the exercise of options granted at any time prior to the date of this prospectus will generally be able to freely resell those common shares in Canada following the date of this prospectus. Any sales of our common shares in Canada will be subject to the terms of applicable lock-up agreements. There are additional restrictions on the ability of control block holders of our common shares to dispose of the common shares they hold. A control block holder is any person, company or combination of persons or companies holding a sufficient number of our common shares to affect materially the control of us, and any person, company or combination holding more than 20 percent of our outstanding common shares will, in the absence of evidence to the contrary, be deemed to affect materially the control of us. Upon the closing of this offering, we do not expect that we will have any control block holders of our common shares.

### **Lock-Up Agreements**

We have agreed not to issue, without the consent of the underwriters, during the period ending 180 days after the closing of this offering, any additional shares of our common stock or securities convertible or exchangeable into shares of our common stock, or rights to acquire any such securities. In addition, our President and Chief Executive Officer will enter into a lock-up agreement prior to the closing of the offering pursuant to which he will agree not to sell, transfer or otherwise assign or charge any of his securities of NovaBay except pursuant to the following schedule: (i) 15% after six months following the closing of this offering, (ii) 25% after 12 months following the closing of this offering, (iii) 30% after 18 months following the closing of this offering, and (iv) the remaining 30% after 24 months following the closing of this offering. Each of our other directors and officers will enter into lock-up agreements prior to the closing of the offering pursuant to which they will agree not to sell, transfer or otherwise assign or charge any of their securities of NovaBay except pursuant to the following schedule: (i) 50% after six months following the closing of this offering, (ii) 25% after nine months following the closing of this offering, and (iii) the remaining 25% after 12 months following the closing of this offering.

The foregoing lock-up periods will be extended if:

during the last 17 days of such lock-up period, we issue an earnings release or we disclose material news or a material event relating to our company occurs; or

prior to the expiration of such lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of such lock-up period,

in which case the restrictions described in the preceding paragraph (and in each individual lock-up agreement) will continue to apply until the expiration of a 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

**Table of Contents**

**Canadian Escrow Requirements**

Pursuant to applicable Canadian securities laws, certain of our officers, directors and shareholders may be required to comply with Canadian escrow provisions, whereby such parties would be required to deposit the following securities into escrow: our common stock held by such parties immediately prior to this offering; any securities held by such parties immediately prior to this offering that are convertible into or permit the holder to acquire our shares or other convertible securities, except for non-transferable incentive stock options to purchase our common stock solely for cash at a price equal to or greater than the offering price for our common stock under this offering; and, any of our common stock or convertible securities that are acquired by such parties in relation to securities that are in escrow at the time, including by way of dividend, other distribution, conversion or subdivision. Escrowed securities would be released from escrow in accordance with the following schedule: 25% of the escrowed securities may be initially released from escrow on the date of the listing of our common stock on the TSX (the Initial Release); 33% of the then remaining escrowed securities may be released from escrow six months after the Initial Release; 50% of the then remaining escrowed securities may be released from escrow twelve months after the Initial Release; and the remaining escrowed securities may be released from escrow eighteen months after the Initial Release. The escrowed securities may not be transferred or otherwise dealt with while held in escrow, except for certain specified exceptions permitted under the Canadian escrow provisions.

**Table of Contents**

**MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX**

**CONSIDERATIONS TO NON-U.S. HOLDERS**

The following discussion is a summary of the material U.S. federal income tax considerations generally applicable to the purchase, ownership and disposition of our common stock by Non-U.S. Holders (as defined below). This summary deals only with our common stock held as capital assets by holders who purchase common stock in this offering. This discussion does not cover all aspects of U.S. federal income taxation that may be relevant to the purchase, ownership or disposition of our common stock by prospective investors in light of their particular circumstances. In particular, this discussion does not address all of the tax considerations that may be relevant to certain types of investors subject to special treatment under U.S. federal income tax laws, such as:

dealers in securities or currencies;

financial institutions;

regulated investment companies;

real estate investment trusts;

tax-exempt entities;

insurance companies;

persons that own or are deemed to own more than 5% of our common stock;

persons holding common stock as part of a hedging, integrated, conversion or constructive sale transaction or a straddle;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons liable for alternative minimum tax;

U.S. expatriates;

partnerships or entities or arrangements treated as a partnership or other pass-through entity for U.S. federal tax purposes (or investors therein); or

U.S. Holders (as defined below).

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Furthermore, this summary is based upon the provisions of the Internal Revenue Code, the Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as of the date hereof. Such authorities may be repealed, revoked, modified or subject to differing interpretations, possibly on a retroactive basis, so as to result in U.S. federal income tax consequences materially different from those discussed below. We have not received a ruling from the Internal Revenue Service, or the IRS, with respect to any of the matters discussed herein, and therefore there can be no assurance that the IRS would agree with the conclusions stated herein. This discussion does not address any state, local or non-U.S. tax considerations.

For purposes of this summary, a **Non-U.S. Holder** is a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not a U.S. Holder. A **U.S. Holder** means a beneficial owner of our common stock that is for U.S. federal income tax purposes one of the following:

a citizen or an individual resident of the United States;

a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;



## **Table of Contents**

an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust if it (i) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If a partnership or other entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. If you are a partnership or a partner of a partnership holding our common stock, we particularly urge you to consult your own tax advisors.

Special rules may apply to you if you are a controlled foreign corporation or a passive foreign investment company, or are otherwise subject to special treatment under the Internal Revenue Code. Any such holders should consult their own tax advisors to determine the U.S. federal, state, local and non-U.S. income and other tax consequences that may be relevant to them.

If you are considering the purchase of our common stock, we urge you to consult your own tax advisors concerning the particular U.S. federal income tax consequences to you of the purchase, ownership and disposition of our common stock, as well as any consequences to you arising under state, local and non-U.S. tax laws.

### **Dividends**

Dividends paid to you (to the extent paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes) generally will be subject to U.S. federal withholding tax at a 30% rate, or such lower rate as may be specified by an applicable tax treaty. However, dividends that are effectively connected with a trade or business you conduct within the United States, or, if certain tax treaties apply to you, are attributable to a permanent establishment you maintain in the United States, are not subject to the U.S. federal withholding tax, but instead are subject to U.S. federal income tax on a net income basis at the applicable graduated individual or corporate rates. Special certification and disclosure requirements must be satisfied for effectively connected income to be exempt from withholding. If you are a corporation, any such effectively connected dividends that you receive may be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

If you wish to claim the benefit of an applicable treaty rate for dividends paid on our common stock, you must provide the withholding agent with a properly executed IRS Form W-8BEN, claiming an exemption from or reduction in withholding under the applicable income tax treaty. In the case of common stock held by a foreign intermediary (other than a qualified intermediary), the intermediary generally must provide an IRS Form W-8IMY and attach thereto an appropriate certification by each beneficial owner for which it is receiving the dividends.

If you are eligible for a reduced rate of U.S. federal withholding tax pursuant to an applicable income tax treaty, you may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS.

### **Sale, Exchange or Other Taxable Disposition of Common Stock**

You generally will not be subject to U.S. federal income tax with respect to gain recognized on a sale, exchange or other taxable disposition of shares of our common stock unless:

the gain is effectively connected with your conduct of a trade or business in the United States, or, if certain tax treaties apply, is attributable to a permanent establishment you maintain in the United States; or

## **Table of Contents**

if you are an individual and hold shares of our common stock as a capital asset, you are present in the United States for 183 or more days in the taxable year of the sale, exchange or other taxable disposition, and you have a tax home in the United States.

If you are an individual and are described in the first bullet above, you will be subject to tax on any gain derived from the sale, exchange or other taxable disposition at applicable graduated U.S. federal income tax rates. If you are an individual and are described in the second bullet above, you will generally be subject to a flat 30% tax on any gain derived from the sale, exchange or other taxable disposition that may be offset by U.S. source capital losses (even though you are not considered a resident of the United States). If you are a corporation and are described in the first bullet above, you will be subject to tax on your gain at applicable graduated U.S. federal income tax rates and, in addition, may be subject to the branch profits tax on your effectively connected earnings and profits for the taxable year, which would include such gain, at a rate of 30% or at such lower rate as may be specified by an applicable income tax treaty, subject to adjustments.

### **U.S. Federal Estate Tax**

Shares of our common stock held by an individual Non-U.S. Holder at the time of his or her death will be included in such Non-U.S. Holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

### **Information Reporting and Backup Withholding**

You may be subject to information reporting and backup withholding with respect to any dividends on, and the proceeds from dispositions of, our common stock paid to you, unless you comply with certain reporting procedures (usually satisfied by providing an IRS Form W-8BEN) or otherwise establish an exemption. Additional rules relating to information reporting requirements and backup withholding with respect to the payment of proceeds from the disposition of shares of our common stock will apply as follows: If the proceeds are paid to or through the U.S. office of a broker (U.S. or foreign), they generally will be subject to backup withholding and information reporting, unless you certify that you are not a U.S. person under penalties of perjury (usually on an IRS Form W-8BEN) or otherwise establish an exemption;

If the proceeds are paid to or through a non-U.S. office of a broker that is not a U.S. person and is not a foreign person with certain specified U.S. connections, or a U.S. Related Person, they will not be subject to backup withholding or information reporting; and

If the proceeds are paid to or through a non-U.S. office of a broker that is a U.S. person or a U.S. Related Person, they generally will be subject to information reporting (but not backup withholding), unless you certify that you are not a U.S. person under penalties of perjury (usually on an IRS Form W-8BEN) or otherwise establish an exemption.

In addition, the amount of any dividends paid to you and the amount of tax, if any, withheld from such payment generally must be reported annually to you and the IRS. The IRS may make such information available under the provisions of an applicable income tax treaty to the tax authorities in the country in which you reside.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your U.S. federal income tax liability provided the required information is timely furnished by you to the IRS. Non-U.S. Holders should consult their own tax advisors regarding the filing of a U.S. tax return for claiming a refund of such backup withholding.

**Table of Contents**

**MATERIAL CANADIAN FEDERAL INCOME TAX CONSIDERATIONS**

The following is, as of the date hereof, a summary of the principal Canadian federal income tax considerations generally applicable to a purchaser who purchases common stock pursuant to the offering. This summary applies only to a purchaser who, for purposes of the *Income Tax Act* (Canada) ( *Tax Act* ), and at all relevant times, is or is deemed to be resident in Canada, deals at arm's length with and is not affiliated with NovaBay and holds common stock as capital property (a *Holder* ). The common stock will generally constitute capital property to a holder thereof unless the holder holds the shares in the course of carrying on a business of buying and selling securities or acquires the shares in a transaction or transactions considered to be an adventure in the nature of trade.

This summary is based on the current provisions of the *Tax Act* and the regulations thereunder, ( *Regulations* ), all proposals to amend the *Tax Act* and the *Regulations* publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (the *Proposed Amendments* ), and our counsel's understanding of the current published administrative policies and practices of the Canada Revenue Agency ( *CRA* ) made publicly available prior to the date hereof. Except for the *Proposed Amendments*, this summary does not take into account or anticipate any changes in law or in administrative policies or assessing practices, nor does it take into account provincial or territorial tax laws of Canada or the tax laws of any foreign jurisdiction. No assurance can be given that the *Proposed Amendments* will be enacted as proposed (or at all) or that legislative, judicial or administrative changes will not alter the statements made herein.

This summary does not apply to a Holder (i) that is either a specified financial institution as defined in the *Tax Act* or a financial institution within the meaning of the *Tax Act* for purposes of the mark-to-market rules; (ii) an interest in which constitutes a tax shelter investment within the meaning of the *Tax Act*; or (iii) with respect to whom NovaBay is a foreign affiliate within the meaning of the *Tax Act*. The federal income tax consequences to a particular purchaser of an investment in our common stock will vary according to a number of factors including the legal status of the purchaser as an individual, a trust, a corporation or a partnership, and the province or provinces in which the purchaser resides, carries on business or has a permanent establishment.

This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice to any particular purchaser. Accordingly, each potential purchaser should obtain independent advice regarding the income tax consequences of investing in the common stock with reference to the purchaser's own particular circumstances.

For the purposes of the *Tax Act*, all amounts relating to the acquisition, holding or disposition of our common stock, including dividends, adjusted cost base and proceeds of disposition, must be converted into Canadian dollars using the Canadian/U.S. dollar exchange rate prevailing at the time such amounts arise.

**Disposition of Shares**

A Holder of our common stock will realize a capital gain (or capital loss) on a disposition, or a deemed disposition of such common stock equal to the amount by which the proceeds of disposition of the common stock, net of any reasonable costs of disposition, exceed (or are less than) the adjusted cost base of the common stock to the Holder. The cost of any common stock acquired pursuant to the offering must be averaged with the adjusted cost base of all other shares of our common stock that are held by the Holder as capital property.

One-half of any such capital gain (a taxable capital gain) must be included in computing the income of the holder in the year of disposition, and one-half of any such capital loss (an allowable capital loss) generally must be deducted against taxable capital gains realized by the holder in the year of disposition. Allowable capital losses in excess of taxable capital gains for the year of disposition generally may be deducted by the holder against net taxable capital gains realized in any of the three preceding years or in any subsequent year, subject to the detailed provisions of the *Tax Act*.

## **Table of Contents**

A Holder that is, throughout the relevant taxation year, a Canadian-controlled private corporation as defined in the Tax Act may be liable to pay, in addition to the tax otherwise payable under the Tax Act, a refundable tax of 6<sup>2</sup>/<sub>3</sub>% of its aggregate investment income for the year which is defined to include taxable capital gains.

Capital gains realized by an individual (including certain trusts) may give rise to a liability for alternative minimum tax as calculated under the detailed rules set out in the Tax Act.

## **Dividends**

Dividends received or deemed to be received on our common stock will be included in the Holder's income for the purposes of the Tax Act. Such dividends received by a Holder who is an individual will not be subject to the gross-up and dividend tax credit rules in the Tax Act. A Holder that is a corporation will not be entitled to deduct the amount of such dividends in computing its taxable income. A Holder that is throughout the relevant taxation year a Canadian-controlled private corporation, as defined in the Tax Act, may be liable to pay an additional refundable tax of 6<sup>2</sup>/<sub>3</sub>% on its aggregate investment income for the year, which will include such dividends. Subject to the detailed rules in the Tax Act, a Holder may be entitled to a foreign tax credit or deduction for any U.S. withholding tax paid with respect to dividends that the Holder receives on our common stock.

## **Foreign Property Information Reporting**

A Holder who is a specified Canadian entity for a taxation year or a fiscal period and whose total cost amount of specified foreign property, including our common stock at any time in the year or fiscal period exceeds Cdn\$100,000 will be required to file an information return for the year or period disclosing prescribed information in respect of such property. Subject to certain exceptions, a taxpayer resident in Canada in the year will be a specified Canadian entity. Holders are encouraged to consult their own tax advisors as to whether they must file an information return under these rules.

## **Foreign Investment Entity Status**

Bill C-33 contains revised draft legislation relating to the income tax treatment of investments by Canadian residents in non-resident entities that constitute foreign investment entities ( FIEs ) applicable for taxation years commencing after 2006 (the FIE Tax Proposals ). The FIE Tax Proposals, as currently drafted, would apply to require a Holder that holds a participating interest (that is not an exempt interest ) in a non-resident entity that is an FIE at the entity's taxation year-end to take into account in computing the Holder's income for the Holder's taxation year that includes such taxation year-end: (i) an amount based on a prescribed rate of return on the designated cost of such participating interest held by the Holder at the end of each month ending in the Holder's taxation year at which time the participating interest is held by the Holder; or (ii) in certain limited circumstances, and only where the Holder elects such treatment, any gains and losses accrued on such participating interest for the year under a mark-to-market rule.

For the purposes of the FIE Tax Proposals, shares of our common stock will constitute participating interests in NovaBay. However, NovaBay will not be an FIE at a particular time if either (a) at the end of the taxation year that includes that time, the carrying value of all of our investment property is not greater than one-half of the carrying value of all of our property, or (b) throughout the taxation year that includes that time, our principal undertaking was the carrying on of a business that is not an investment business. The determination of whether or not NovaBay is an FIE must be made on an annual basis at the end of each taxation year of NovaBay.

Even if NovaBay were an FIE, a share of common stock will be an exempt interest provided that at all relevant times: (i) NovaBay is resident in the United States; (ii) our common stock is listed on a prescribed stock exchange (which currently includes the TSX and the AMEX); (iii) our common stock constitutes an arm's length interest (as defined for the purposes of the FIE Tax Proposals), and (iv) it is reasonable to conclude that the Holder has no tax avoidance motive in respect of such share.

**Table of Contents**

We believe that a share of our common stock will constitute an arm's length interest of a particular Holder for this purpose provided such Holder (together with entities and individuals with whom the Holder does not deal at arm's length for purposes of the Tax Act) does not hold, in the aggregate, more than 10% of all or our issued and outstanding common stock.

For purposes of determining whether a share of our common stock is an arm's length interest, a Holder generally will be regarded as having a tax avoidance motive only if it is reasonable to conclude that the main reasons for acquiring or holding such share include directly or indirectly benefiting principally from income, profits, gains or increases in value in respect of investment property (as defined for this purpose) and from the deferral or reduction of tax that would have been payable on such income, profits or gains. The determination of whether common stock constitutes an exempt interest to a particular Holder must be made on an annual basis at the end of the taxation year of NovaBay and no assurances can be given that the common stock will constitute an exempt interest at any particular time.

Holders should consult their own tax advisors about the application of the FIE Tax Proposals having regard to their particular circumstances.

**Table of Contents**

**UNDERWRITING**

**General**

We intend to enter into an underwriting agreement with the underwriters named below (collectively, the Underwriters ). Dundee Securities Corporation, and are acting as representatives of the Underwriters. Subject to the terms and conditions in the underwriting agreement, we have agreed to issue and sell and each Underwriter named below has agreed, severally, to purchase from us upon the closing of this offering, on a firm commitment basis, the respective number of shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Dundee Securities Corporation	
Total	

The obligations of the Underwriters under the underwriting agreement are conditional and may be terminated at their discretion on the basis of their assessment of the state of the financial markets and may also be terminated upon the occurrence of certain stated events. The Underwriters are, however, severally obligated to take up and pay for all shares of our common stock they have obligated themselves to purchase if any of the shares are purchased under the underwriting agreement. However, the Underwriters are not required to take or pay for the shares covered by the over-allotment option described below.

The offering is being made concurrently in the United States and in British Columbia, Alberta, Manitoba and Ontario, Canada. The shares of our common stock will be offered in the United States through those Underwriters or their United States affiliates who are registered to offer the shares for sale in the United States and such other registered dealers as may be designated by the Underwriters. The shares of our common stock will be offered in the relevant provinces of Canada through those Underwriters or their Canadian affiliates who are registered to offer the shares for sale in such provinces and such other registered dealers as may be designated by the Underwriters. Subject to applicable law, the Underwriters may offer the shares outside of the United States and Canada.

**Over-Allotment Option**

We have granted to the Underwriters an option to purchase up to an aggregate of shares of our common stock, exercisable solely to cover over-allotments, if any, at the public offering price less the underwriting discounts and commissions shown on the cover page of this prospectus. The Underwriters may exercise this option in whole or in part at any time until 30 days after the closing of this offering. To the extent the Underwriters exercise this option, each Underwriter will be committed, so long as the conditions of the underwriting agreement are satisfied, to purchase a number of shares from us proportionate to that Underwriter's initial commitment as indicated in the preceding table. We will be obligated to issue and sell the shares to the Underwriters to the extent the option is exercised. This prospectus also qualifies the grant of this option and the distribution of the common shares transferable upon the exercise of this option.

**Commissions and Expenses**

The Underwriters have advised us that they propose to offer the common stock directly to the public at the public offering price presented on the cover page of this prospectus, and to selected dealers, who may include the Underwriters, at the public offering price less a selling concession not in excess of \$ per share. The Underwriters may allow, and the selected dealers may reallow, a concession not in excess of \$ per share to brokers and dealers. If all the shares are not sold at the initial public offering price, the Underwriters may decrease and thereafter further change, from time to time, the public offering price to an amount not greater than

**Table of Contents**

the initial public offering price and may change other selling terms, and the compensation realized by the Underwriters will be decreased by the amount that the aggregate price paid by purchasers for the shares is less than the gross proceeds paid by the Underwriters to us. The public offering price for the shares offered in the United States is payable in U.S. dollars and the public offering price for the shares offered in Canada is payable in Canadian dollars. The Canadian dollar amount is the equivalent of the U.S. price of the shares based on the prevailing U.S.-Canadian dollar exchange rate on the date of the underwriting agreement.

The following table summarizes the underwriting discounts and commissions that we will pay to the Underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the Underwriters' option to purchase additional shares of common stock.

	No Exercise	Full Exercise
Discounts and commissions per share	\$	\$
Total discounts and commissions paid by us	\$	\$

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.

We have also agreed to grant to the Underwriters broker warrants that include the option to purchase an amount of our common stock equal to up to 7% of the number of shares sold pursuant to this offering (including the over-allotment option) at the offering price of the shares. The warrants are not exercisable until one year after the closing of this offering. These warrants are not assignable and will expire 3 years after the closing of this offering, subject to regulatory approval. The warrants have certain rights of registration in the United States of the common stock issuable upon exercise of the warrants.

In connection with the execution of an engagement letter with Dundee Securities Corporation ( Dundee ) related to this offering, we paid a non-refundable work fee to Dundee in the amount of \$10,000. Upon the successful completion of this offering, the work fee will be credited to us by Dundee against the Underwriters' commission; and conditioned on the successful completion of this offering, we granted to Dundee for the term of the engagement letter, and for the twelve month period following the term, a right of first refusal to participate as financial advisor and capital markets advisor, co-manager, co-placement agent or co-arranger, as the case may be, for any public offering or private placement of our equity, equity-linked or debt (including, without limitation, asset-backed securities or mezzanine financing). The term of the engagement letter will terminate on the earlier of (a) June 30, 2007, (b) the execution of an underwriting agreement related to this offering, and (c) the termination of the engagement letter by either us or Dundee upon thirty days' prior written notice.

We estimate that the total expenses of the offering, including prospectus, registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately \$ .

**Lock-Up Agreements**

We have agreed not to issue, without the consent of the Underwriters, during the period ending 180 days after the closing of this offering, any additional shares of our common stock or securities convertible or exchangeable into shares of our common stock, or rights to acquire any such securities. In addition, our President and Chief Executive Officer will enter into a lock-up agreement prior to the closing of the offering pursuant to which he will agree not to sell, transfer or otherwise assign or charge any of his securities of NovaBay except pursuant to the following schedule: (i) 15% after six months following the closing of this offering, (ii) 25% after 12 months following the closing of this offering, (iii) 30% after 18 months following the closing of this offering, and (iv) the remaining 30% after 24 months following the closing of this offering. Each of our other directors and officers will enter into lock-up agreements prior to the closing of the offering pursuant to which they will agree

## **Table of Contents**

not to sell, transfer or otherwise assign or charge any of their securities of NovaBay except pursuant to the following schedule: (i) 50% after six months following the closing of this offering, (ii) 25% after nine months following the closing of this offering, and (iii) the remaining 25% after 12 months following the closing of this offering.

### **Offering Price Determination**

Prior to this offering, there has been no public market for our common stock. The initial public offering price has been negotiated between the representatives and us. Among the factors to be considered in determining the initial public offering price of our common stock will be the following:

prevailing market conditions;

our historical performance and capital structure;

estimates of our business potential and earnings prospects;

an overall assessment of our management; and

the consideration of these factors in relation to market valuation of companies in related businesses.

### **Listing on Stock Exchange**

We have applied to list our shares on the AMEX and on the TSX under the symbol NBY. Any such listing will be subject to the approval of the relevant stock exchange, and any such approval would not be given unless all of the original listing requirements were met.

### **Indemnification and Contribution**

We have agreed to indemnify the Underwriters against certain liabilities relating to the offering, including liabilities under the Securities Act and applicable securities laws in Canada, and to contribute to payments that the Underwriters may be required to make for these liabilities. If we are unable to provide this indemnification, we will contribute to payments the Underwriters and their controlling persons may be required to make in respect of those liabilities.

### **Stabilization, Short Positions and Penalty Bids**

The representatives may engage in over-allotment, stabilizing transactions, syndicate covering transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the U.S. Securities Exchange Act of 1934, as amended.

In addition, in accordance with rules and policy statements of certain Canadian provincial securities commissions, an Underwriter may not, throughout the period of distribution, bid for or purchase our common shares for its own account or the account of a person over which it exercises direction and control. Exceptions, however, exist where the bid or purchase is not made for the purpose of creating actual or apparent active trading in, or raising prices of, the common shares. These exceptions include a bid or purchase permitted under the by-laws and rules of applicable regulatory authorities, the Universal Market Integrity Rules for Canadian Marketplaces administered by Market Regulation Services Inc., the TSX and AMEX relating to market stabilization and passive market making activities and a bid or purchase made for and on behalf of a customer where the order was not solicited during the period of distribution.

Over-allotment transactions involve sales by the Underwriters of shares in excess of the number of shares the Underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-





## **Table of Contents**

allotted by the Underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The Underwriters may close out any short position by either exercising their over-allotment option and/or purchasing shares in the open market.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

Syndicate covering transactions involve purchases of our common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the Underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the Underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the Underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the TSX, AMEX or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the Underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the Underwriters make any representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

## **Directed Share Program**

At our request, the Underwriters have reserved up to \_\_\_\_\_ shares, or \_\_\_\_\_ % of the shares offered by this prospectus, for sale under a directed share program to our officers, directors, employees and related parties, immediate family members and entities of which employees or family members are the sole beneficiaries. All of the persons purchasing such reserved shares must commit to purchase them upon the date of this prospectus but no later than the close of business on the day following that date. The number of shares available for sale to the general public will be reduced to the extent these persons purchase the reserved shares. Shares committed to be purchased by directed share program participants which are not so purchased will be reallocated for sale to the general public in this offering. All sales of shares pursuant to the directed share program will be made at the initial public offering price set forth on the cover page of this prospectus.

## **Affiliations**

The Underwriters and their affiliates may provide certain commercial banking, financial advisory and investment banking services for us for which they receive fees. The Underwriters and their affiliates may from time to time in the future engage in transactions with us and perform services for us in the ordinary course of their business

**Table of Contents**

**NOTICE TO INVESTORS**

**European Economic Area**

With respect to each Member State of the European Economic Area which has implemented Prospectus Directive 2003/71/EC, including any applicable implementing measures, from and including the date on which the Prospectus Directive is implemented in that Member State, the offering of our shares in this offering is only being made:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than 443,000,000 and (iii) an annual net turnover of more than 450,000,000, as shown in its last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

**United Kingdom**

Our shares may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000 (FSMA) with respect to anything done in relation to our shares in, from or otherwise involving the United Kingdom. In addition, any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) in connection with the issue or sale of our shares may only be communicated in circumstances in which Section 21(1) of the FSMA does not apply to us. Without limitation to the other restrictions referred to herein, this offering circular is directed only at (1) persons outside the United Kingdom; (2) persons having professional experience in matters relating to investments who fall within the definition of investment professionals in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005; or (3) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Without limitation to the other restrictions referred to herein, any investment or investment activity to which this offering circular relates is available only to, and will be engaged in only with, such persons, and persons within the United Kingdom who receive this communication (other than persons who fall within (2) or (3) above) should not rely or act upon this communication.

**Switzerland**

Our shares may be offered in Switzerland only on the basis of a non-public offering. This prospectus does not constitute an issuance prospectus according to articles 652a or 1156 of the Swiss Federal Code of Obligations or a listing prospectus according to article 32 of the Listing Rules of the Swiss exchange. Our shares may not be offered or distributed on a professional basis in or from Switzerland and neither this prospectus nor any other offering material relating to our shares may be publicly issued in connection with any such offer or distribution. The shares have not been and will not be approved by any Swiss regulatory authority. In particular, the shares are not and will not be registered with or supervised by the Swiss Federal Banking Commission, and investors may not claim protection under the Swiss Investment Fund Act.

**Table of Contents**

**LEGAL MATTERS**

The validity of the issuance of the shares of common stock offered by this prospectus will be passed upon for us by Dorsey & Whitney LLP, as to matters of U.S. law, and Fasken Martineau DuMoulin LLP, as to matters of Canadian law. Legal matters relating to the sale of common stock in this offering will be passed upon for the underwriters by Skadden, Arps, Slate, Meagher & Flom LLP, as to matters of U.S. law, and Blake, Cassels & Graydon LLP, as to matters of Canadian law.

**EXPERTS**

The financial statements as of December 31, 2006 and 2005 and for each of the years in the three year period ended December 31, 2006 included in this prospectus have been audited by Davidson & Company LLP, independent registered public accountants, as indicated in their reports with respect thereto, and are included herein in reliance upon the authority of said firm as experts in auditing and accounting in giving said reports. The offices of Davidson & Company LLP are located at 1200-609 Granville Street, P.O. Box 10372, Pacific Centre, Vancouver, B.C. V7Y 1G6.

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement on Form S-1 with the SEC under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and our common stock, please see the registration statement and the exhibits and schedules filed with the registration statement.

Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The registration statement, including its exhibits and schedules, may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov). We will also be subject to the informational requirements of the securities commissions in all provinces of Canada. In this respect, we intend to file certain reports, statements or other information with the Canadian provincial securities commissions. These filings, other than confidential filings, are electronically available from the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>), the Canadian equivalent of the SEC's electronic document gathering and retrieval system.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and on the SEC website referred to above.

Upon the filing of a final prospectus with the securities regulatory authorities in the provinces of Canada in which shares of our common stock are being offered pursuant hereto, we will become a reporting issuer under the securities laws of those jurisdictions that provide for a reporting issuer regime. Pursuant to the rules of the securities regulatory authorities of such jurisdictions, we are generally exempt from the requirements of the laws of such jurisdictions relating to continuous disclosure and proxy solicitation. Our insiders may also, in certain circumstances, be exempt from Canadian insider reporting requirements. These rules generally permit us to comply with certain informational requirements applicable in the U.S. instead of the continuous disclosure requirements normally applicable in such Canadian jurisdictions, provided that the relevant documents are filed with the securities regulatory authorities in the relevant Canadian jurisdictions and are provided to security holders in Canada to the extent and in the manner and within the time required by applicable U.S. requirements. These filings will be electronically available from the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>).

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets as of December 31, 2005 and 2006</u>	F-3
<u>Statements of Operations for the Years Ended December 31, 2004, 2005, and 2006 and for the Cumulative Period from July 1, 2002 (date of development stage inception) to December 31, 2006</u>	F-4
<u>Statements of Stockholders' Equity as of December 31, 2002, 2003, 2004, 2005 and 2006</u>	F-5
<u>Statements of Cash Flows for the Years Ended December 31, 2004, 2005, and 2006 and for the Cumulative Period from July 1, 2002 (date of development stage inception) to December 31, 2006</u>	F-7
<u>Notes to Financial Statements</u>	F-8

F-1

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and the Stockholders of

NovaBay Pharmaceuticals, Inc.

(formerly NovaCal Pharmaceuticals, Inc.)

We have audited the accompanying balance sheets of NovaBay Pharmaceuticals, Inc. (formerly NovaCal Pharmaceuticals, Inc.) (a development stage company) as at December 31, 2006 and 2005 and the related statements of operations, cash flows and stockholders' equity for the years ended December 31, 2006, 2005 and 2004 and the period from July 1, 2002 (date of development stage inception) to December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as at December 31, 2006 and 2005 and the results of its operations and its cash flows for the years ended December 31, 2006, 2005 and 2004 and the period from July 1, 2002 (date of development stage inception) to December 31, 2006 in conformity with generally accepted accounting principles in the United States of America.

/s/ Davidson & Company LLP

Chartered Accountants

Vancouver, Canada

February 15, 2007 (except as to Note 14

which is as of April 18, 2007)

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**BALANCE SHEETS**

(in thousands, except per share data)

	December 31,		Pro Forma Stockholders Equity at December 31, 2006 (unaudited)
	2005	2006	
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 2,208	\$ 4,903	
Short-term investments	1,004	6,183	
Prepaid expenses and other current assets	83	226	
Total current assets	3,295	11,312	
Property and equipment, net	267	554	
<b>TOTAL ASSETS</b>	<b>\$ 3,562</b>	<b>\$ 11,866</b>	
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
Liabilities:			
Current liabilities:			
Accounts payable	\$ 137	\$ 365	
Accrued liabilities	173	521	
Deferred revenue		2,500	
Total current liabilities	310	3,386	
Deferred revenue non-current		6,667	
Total liabilities	310	10,053	
Commitments and contingencies (note 7)			
Stockholders Equity:			
Convertible preferred stock			
Series A, \$0.01 par value; 4,000 shares authorized at all periods; issued and outstanding, 3,215 at all periods; no shares outstanding pro forma; liquidation value of \$1,286 at all periods	32	32	
Series B, \$0.01 par value; 7,000 shares authorized at all periods; issued and outstanding, 6,865 at all periods; no shares outstanding pro forma; liquidation value of \$3,226 at all periods	69	69	
Series C preferred stock, \$0.01 par value; 8,000 shares authorized at all periods; issued and outstanding, 6,666 at all periods; no shares outstanding pro forma; liquidation value of \$5,667 at all periods	67	67	
Series D preferred stock, \$0.01 par value; 20,000 shares authorized; issued and outstanding, 742 at December 31, 2005 and 2,481 at December 31, 2006; no shares outstanding pro forma; liquidation value of \$1,113 at December 31, 2005 and \$3,722 at December 31, 2006	7	24	
Total convertible preferred stock	175	192	
Common stock, \$0.01 par value; authorized, 64,000 shares at all periods issued and outstanding, 10,099 at December 31, 2005 and 12,623 at December 31, 2006; 31,850 shares outstanding pro forma	101	126	\$ 318
Additional paid-in capital	10,768	14,557	14,557
Accumulated other comprehensive income (loss)	(4)	12	12



## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Accumulated deficit during development stage	(7,788)	(13,074)	(13,074)
Total stockholders' equity	3,252	1,813	\$ 1,813
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 3,562</b>	<b>\$ 11,866</b>	

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

F-3

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.****(formerly NovaCal Pharmaceuticals, Inc.)****(a development stage company)****STATEMENTS OF OPERATIONS****(in thousands, except per share data)**

	Year Ended December 31,			Cumulative Period from July 1, 2002 (date of development stage inception) to December 31, 2006
	2004	2005	2006	
<b>REVENUE</b>				
License and collaboration revenue	\$	\$	\$ 1,533	\$ 1,533
Total revenue			1,533	1,533
<b>EXPENSES</b>				
Operating Expenses:				
Research and development	1,481	1,952	4,087	7,991
General and administrative	1,345	1,617	2,972	6,960
Total operating expenses	2,826	3,569	7,059	14,951
Other income, net	22	106	240	344
Net loss before income taxes	(2,804)	(3,463)	(5,286)	(13,074)
Provision for income taxes				
Net loss	\$ (2,804)	\$ (3,463)	\$ (5,286)	\$ (13,074)
Net loss per share:				
Basic and diluted	\$ (0.32)	\$ (0.36)	\$ (0.46)	
Shares used in per share calculations:				
Basic and diluted	8,755	9,704	11,429	
Pro forma net loss per share (unaudited):				
Basic and diluted			\$ (0.18)	
Shares used in pro forma per share calculations (unaudited):				
Basic and diluted			29,935	
Stock-based compensation expense included above:				
Research and development	\$ 11	\$ 55	\$ 86	\$ 169
General and administrative		16	281	297
Total stock-based compensation expense	\$ 11	\$ 71	\$ 367	\$ 466

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



**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**STATEMENTS OF STOCKHOLDERS EQUITY**

(in thousands)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Stockholders Equity
	Shares	Amount	Shares	Amount					
<b>Balance at July 1, 2002</b>		\$		\$	\$	\$	\$	\$	\$
Comprehensive loss:									
Net loss							(544)		(544)
Comprehensive loss									(544)
Issuance of Series A preferred stock and common stock for acquisition of LLC	2,723	27	7,804	78	423				528
Issuance of stock options for services					15				15
Sale of stock warrants					10				10
<b>Balance at December 31, 2002</b>	2,723	27	7,804	78	448		(544)		9
Comprehensive loss:									
Net loss							(977)		(977)
Comprehensive loss									(977)
Issuance of Series A preferred stock	492	5			192				197
Issuance of Series B preferred stock net of issuance costs of \$86	3,258	33			1,413				1,446
Issuance of stock			50		7				7
Issuance of stock for option exercises			80	1	7				8
Issuance of stock for warrant exercises			274	3	107				110
Issuance of stock options for services					2				2
<b>Balance at December 31, 2003</b>	6,473	65	8,208	82	2,176		(1,521)		802
Comprehensive loss:									
Net loss							(2,804)		(2,804)

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Comprehensive loss								(2,804)
Issuance of Series B preferred stock net of issuance costs of \$127	2,694	27			1,112			1,139
Issuance of Series B preferred stock upon conversion of notes	913	9			420			429
Issuance of Series C preferred stock net of issuance costs of \$123	6,311	63			5,178	(873)		4,368
Issuance of stock for option exercises			10		1			1
Issuance of stock for warrant exercises			63	1	36			37
Issuance of stock for Series B offering costs			735	7	103			110
Issuance of stock for services			30		4			4
Issuance of stock options for services					7			7
<b>Balance at December 31, 2004</b>	16,391	164	9,046	90	9,037	(873)	(4,325)	4,093

F-5

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**STATEMENTS OF STOCKHOLDERS EQUITY (Continued)**

(in thousands)

	Preferred Stock		Common Stock			Additional Paid In Capital	Stock Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Amount					
Comprehensive loss:										
Net loss									(3,463)	(3,463)
Change in unrealized gains (losses) on investments, net of tax								(4)		(4)
Comprehensive loss										(3,467)
Issuance of Series C preferred stock net of issuance costs of \$140	355	4			158					162
Issuance of Series D preferred stock net of issuance costs of \$36	742	7			1,070					1,077
Issuance of stock for option exercises			100	1	11					12
Issuance of stock for warrant exercises			584	6	321					327
Issuance of stock and options for Series C offering costs			329	3	100					103
Issuance of stock for services			40	1	16					17
Issuance of stock options for services					55					55
Proceeds from stock subscription receivable							873			873
<b>Balance at December 31, 2005</b>	<b>17,488</b>	<b>175</b>	<b>10,099</b>	<b>101</b>	<b>10,768</b>			<b>(4)</b>	<b>(7,788)</b>	<b>3,252</b>
Comprehensive loss:										
Net loss									(5,286)	(5,286)
Change in unrealized gains (losses) on investments, net of tax								16		16
Comprehensive loss										(5,270)
Issuance of Series D preferred stock net of issuance costs of \$114	1,739	17			2,477					2,494
Issuance of stock for option exercises			159	1	22					23
Issuance of stock for warrant exercises			2,298	23	953					976
Issuance of stock and options for Series D offering costs			61	1	63					64
Stock-based compensation expense related to employee and director stock options					313					313

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Issuance of stock for services					6					5										5	
Issuance of stock options for services																				49	49
Initial public offering costs																				(93)	(93)
<b>Balance at December 31 2006</b>	19,227	\$	192	12,623	\$	126	\$	14,557	\$		\$	12	\$	(13,074)	\$						1,813

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

F-6

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,			Cumulative Period
	2004	2005	2006	from July 1, 2002 (date of development stage inception) to December 31, 2006
<b>Cash flows from operating activities:</b>				
Net loss	\$ (2,804)	\$ (3,463)	\$ (5,286)	\$ (13,074)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	40	48	74	217
Loss on disposal of property and equipment	120		1	121
Net realized (gain) loss on sales of short-term investments		12	(12)	
Stock-based compensation expense for options issued to employees and directors			313	313
Stock-based compensation expense for options and stock issued to non-employees	11	71	54	153
Taxes paid by LLC				1
Changes in operating assets and liabilities:				
(Increase) decrease in prepaid expenses and other assets	(100)	38	(143)	(221)
Increase in accounts payable and accrued liabilities	193	64	576	911
Increase in deferred revenue			9,167	9,167
Net cash provided by (used in) operating activities	(2,540)	(3,230)	4,744	(2,412)
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(162)	(123)	(362)	(887)
Proceeds from disposal of property and equipment	1	1	1	43
Purchases of short-term investments		(1,957)	(11,293)	(13,250)
Proceeds from maturities and sales of short-term investments		936	6,141	7,077
Cash acquired in purchase of LLC				516
Net cash used in investing activities	(161)	(1,143)	(5,513)	(6,501)
<b>Cash flows from financing activities:</b>				
Proceeds from preferred stock issuances, net	5,617	1,342	2,558	11,160
Proceeds from common stock issuances				7
Proceeds from exercise of options and warrants	38	339	999	1,494
Initial public offering costs			(93)	(93)
Proceeds from stock subscription receivable		873		873
Proceeds from sale of warrant rights				10
Proceeds from issuance of notes				405



Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Principal payments on capital lease	(11)	(20)		(40)
Net cash provided by financing activities	5,644	2,534	3,464	13,816
Net increase (decrease) in cash and cash equivalents	2,943	(1,839)	2,695	4,903
Cash and cash equivalents, beginning of period	1,104	4,047	2,208	
Cash and cash equivalents, end of period	\$ 4,047	\$ 2,208	\$ 4,903	\$ 4,903
Supplemental disclosure of cash flow information:				
Interest paid	\$ 3	\$ 1	\$ 2	\$ 10
Income taxes paid	\$	\$	\$	\$
Non-cash activities:				
Conversion of notes and accrued interest to preferred stock	\$ 429	\$	\$	\$ 429
Issuance of stock for subscription receivable	\$ 873	\$	\$	\$ 873
Issuance of stock and options for stock offering costs	\$ 110	\$ 103	\$ 64	\$ 277
Net unrealized gains (losses) on short-term investments	\$	\$ (6)	\$ 18	\$ 12
Current assets acquired in acquisition of LLC	\$	\$	\$	\$ 2
Property and equipment acquired in acquisition of LLC	\$	\$	\$	\$ 9

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

F-7

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**NOTE 1. ORGANIZATION**

NovaBay Pharmaceuticals, Inc. ( NovaBay or the Company) is 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.

NovaBay has developed a novel 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 antimicrobial area. Our antimicrobial compounds are based upon small molecules that are generated by white blood cells and that enable them to perform their function of defending the body against invading pathogens. In the body these compounds are produced on demand and are transient. We have focused our efforts on understanding these molecules and finding ways, primarily by chemical modification, to impart qualities to allow them to be developed as therapeutic products.

Our current development efforts are focused on Aganocide compounds to treat patients with infections of the eye, ear and sinus, to create an improved environment for the healing of wounds, whether chronic or acute, and to prevent infections that either 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. NovaBay operates in one business segment.

NovaCal Pharmaceuticals, Inc. was incorporated under the laws of the State of California on January 19, 2000. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC ( LLC ), a California limited liability company, in exchange for the issuance of 7.8 million and 2.7 million shares of our common stock and Series A preferred stock, respectively. Additionally, we issued warrant rights to purchase 832,000 shares of common stock and an offer to sell warrant rights to purchase an aggregate of 257,000 shares of common stock to certain holders of common and preferred units of the LLC. Under this transaction, we acquired cash, property and equipment, and other current assets of \$516,000, \$9,000 and \$2,000, respectively. The transaction was accounted for using the purchase method of accounting.

In February 2007, we changed our name to NovaBay Pharmaceuticals, Inc. See Note 14 for information pertaining to the corporate name change.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ) and are expressed in U.S. dollars. The financial statements have been prepared under the guidelines of Statement of Financial Accounting Standard ( SFAS ) No. 7, Accounting and Reporting by Development Stage Enterprises . A development stage enterprise is one in which planned principal operations have not commenced, or if its operations have commenced, there have been no significant revenues therefrom. As of December 31, 2006, we have not commenced our planned principal operations.

***Use of Estimates***

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities the disclosure of contingent

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

***Cash and Cash Equivalents and Short-Term Investments***

We consider all highly liquid instruments with a stated maturity of three months or less to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value, based on quoted market prices. Cash is deposited in institutions that are generally federally insured in limited amounts.

We classify all highly liquid investments with a stated maturity of greater than three months as short-term investments. We have classified our short-term investments as available-for-sale. The Company does not intend to hold securities with stated maturities greater than twelve months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company occasionally sells these securities prior to their stated maturities. All short-term investments are recorded at fair value and unrealized gains and losses are recorded as a separate component of stockholders' equity (deficit) until realized. Realized gains and losses on sale of all such securities are reported in earnings, computed using the specific identification cost method.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight line method over the estimated useful lives of the related assets of five to seven years for office and lab equipment, three years for software and seven years for furniture and fixtures. Leasehold improvements are depreciated on the shorter of seven years or the life of the lease term.

The costs of normal maintenance, repairs, and minor replacements are charged to operations when incurred.

***Fair Value of Financial Instruments***

The carrying values of financial instruments such as cash and cash equivalents, short-term investments, accounts payable, and accrued liabilities approximate their fair values due to the short settlement period for these instruments.

***Impairment of Long-Lived Assets***

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

***Accumulated Other Comprehensive Income (Loss)***

Accumulated other comprehensive income (loss) consists of net income and other related gains and losses affecting stockholders' equity that, under generally accepted accounting principles, are excluded from net



**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

income. At December 31, 2005 and 2006, other comprehensive income (loss) consisted of net unrealized gains and losses on short-term investments classified as available-for-sale. We had no other comprehensive income (loss) items during 2002, 2003 and 2004.

***Revenue Recognition***

License and collaboration revenue is primarily generated through an agreement with a strategic partner for the development and commercialization of our product candidates. The Company may enter into additional agreements with other strategic partners as opportunities arise. The terms of such agreements may include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with Emerging Issues Task Force ( EITF ) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables , we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period. We recognize revenue in accordance with SEC Staff Accounting Bulletin ( SAB ) No. 101, Revenue Recognition in Financial Statements , as amended by SAB No. 104 (together, SAB 104 ). In accordance with SAB 104, revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured.

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

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

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

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

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

***Advertising Costs***

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

***Research and Development Costs***

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

***Patent Costs***

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

***Stock-Based Compensation***

On January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method. The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified.

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

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

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

---

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Income Taxes***

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

***Net Income (Loss) per Share***

We compute net income (loss) per share in accordance with SFAS No. 128, *Earnings per Share* which requires presentation of both basic and diluted earnings (loss) per share ( *EPS* ).

Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and stock warrants, using the treasury stock method, and convertible preferred stock, using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods as their effect would be anti-dilutive. See Note 13 for further information regarding the calculation of net income (loss) per share.

***Recently Issued Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board ( *FASB* ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( *FIN 48* ). FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. FIN 48 prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently assessing the impact of FIN 48 on our financial position and results of operations.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* . SAB No. 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year's financial statements are materially misstated. SAB No. 108 is effective for fiscal years ending on or after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* . SFAS No. 157 establishes a framework for measuring the fair value of assets and liabilities. This framework is intended to provide increased consistency in how fair value determinations are made under various existing accounting standards which permit, or in some cases require, estimates of fair market value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year,

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (Continued)**

including any financial statements for an interim period within that fiscal year. We are currently assessing the impact of SFAS No. 157 on our financial position and results of operations.

In September 2006, the FASB issued SFAS No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans*. SFAS No. 158 requires that employers recognize on a prospective basis the funded status of their defined benefit pension and other postretirement benefit plans on their consolidated balance sheet and recognize as a component of other comprehensive income (loss), net of tax, the gains or losses and prior service costs or credits that arise during the period but are not recognized as components of net periodic benefit cost. The adoption of SFAS No. 158 did not have a material impact on our financial position or results of operations.

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

**NOTE 3. SHORT-TERM INVESTMENTS**

Short-term investments at December 31, 2005 and December 31, 2006 consisted of the following:

	Amortized Cost	December 31, 2005		Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	
		(in thousands)		
Corporate bonds	\$ 334	\$	(4)	\$ 330
U.S. Treasuries	551	2	(3)	550
U.S. Agencies	125		(1)	124
Total	\$ 1,010	\$ 2	\$ (8)	\$ 1,004

	Amortized Cost	December 31, 2006		Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	
		(in thousands)		
Corporate bonds	\$ 3,778	\$ 8	\$	\$ 3,786
Municipal bonds	200			200
U.S. Agencies	2,193	4		2,197
Total	\$ 6,171	\$ 12	\$	\$ 6,183





**Table of Contents****NOVABAY PHARMACEUTICALS, INC.****(formerly NovaCal Pharmaceuticals, Inc.)****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

Contractual maturities of short-term investments as of December 31, 2005 and 2006 were as follows:

	December 31, 2005		December 31, 2006	
	Amortized Cost	Market Value	Amortized Cost	Market Value
	(in thousands)			
Due in one year or less	\$ 233	\$ 233	\$ 4,771	\$ 4,783
Due in one to five years	303	300		
Due in five to ten years	354	350		
Due after ten years	120	121	1,400	1,400
<b>Total</b>	<b>\$ 1,010</b>	<b>\$ 1,004</b>	<b>\$ 6,171</b>	<b>\$ 6,183</b>

We recognized a net realized loss on sales or maturities of short-term investments of \$12,000 during the year ended December 31, 2005 and a net realized gain of \$12,000 during the year ended December 31, 2006.

**NOTE 4. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

	December 31,	
	2005	2006
	(in thousands)	
Office and laboratory equipment	\$ 242	\$ 550
Furniture and fixtures	58	88
Software	13	31
Leasehold equipment	33	36
<b>Total property and equipment, cost</b>	<b>346</b>	<b>705</b>
Less: accumulated depreciation	(79)	(151)
<b>Total property and equipment, net</b>	<b>\$ 267</b>	<b>\$ 554</b>

## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Depreciation expense was \$40,000, \$48,000, and \$74,000 for the years ended December 31, 2004, 2005 and 2006, respectively, and \$217,000 for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2006.

### NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

	December 31,	
	2005	2006
	(in thousands)	
Research and development	\$ 99	\$ 225
Employee payroll and benefits	74	119
Professional fees		143
Other		34
<b>Total accrued liabilities</b>	<b>\$ 173</b>	<b>\$ 521</b>

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (Continued)****NOTE 6. CAPITAL LEASE OBLIGATION**

During 2005, we leased \$40,000 of property and equipment under a capital lease with California Pacific Labs, Inc., a related party. Accumulated depreciation associated with the leased equipment was \$18,000 at December 31, 2005. Effective December 31, 2005, we exercised our option to terminate the lease and purchased the equipment at the remaining lease obligation amount of \$8,000.

In December 2006, we entered into a lease to finance the purchase of laboratory equipment. Under the terms of the arrangement, we will lease \$149,000 of equipment over a 36 month term. The arrangement will be accounted for as a capital lease. At December 31, 2006, we had not yet received the equipment to be leased under this arrangement and therefore, no capital asset or corresponding liability was recorded.

**NOTE 7. COMMITMENTS AND CONTINGENCIES***Lease Commitments*

We lease laboratory facilities and office space under operating leases which expire at various dates through 2011. Rent expense was \$103,000, \$270,000 and \$317,000 for the years ended December 31, 2004, 2005, and 2006, respectively. For the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2006, rent expense was \$795,000.

The future minimum operating lease commitments were as follows as of December 31, 2006:

	<b>Lease Commitment (in thousands)</b>
Year ending December 31:	
2007	\$ 474
2008	519
2009	480
2010	189
2011	195
<b>Total lease commitment</b>	<b>\$ 1,857</b>

**NOTE 8. STOCKHOLDERS EQUITY***Convertible Preferred Stock*

In 2002 and 2003, we issued 3.2 million shares of Series A Convertible Preferred Stock ( Series A ) for net proceeds of \$647,000. In 2003 and 2004, we issued 6.9 million shares of Series B Convertible Preferred Stock ( Series B ) for net proceeds of \$3.0 million. In 2004 and 2005, we issued 6.7 million shares of Series C Convertible Preferred Stock ( Series C ) for net proceeds of \$5.4 million. In 2005 and 2006, we issued 2.5 million shares of Series D Convertible Preferred Stock ( Series D ) for net proceeds of \$3.6 million. Preferred shares authorized were 19 million at December 31, 2004 and 39 million at December 31, 2005 and 2006.



**Table of Contents****NOVABAY PHARMACEUTICALS, INC.****(formerly NovaCal Pharmaceuticals, Inc.)****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

Significant terms of the Series A, Series B, Series C and Series D are as follows:

Preferred stock is convertible into common stock at the option of the shareholder or automatically in the event of a public offering of our common stock or in the event we are acquired at a price that exceeds the liquidation preference of the outstanding preferred stock. The conversion rate is one to one, subject to anti-dilution adjustments.

The preferred stock have liquidation preferences equal to \$0.40 for Series A, \$0.47 for Series B, \$0.85 for Series C and \$1.50 for Series D.

Voting rights are equal to those of the underlying common stock, except that Series B holders have the right to elect one member of the Board of Directors and holders of Series C and Series D voting together have the right to elect one member of the Board of Directors.

Dividends are payable at the discretion of the Board. In the event that dividends are declared on common stock, holders of preferred stock shall be entitled to receive \$0.02 per share. To date, no dividends have been declared.

In the event that we issue shares to investors under terms that are more favorable to those investors than those granted to the Series D within a certain time period, then the Series D holders have the right to exchange their stock for new stock issued under the more favorable terms.

***Common Stock***

The holders of common stock are entitled to one vote per share on matters submitted to shareholders. The common stock carries dividends as declared by the Board. As of December 31, 2006, we have not declared any dividends to the holders of our common stock.

The number of authorized shares of common stock to be issued was amended by NovaBay's Board of Directors on May 20, 2004 and June 9, 2005 to 44 million and 64 million shares, respectively. The following table summarizes the common shares available for issuance:

	<b>December 31,</b>	
	<b>2005</b>	<b>2006</b>
	<b>(in thousands)</b>	
Authorized	64,000	64,000
Issued and outstanding	(10,099)	(12,623)
Available for issuance	53,901	51,377

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

*Reserved for future issuance:*

For conversion of Series A	3,215	3,215
For conversion of Series B	6,865	6,865
For conversion of Series C	6,666	6,666
For conversion of Series D	742	2,481
Outstanding stock warrants	2,656	
Outstanding stock options	3,565	4,791
Possible future issuance under stock option plans	2,424	836
Total reserved for future issuance	26,133	24,854

F-16

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.****(formerly NovaCal Pharmaceuticals, Inc.)****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)****Stock Warrants**

Stock warrants to acquire shares of common stock were issued in connection with the sales of Series A and Series B and the convertible notes. The significant terms of the Series A, Series B and Note Warrants were as follows:

*Series A Warrants* The warrants issued with the sale of Series A were issued on the basis of 0.40 of a warrant for every share of Series A purchased. The warrants expired on July 1, 2005, except for later purchases for which the expiration date was extended to July 1, 2006. The exercise price of these warrants was \$0.60. We extended a limited-time offer to holders of the warrants to exercise them at a price of \$0.40.

*Series B Warrants* The warrants issued with the sale of Series B were issued on the basis of 0.35 of a warrant for every share of Series B purchased. The warrants expired on June 30, 2006. The exercise price of these warrants was \$0.40.

*Note Warrants* Stock warrants were granted in connection with promissory notes issued to certain of our shareholders in 2002 and 2003. The notes converted into shares of our Series B preferred stock in January of 2004. The stock warrants issued to these shareholders had an exercise price of \$0.60 and an expiration date of June 30, 2006.

The following table summarizes our stock warrant activities:

	Warrants (in thousands, except per share data)	Weighted Average Exercise Price
Balance at December 31, 2004	3,486	\$ 0.46
Warrants issued	5	\$ 0.40
Warrants expired	(251)	\$ 0.60
Warrants exercised	(584)	\$ 0.56
Balance at December 31, 2005	2,656	\$ 0.43
Warrants issued		
Warrants expired	(358)	\$ 0.45
Warrants exercised	(2,298)	\$ 0.43
Balance at December 31, 2006		

**Stock Option Plans**



## Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

We have two stock option plans. In June 2002, we adopted a stock option plan ( 2002 Plan ) under which 2.5 million shares of common stock had been reserved. In May 2003, the number of shares reserved under the 2002 Plan was increased to 4.5 million shares. In May 2005, we adopted an additional but substantially similar plan ( 2005 Plan ) under which 2.5 million shares of common stock were reserved for grant under the plan. Under these plans, options that terminate and expire may be re-issued. In conjunction with the adoption of the 2005 Plan, the Board stipulated that no further options may be granted from the 2002 Plan and any option terminations or expirations from the 2002 plan may not be re-issued. At December 31, 2005 and 2006, there were 2.4 million and 0.8 million options available for grant, respectively.

F-17

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The options typically expire ten years from the date of grant or three months from the end of an employee's employment with the Company. Options granted to employees generally vest over four years while options granted to directors, Advisory Board members and consultants typically vest over two years or less, subject to continued service. Under the terms of these plans, the option exercise price may not be less than 100% of the fair market value of the common stock on the date of grant. The Board of Directors estimates the fair market value of a share of common stock upon each grant of stock options. All of the options include early exercise provisions that allow for full exercise of the option prior to option vesting, subject to certain repurchase provisions.

**Stock Option Activity**

The following table summarizes our stock option activities:

	Year Ended December 31,			
	2005	2006	2005	2006
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
	(in thousands, except per share data)			
Outstanding and exercisable at beginning of period	3,286	\$ 0.16	3,565	\$ 0.23
Options granted	931	\$ 0.55	1,644	\$ 0.78
Options exercised	(100)	\$ 0.12	(159)	\$ 0.14
Options forfeited/cancelled	(552)	\$ 0.36	(259)	\$ 0.34
Outstanding and exercisable at end of period	3,565	\$ 0.23	4,791	\$ 0.42
Vested at end of period	2,808	\$ 0.25	3,263	\$ 0.33

The following table summarizes information about options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding and Exercisable			Options Vested	
	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (yrs)	Weighted Average Exercise Price	Number Vested	Weighted Average Exercise Price
	(in thousands, except per share data)				
\$0.10	1,502	6.23	\$ 0.10	1,237	\$ 0.10
\$0.15	920	7.43	\$ 0.15	575	\$ 0.15
\$0.28	656	7.96	\$ 0.28	579	\$ 0.28
\$0.47 - \$0.60	182	5.82	\$ 0.52	112	\$ 0.48
\$0.85	279	8.50	\$ 0.85	279	\$ 0.85
\$0.94 - \$1.00	26	8.50	\$ 0.94	26	\$ 0.94

3,565	7.03	\$ 0.23	2,808	\$ 0.25
-------	------	---------	-------	---------

F-18

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about options outstanding at December 31, 2006:

Range of Exercise Prices	Options Outstanding and Exercisable				Options Vested		
	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (yrs)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number Vested	Weighted Average Exercise Price	Aggregate Intrinsic Value
	(in thousands, except per share data)						
\$0.10	1,367	5.18	\$ 0.10		1,267	\$ 0.10	
\$0.15	865	6.76	\$ 0.15		575	\$ 0.15	
\$0.28	479	7.47	\$ 0.28		452	\$ 0.28	
\$0.47 - \$0.60	698	7.95	\$ 0.58		318	\$ 0.56	
\$0.85	1,278	9.17	\$ 0.85		625	\$ 0.85	
\$0.94 - \$1.00	104	9.35	\$ 0.98		26	\$ 0.94	
	4,791	7.25	\$ 0.42	\$ 3,468	3,263	\$ 0.33	\$ 2,648

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the fair value of our common stock at December 31, 2006. For the years ended December 31, 2004, 2005 and 2006, the aggregate intrinsic value of stock option awards exercised was \$1,800, \$16,000 and \$126,000, respectively, determined at the date of option exercise. We received cash payments in the amount of \$1,000, \$12,000 and \$23,000 for the exercise of stock options during the years ended December 31, 2004, 2005 and 2006, respectively.

***Valuation of Stock-Based Awards to Employees and Directors***

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

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

Assumption	Year Ended		
	2004	December 31, 2005	2006
Expected price volatility	0.0%	0.0%	74.0%
Expected life (in years)	10.0	10.0	5.7

Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Risk-free interest rate	4.2%	4.2%	4.8%
Dividend yield	0.0%	0.0%	0.0%
Weighted average fair value of options granted during the period	\$ 0.08	\$ 0.11	\$ 0.53

*Expected Price Volatility* This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. Prior to the adoption of SFAS No. 123R, we assumed 0% price volatility in accordance

F-19

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

with the minimum value method requirements of SFAS No. 123. In accordance with the fair value method of SFAS No. 123R, which we adopted on January 1, 2006, the computation of expected volatility for the year ended December 31, 2006 was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization data. An increase in the expected price volatility will increase the value of the option granted and the related compensation expense.

*Expected Life* This is the period of time over which the options granted are expected to remain outstanding and is based on management's estimate, taking into consideration vesting term, contractual term and historical actual lives. Options granted have a maximum term of ten years. An increase in the expected life will increase the value of the option granted and the related compensation expense.

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

*Dividend Yield* The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease the value of the option granted and the related compensation expense.

Under SFAS No. 123R, forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. For the year ended December 31, 2006, we applied an estimated forfeiture rate of 5% to employee grants and 0% to director grants. For the periods prior to January 1, 2006, we accounted for forfeitures as they occurred.

***Stock-Based Compensation Expense***

Upon the adoption of SFAS No. 123R on January 1, 2006, we began recognizing stock-based compensation expense in the statements of operations for all employee or director options granted or modified on or after January 1, 2006. Stock-based compensation expense is classified in the statements of operations in the same expense line items as cash compensation. No amounts were recognized for stock-based compensation paid to employees and directors in our statements of operations for any of the prior periods presented.

As of December 31, 2006, total unrecognized compensation cost related to unvested stock options granted or modified on or after January 1, 2006 was \$443,000. This amount is expected to be recognized as stock-based compensation expense in our Statements of Operations over the remaining weighted average vesting period of 2.0 years.

Prior to the adoption of SFAS No. 123R, we valued our stock-based awards using the minimum value method and provided pro-forma information regarding stock-based compensation and net income required by SFAS No. 123. We did not recognize stock-based compensation expense in our statements of operations for option grants to our employees or directors for the periods prior to our adoption of SFAS No. 123R because the exercise price of options granted was generally equal to the fair market value of the underlying common stock on the date of grant. Under the prospective application method, we continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. Pro forma disclosures for these awards are precluded.

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**NOTE 9. COLLABORATION AND LICENSE AGREEMENT**

***Alcon Manufacturing, Ltd.***

In August 2006, we entered into a Collaboration and License agreement with Alcon Manufacturing, Ltd. ( Alcon ) to license the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds to Alcon for application in connection with the eye, ear and sinus and for use in contact lens solution. Under the terms of the agreement, we received an up-front technology access fee of \$10.0 million in September 2006 and will receive semi-annual payments to support on-going research and development over the next four years. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compound.

The up-front technology access fee is expected to be amortized into revenue on a straight-line basis through August 2010. During the year ended December 31, 2006, we received a payment of \$700,000 for the research and development activities performed through December 31, 2006. We recognized revenue of \$1.5 million from the amortization of the up-front fee and funding of research and development activities during the year ended December 31, 2006.

**NOTE 10. EMPLOYEE BENEFIT PLAN**

We have a 401(k) plan covering all eligible employees. We are not required to contribute to the plan and have made no contributions through December 31, 2006.

**NOTE 11. LEGAL MATTERS**

From time to time, we may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at December 31, 2006 that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

**NOTE 12. INCOME TAXES**

We have not recorded a provision for income taxes for any of the periods presented. The difference between the expected provision for income taxes, based on the United States federal statutory rate of 34%, from our actual provision for income taxes, an effective tax rate of 0%, is attributable to the net deferred tax assets offset by a full valuation allowance.

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.****(formerly NovaCal Pharmaceuticals, Inc.)****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about our provision for income taxes for the years ended December 31, 2004, 2005 and 2006.

	Year Ended December 31,		
	2004	2005	2006
	(in thousands)		
<i>Current taxes payable:</i>			
Federal	\$	\$	\$
State			
Total current taxes payable			
<i>Deferred taxes:</i>			
Federal			461
State			79
Total deferred taxes			540
<i>Benefit of net operating loss:</i>			
Federal			(461)
State			(79)
Total benefit of net operating loss			(540)
Provision for income taxes	\$	\$	\$

Significant components of our deferred tax assets and liabilities as of December 31, 2005 and 2006 are as follows:

	December 31,	
	2005	2006
	(in thousands)	
<i>Deferred tax assets:</i>		
Net operating loss carryforwards	\$ 3,089	\$ 2,550
Deferred revenue		2,655
Accrued vacation	29	22
Contribution carryforwards		12
Total deferred tax assets	3,118	5,239
<i>Deferred tax liabilities:</i>		
Depreciation	20	30



Edgar Filing: NovaBay Pharmaceuticals, Inc. - Form S-1/A

Total deferred tax liabilities	20	30
Net deferred tax assets	3,098	5,209
Less: valuation allowance	(3,098)	(5,209)
	\$	\$

The net change in the valuation allowance for the years ended December 31, 2005 and 2006 was an increase of \$1.4 million and \$2.1 million, respectively. We believe that sufficient uncertainty exists regarding the future realization of deferred tax assets. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

**Table of Contents****NOVABAY PHARMACEUTICALS, INC.**

(formerly NovaCal Pharmaceuticals, Inc.)

(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

**NOTE 13. NET INCOME (LOSS) PER SHARE**

The components of net income (loss) per share were as follows:

	Year Ended December 31,		
	2004	2005	2006
	(in thousands,		
	except per share data)		
<b>Net loss per share basic and diluted:</b>			
Numerator:			
Net loss	\$ (2,804)	\$ (3,463)	\$ (5,286)
Denominator:			
Weighted-average number of common shares outstanding during the period	8,755	9,704	11,429
Net loss per share basic and diluted	\$ (0.32)	\$ (0.36)	\$ (0.46)
<b>Pro forma net loss per share basic and diluted (unaudited):</b>			
Numerator:			
Net loss			\$ (5,286)
Denominator:			
Weighted-average number of common shares outstanding during the period			11,429
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock			18,506
Shares used in pro forma per share calculation basic and diluted			29,935
Pro forma net loss per share basic and diluted			\$ (0.18)

The following outstanding stock options, stock warrants and preferred stock were excluded from the diluted EPS computation as their effect would be anti-dilutive.

	<b>2004</b>	<b>Year Ended December 31, 2005 (in thousands)</b>	<b>2006</b>
Stock options	3,286	3,565	4,791
Preferred stock warrants	3,486	2,656	
Convertible preferred stock	16,391	17,488	19,227

F-23

**Table of Contents**

**NOVABAY PHARMACEUTICALS, INC.**

**(formerly NovaCal Pharmaceuticals, Inc.)**

**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Pro forma net loss per share for the year ended December 31, 2006 was computed using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of the preferred stock into shares of common stock effective upon the closing of the offering as if such conversion occurred on January 1, 2006, or at the date of the original issuance, if later.

**NOTE 14. SUBSEQUENT EVENTS**

***Initial Public Offering***

During October 2006, we engaged an underwriter to facilitate the sale of shares of common stock in an initial public offering ( IPO ). Upon the closing of the IPO, all shares of the Series A, Series B, Series C and Series D will automatically convert into shares of common stock at a 1-for-1 conversion ratio. Based on the Company's outstanding shares as of December 31, 2006, if the IPO closes, all of the preferred stock outstanding will automatically convert into approximately 19.2 million shares of common stock.

***Corporate Name Change***

During January 2007, management made a preliminary recommendation to the Board of Directors and shareholders to rename the company NovaBay Pharmaceuticals, Inc. This matter was approved by the Board of Directors in February 2007. In February 2007, we changed our name to NovaBay Pharmaceuticals, Inc.

***Stock Issuance***

During February 2007, we issued 70,000 shares of common stock to one of our consultants as compensation for consulting services rendered to us.

**Table of Contents**

Through and including \_\_\_\_\_, 2007 (the 25th day after the date of this prospectus), U.S. federal securities law may require all dealers that effect transactions in these securities, whether or not participating in this offering, to deliver a prospectus. This requirement is in addition to the dealers' obligations to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

---

**Table of Contents**

**Alternate Page for Canadian Prospectus**

*A copy of this preliminary prospectus has been filed with the securities regulatory authorities in each of British Columbia, Alberta, Manitoba and Ontario but has not yet become final for the purpose of the sale of securities. Information contained in this preliminary prospectus may not be complete and may have to be amended. The securities may not be sold until a receipt for the prospectus is obtained from the securities regulatory authorities.*

*No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise.*

*This preliminary prospectus is a base PREP prospectus. This prospectus has been filed under procedures in British Columbia, Alberta, Manitoba and Ontario that permit certain information about these securities to be determined after the prospectus has become final and that permit the omission of that information from this prospectus. The procedures require the delivery to purchasers of a supplemented PREP prospectus containing the omitted information within a specified time after agreeing to purchase any of the securities. All disclosure contained in the supplemented PREP prospectus that is not contained in the base PREP prospectus will be incorporated by reference into the base PREP prospectus as of the date of the supplemented PREP prospectus.*

*This prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell these securities. NovaBay Pharmaceuticals, Inc. has filed a registration statement on Form S-1 with the United States Securities and Exchange Commission under the United States Securities Act of 1933, as amended, with respect to these securities. See Underwriting .*

**AMENDED AND RESTATED**

**PRELIMINARY BASE PREP PROSPECTUS**

Initial Public Offering

April 18, 2007

**NOVABAY PHARMACEUTICALS, INC.**

**U.S.\$•**

• Shares

This prospectus qualifies the distribution of shares of common stock of NovaBay Pharmaceuticals, Inc., the over-allotment option granted to the underwriters and the distribution of any shares of our common stock issuable upon exercise of the over-allotment option and the distribution of broker warrants granted to the underwriters. Unless otherwise noted, the terms NovaBay , we , our and us refer to NovaBay Pharmaceuticals, Inc. A total of • shares of common stock are being offered. We are offering our shares of common stock concurrently in Canada under the terms of this prospectus and in the United States under the terms of a registration statement on Form S-1. Our shares are being offered in Canada by an underwriting syndicate led by Dundee Securities Corporation and including • and in the United States by •. We anticipate that the public offering price will be between U.S.\$• and U.S.\$• per share. The offering price of the shares will be determined by negotiation between the representatives of the underwriters and us. In connection with the offering, the underwriters may over-allot or effect transactions that stabilize or maintain the market price of our common stock at levels other than those which otherwise might prevail on the open market. See Underwriting .

**There is currently no market through which our common stock may be sold and purchasers may not be able to resell securities purchased under this prospectus. We have applied to list our common stock on the Toronto Stock Exchange ( TSX ) and the American Stock Exchange ( AMEX ) under the symbol NBY . Any such listings will be subject to the approval of the relevant stock exchanges and any such approvals will not be given unless all of the original listing requirements are satisfied. An investment in our common stock is subject to a number of risks that should be carefully considered by a prospective purchaser. Investors should carefully consider the risk factors described under Risk Factors .**

---

**Price: U.S.\$• per Share**

	<b>Price to the Public</b>	<b>Underwriting discounts and commissions<sup>(1)</sup></b>	<b>Net Proceeds<sup>(2)</sup></b>
Per Share	U.S.\$•	U.S.\$•	U.S.\$•
Total Offering <sup>(3)</sup>	U.S.\$•	U.S.\$•	U.S.\$•

**Table of Contents****Alternate Page for Canadian Prospectus**

## Notes:

- (1) The underwriting discounts and commissions represent the aggregate cash amount payable to the underwriters in connection with the offering. 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. See Underwriting . NovaBay has also granted 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. This prospectus also qualifies the distribution of such warrants to the underwriters. See Underwriting .
- (2) Before deducting the expenses of the offering estimated to be U.S.\$●, which expenses, together with the amount representing the underwriting discounts and commissions, will be paid out of the gross proceeds of the offering.
- (3) We have granted to the underwriters an over-allotment option, exercisable until 30 days after the date of the closing of the offering, to purchase at the offering price additional shares of our common stock equal to up to 15% of the shares sold pursuant to the offering solely to cover over-allotments, if any, and for market stabilization purposes. If the over-allotment option is exercised in full, the total Price to the Public , Underwriting discounts and commissions and Net Proceeds will be U.S.\$●, U.S.\$● and U.S.\$●, respectively. This prospectus also qualifies the distribution of the over-allotment option and the distribution of any shares of our common stock issuable upon exercise of the over-allotment option. See Underwriting .

Underwriters Position	Maximum size	Exercise period	Exercise price
Over-allotment option	●	30 days from the date of the closing	U.S.\$●
Broker warrants	●	24 months from the one year anniversary of the date of the closing	U.S.\$●

**NovaBay Pharmaceuticals, Inc. is incorporated under the laws of a foreign jurisdiction and resides outside of Canada. Although we have appointed FMD Service (Ontario) Inc., Toronto Dominion Tower, Toronto-Dominion Centre, 66 Wellington Street West, Suite 4200, Toronto, Ontario, M5K 1N6, as our agent for service of process in Ontario, it may not be possible for investors to collect from us judgments obtained in courts of Canada predicated on the civil liability provisions of applicable securities laws of Canada.**

The underwriters, as principals, conditionally offer shares of our common stock, subject to prior sale, if, as and when issued and sold by us, and delivered to and accepted by the underwriters in accordance with the conditions contained in the underwriting agreement referred to under Underwriting and subject to the approval of certain legal matters on behalf of us by Fasken Martineau DuMoulin LLP, as to matters of Canadian law, and Dorsey & Whitney LLP, as to matters of United States law, and on behalf of the underwriters by Blake, Cassels & Graydon LLP, as to matters of Canadian law, and Skadden, Arps, Slate, Meagher & Flom LLP, as to matters of United States law. **The underwriters may, in certain circumstances, offer the common stock at a lower price than stated above. See Underwriting .**

Subscriptions for shares of our common stock will be received subject to rejection or allotment in whole or in part and the right is reserved to close the subscription books at any time without notice. It is expected that the closing of the offering will take place on ●, 2007 or such other date as NovaBay and the underwriters may agree, but no later than ●, 2007, and that certificates representing shares of our common stock will be issued on the date of the closing of the offering. See Underwriting .



**Table of Contents****Alternate Page for Canadian Prospectus****TABLE OF CONTENTS**

	<b>Page</b>
<u>NOTICE TO CANADIAN INVESTORS REGARDING GAAP</u>	i
<u>ENFORCEMENT OF LEGAL RIGHTS</u>	i
<u>ELIGIBILITY FOR INVESTMENT</u>	i
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	8
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	27
<u>USE OF PROCEEDS</u>	28
<u>DIVIDEND POLICY</u>	28
<u>CAPITALIZATION</u>	29
<u>DILUTION</u>	30
<u>SELECTED FINANCIAL DATA</u>	32
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	34
<u>BUSINESS</u>	48
<u>MANAGEMENT</u>	80
<u>RELATED PARTY TRANSACTIONS</u>	94
<u>PRINCIPAL SHAREHOLDERS</u>	95
<u>DESCRIPTION OF CAPITAL STOCK</u>	97
<u>PRIOR SALES OF SHARES</u>	100
<u>SHARES ELIGIBLE FOR FUTURE SALE</u>	101
<u>MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS TO NON-U.S. HOLDERS</u>	105
<u>MATERIAL CANADIAN FEDERAL INCOME TAX CONSIDERATIONS</u>	108
<u>UNDERWRITING</u>	111
<u>NOTICE TO INVESTORS</u>	115
<u>LEGAL MATTERS</u>	116
<u>EXPERTS</u>	117
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	110
<u>MATERIAL CONTRACTS</u>	111
<u>STATUTORY RIGHTS OF WITHDRAWAL AND RESCISSION</u>	111
<u>AUDITORS' CONSENT</u>	112
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1
<u>CERTIFICATE OF THE COMPANY</u>	C-1
<u>CERTIFICATE OF THE CANADIAN UNDERWRITERS</u>	C-2

---

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.

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**NOTICE TO CANADIAN INVESTORS REGARDING GAAP**

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. We have been advised by such Canadian provincial securities commissions that exemptive relief, permitting us to include financial statements in this preliminary prospectus as it may be amended from time to time, and in our final prospectus and any supplemented prospectus, which are prepared in accordance with U.S. GAAP only, will be granted and will be evidenced by the final Mutual Reliance Review System decision document issued in respect of our prospectus. We therefore, have not provided, and, assuming that the relief for which we have applied is granted, we will not be required to provide, a reconciliation of our financial statements to Canadian GAAP.

**ENFORCEMENT OF LEGAL RIGHTS**

We are organized under the laws of the State of California and, accordingly, the rights and remedies generally available to shareholders under Canadian corporate law will not be available to investors. In addition, certain of our officers and directors reside outside of Canada. Furthermore, substantially all of our assets and the assets of our officers and directors are located outside of Canada. Although we have appointed FMD Service (Ontario) Inc., Toronto Dominion Tower, Toronto-Dominion Centre, 66 Wellington Street West, Suite 4200, Toronto, Ontario, M5K 1N6 as our agent for service of process within Ontario, it may not be possible for investors to effect service of process within Canada upon our directors or officers. In addition, it may not be possible to enforce against us or our directors or officers judgments obtained in courts in Canada predicated on the civil liability provisions of applicable securities laws of Canada.

**ELIGIBILITY FOR INVESTMENT**

On the date of this prospectus, the shares of our common stock if, as and when listed on a prescribed stock exchange as defined in the regulations to the *Income Tax Act* (Canada), which currently includes the TSX and AMEX, would, if issued on the date hereof, be qualified investments under the *Income Tax Act* (Canada) and the regulations thereunder for trusts governed by registered retirement savings plans, registered retirement income funds, deferred profit sharing plans and registered education savings plans.

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**WHERE YOU CAN FIND MORE INFORMATION**

In connection with this offering, we are and will be subject to the informational requirements of the securities commissions in the provinces of Canada in which shares of our common stock are being offered pursuant hereto. In this respect, we intend to file certain reports, statements or other information with such Canadian provincial securities commissions. These filings, other than confidential filings, will be electronically available from the System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>). For further information with respect to us and our common stock, please see the reports, statements or other information filed pursuant to such informational requirements. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed pursuant to such informational requirements are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed with the applicable Canadian provincial securities commissions.

We have filed a registration statement on Form S-1 with the SEC under the Securities Act with respect to this offering. The registration statement, including its exhibits and schedules, may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov).

Upon completion of this offering, we will also become subject to the information and periodic reporting requirements of the Exchange Act, and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and on the SEC website referred to above.

Upon the filing of a final prospectus with the applicable Canadian provincial securities commissions, we will become a reporting issuer under the securities laws of those jurisdictions that provide for a reporting issuer regime. We are generally exempt from the requirements of the laws of such jurisdictions relating to continuous disclosure and proxy solicitation. Our insiders may also, in certain circumstances, be exempt from Canadian insider reporting requirements. Such exemptions generally permit us to comply with certain informational requirements applicable in the U.S. instead of the continuous disclosure requirements normally applicable in such Canadian jurisdictions, provided that the relevant documents are filed with such Canadian provincial securities commissions and are provided to security holders in Canada to the extent and in the manner and within the time required by applicable U.S. requirements. These filings will be electronically available from SEDAR.

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**MATERIAL CONTRACTS**

The following are the material contracts of NovaBay, other than contracts entered into in the ordinary course of business that were entered into within the two years before the date of this prospectus or which will be entered into at or prior to the closing of the offering:

Underwriting Agreement dated as of \_\_\_\_\_, 2007 among us and the underwriters;

Collaboration and License Agreement dated August 29, 2006 by and between us and Alcon Manufacturing, Ltd.;

Lock-up Agreement dated as of \_\_\_\_\_, 2007 by and between the underwriters and Ramin ( Ron ) Najafi, Ph.D.;

Lock-up Agreements dated as of \_\_\_\_\_, 2007 by and between the underwriters and each of our other officers and directors;

Office Lease dated June 3, 2004 (as amended) by and between us and Emery Station Associates II, LLC; and

Financial Advisory and Investor Relations Consulting Agreement dated February 14, 2007 by and between us and PM Holdings Ltd. The material contracts described above, once entered into, and any other documents regarding NovaBay referred to in this prospectus, may be inspected at the offices of NovaBay's Canadian counsel, Fasken Martineau DuMoulin LLP, Suite 4200, 66 Wellington Street West, Toronto, Ontario, M5K 1N6 during normal business hours during the period of the distribution of the securities hereunder, or they may be viewed on the Internet at [www.sedar.com](http://www.sedar.com).

**STATUTORY RIGHTS OF WITHDRAWAL AND RESCISSION**

Securities legislation in certain of the provinces of Canada provides purchasers with the right to withdraw from an agreement to purchase securities. This right may be exercised within two business days after receipt, or deemed receipt, of a prospectus and any amendment thereto. In several of the provinces, the securities legislation further provides a purchaser with remedies for rescission or, in some provinces, damages if the prospectus and any amendment contains a misrepresentation or is not delivered to the purchaser, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province. **The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal adviser.**

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**AUDITORS' CONSENT**

We have read the amended and restated preliminary base PREP prospectus of NovaBay Pharmaceuticals, Inc. (the Company) (formerly NovaCal Pharmaceuticals, Inc.) dated April 18, 2007 relating to the new issue and sale of common shares of the Company. We have complied with the generally accepted standards of the Public Company Accounting Oversight Board (United States) for an auditor's involvement with offering documents.

We consent to the use in the above mentioned prospectus of our report to the board of directors and the stockholders of the Company on the balance sheets of the Company as at December 31, 2006 and 2005 and the statements of operations, cash flows, and stockholders' equity for the years ended December 31, 2006, 2005 and 2004 and for the period from July 1, 2002 (date of development stage inception) to December 31, 2006. Our report is dated February 15, 2007 (except as to Note 14 which is as of April 18, 2007).

/s/ Davidson & Company LLP

Chartered Accountants

Vancouver, Canada

April 18, 2007

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**CERTIFICATE OF THE COMPANY**

Dated: April 18, 2007

This prospectus, together with the documents and information incorporated herein by reference, will, as of the date of the supplemented prospectus providing the information permitted to be omitted from this prospectus, constitute full, true and plain disclosure of all material facts relating to the securities offered by this prospectus as required under securities legislation of British Columbia, Alberta, Manitoba and Ontario.

**NOVABAY PHARMACEUTICALS, INC.**

By: (Signed) Ramin ( Ron ) Najafi  
President and Chief Executive Officer

By: (Signed) John ( Jack ) O Reilly  
Chief Financial Officer

**On behalf of the Board of Directors of NovaBay Pharmaceuticals, Inc.**

By: (Signed) Paul E. Freiman  
Director

By: (Signed) Robert R. Tufts  
Director

C-1

**Table of Contents**

**Alternate Page for Canadian Prospectus**

**CERTIFICATE OF THE CANADIAN UNDERWRITERS**

Dated: April 18, 2007

To the best of our knowledge, information and belief, this prospectus, together with the documents incorporated herein by reference, will, as of the date of the supplemented prospectus providing the information permitted to be omitted from this prospectus, constitute full, true and plain disclosure of all material facts relating to the securities offered by this prospectus as required under securities legislation of British Columbia, Alberta, Manitoba and Ontario.

**DUNDEE SECURITIES CORPORATION**

By: (Signed) Jolyon Burton

C-2

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable in connection with the sale and distribution of the securities being registered. All amounts are estimated except the SEC registration and the National Association of Securities Dealers, Inc. ( NASD ) filing fees. All of the expenses below will be paid by us.

<b>Item</b>	
SEC registration fee	\$ 2,461
NASD filing fee	2,800
American Stock Exchange listing fee	
Toronto Stock Exchange listing fee	
Blue sky fees and expenses	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Transfer agent and registrar fees	
Miscellaneous	
<b>Total</b>	<b>\$</b>

**Item 14. Indemnification of Directors and Officers.**

Section 317 of the California Corporations Code authorizes a court to award, or a corporation's Board of Directors to grant, indemnity to directors and officers who are parties or are threatened to be made parties to any proceeding (with certain exceptions) by reason of the fact that the person is or was an agent of the corporation, against expenses, judgments, fines, settlements and other amounts actually and reasonably incurred in connection with the proceeding if that person acted in good faith and in a manner the person reasonably believed to be in the best interests of the corporation. Section 204 of the California Corporations Code provides that this limitation on liability has no effect on a director's liability (a) for acts or omissions that involve intentional misconduct or a knowing and culpable violation of law, (b) for acts or omissions that a director believes to be contrary to the best interests of the corporation or its shareholders or that involve the absence of good faith on the part of the director, (c) for any transaction from which a director derived an improper personal benefit, (d) for acts or omissions that show a reckless disregard for the director's duty to the corporation or its shareholders in circumstances in which the director was aware, or should have been aware, in the ordinary course of performing a director's duties, of a risk of a serious injury to the corporation or its shareholders, (e) for acts or omissions that constitute an unexcused pattern of inattention that amounts to an abdication of the director's duty to the corporation or its shareholders, (f) under Section 310 of the law (concerning contracts or transactions between the corporation and a director), or (g) under Section 316 of the law (directors' liability for improper dividends, loans and guarantees). Section 317 does not extend to acts or omissions of a director in his capacity as an officer. Further, Section 317 has no effect on claims arising under federal or state securities laws and does not affect the availability of injunctions and other equitable remedies available to our shareholders for any violation of a director's fiduciary duty to us or our shareholders. Although the validity and scope of the legislation underlying Section 317 have not yet been interpreted to any significant extent by the California courts, Section 317 may relieve directors of monetary liability to us for grossly negligent conduct, including conduct in situations involving attempted takeovers of our company.

In accordance with Section 317, our articles of incorporation eliminate the liability of each of our directors for monetary damages to the fullest extent permissible under California law. Our articles of incorporation further



## **Table of Contents**

authorize us to provide indemnification to our agents (including our officers and directors), subject to the limitations set forth above. The articles of incorporation and our amended and restated bylaws further provide for indemnification of our officers and directors to the maximum extent permitted by California law, and also permit the indemnification of other corporate agents to the maximum extent permitted by California law at the discretion of our Board of Directors. Additionally, we maintain insurance policies which insure our officers and directors against certain liabilities.

The foregoing summaries are necessarily subject to the complete text of the California Corporations Code, our articles of incorporation, our amended and restated bylaws and the agreements referred to above and are qualified in their entirety by reference thereto.

We have entered into agreements to indemnify our directors and certain of our officers in addition to the indemnification provided for in the articles of incorporation and amended and restated bylaws. These agreements will, among other things, indemnify our directors and some of our officers for certain expenses (including attorneys fees), judgments, fines and settlement amounts incurred by such person in any action or proceeding, including any action by or in our right, on account of services by that person as a director or officer of NovaBay or as a director or officer of any of our subsidiaries, or as a director or officer of any other company or enterprise that the person provides services to at our request.

Lastly, the underwriting agreement (Exhibit 1.1 to this registration statement) provides for indemnification by the underwriters of us and our officers and directors, and by us of the underwriters, for certain liabilities arising under the Securities Act of 1933, as amended (the Securities Act ) or otherwise in connection with this offering.

### **Item 15. Recent Sales of Unregistered Securities**

The following is a summary of our transactions since December 31, 2003, involving sales of our securities that were not registered under the Securities Act:

#### *Common Stock Issuances*

- (1) In April 2004, we issued an aggregate of 764,977 shares of our common stock to various individuals as compensation for services rendered to us, which included services in connection with a private placement of Series B Preferred Stock.
- (2) From March 2005 to November 2005, we issued an aggregate of 369,372 shares of our common stock to various individuals as compensation for services rendered to us, which included services in connection with a private placement of our Series C Preferred Stock.
- (3) From June 2006 to December 2006, we issued an aggregate of 66,754 shares of our common stock to various individuals as compensation for services rendered to us, which included services in connection with a private placement of our Series D Preferred Stock.
- (4) In February 2007, we issued an aggregate of 70,000 shares of common stock to one of our consultants as compensation for services rendered to us.
- (5) From April 2004 to December 2004, we sold and issued an aggregate of 62,500 shares of common stock at purchase prices ranging from \$0.40 per share to \$0.60 per share upon the exercise of warrants.
- (6) From March 2005 to September 2005, we sold and issued an aggregate of 583,988 shares of common stock at purchase prices ranging from \$0.40 per share to \$0.60 per share upon the exercise of warrants.

## **Table of Contents**

(7) From January 2006 to June 2006, we sold and issued an aggregate of 2,297,169 shares of common stock at purchase prices ranging from \$0.40 per share to \$0.60 per share upon the exercise of warrants.

### *Preferred Stock Issuances*

(8) From January 2004 to March 2004, we sold and issued an aggregate of 2,693,766 shares of Series B Preferred Stock at a purchase price of \$0.47 per share in connection with a private placement. In January of 2004, we issued an additional 912,850 shares of Series B Preferred Stock at \$0.47 per share upon conversion of outstanding convertible promissory notes.

(9) From May 2004 to October 2005, we sold and issued an aggregate of 6,666,659 shares of Series C Preferred Stock at a purchase price of \$0.85 per share in connection with a private placement.

(10) From June 2005 to September 2006, we sold and issued an aggregate of 2,481,094 shares of Series D Preferred Stock at a purchase price of \$1.50 per share in connection with a private placement.

### *Warrant Issuances*

(11) From January 2004 to March 2004, we issued warrants to purchase up to an aggregate of 1,806,576 shares of our common stock at an exercise price of \$0.40 per share to certain holders of our Series B Preferred Stock. In January 2005, we issued a warrant to purchase up to an aggregate of 4,840 shares of our common stock at an exercise price of \$0.40 per share to one of our holders of Series B Preferred Stock. As of February 14, 2007, there were no warrants outstanding to purchase any shares of our capital stock.

### *Stock Option Issuances*

(12) From January 2004 to December 2004, we issued options to certain of our employees, directors and consultants to acquire up to an aggregate of 1,270,500 shares of our common stock under our 2002 Stock Option Plan (the 2002 Plan ) at prices ranging from \$0.15 per share to \$0.28 per share. From January 2005 to October 2005, we issued options to certain of our employees, directors and consultants to acquire up to an aggregate of 330,000 shares of our common stock under our 2002 Plan at exercise prices ranging from \$0.28 per share to \$0.60 per share. As of March 31, 2007, 2,564,716 shares of our common stock were issuable upon exercise of outstanding options granted under the 2002 Plan.

(13) In May 2005, we issued options to certain of our consultants to acquire up to an aggregate of 46,000 shares of our common stock under our 2005 Stock Option Plan (the 2005 Plan ) at exercise prices ranging from \$0.28 per share to \$0.60 per share. From January 2006 to September 2006, we issued options to certain of our employees and consultants to acquire up to an aggregate of 1,644,000 shares of our common stock under our 2005 Plan at exercise prices ranging from \$0.60 per share to \$1.00 per share. In January 2007, we issued options to certain of our employees and consultants to acquire up to an aggregate of 441,250 shares of our common stock under our 2005 Plan at an exercise price of \$1.14 per share. As of March 31, 2007, 2,045,250 shares of our common stock were issuable upon exercise of outstanding options granted under the 2005 plan.

(14) In March 2005 and January 2007, we issued options to various individuals to acquire up to an aggregate of 561,958 shares of our common stock outside of our 2002 Plan and 2005 Plan at prices ranging from \$0.47 per share to \$1.14 per share as compensation for services rendered to us in connection with a private placement of our preferred stock. As of March 31, 2007, 311,958 shares of our common stock were issuable upon exercise of outstanding options granted outside of our 2002 Plan and 2005 Plan.

The issuances of securities in the transactions described in paragraphs 1 through 3, 5 through 11, and 14 above were effected without registration under the Securities Act in reliance on Section 4(2) thereof or Rule 506 of Regulation D thereunder based on the status of each investor as an accredited investor as defined under the Securities Act. The issuances of securities in the transactions described in paragraphs 12 and 13 above were effected without registration under the Securities Act in reliance on Section 4(2) thereof or Rule 701 thereunder as transactions pursuant to compensatory benefit plans and contracts relating to compensation. None of the

**Table of Contents**

foregoing transactions was effected using any form of general advertising or general solicitation as such terms are used in Regulation D under the Securities Act. The recipients of securities in each such transaction either received adequate information about us or had access, through their relationships with us, to such information.

The issuances of securities in the transaction described in paragraph 4 above were effected without registration under the Securities Act in reliance on Rule 903 of Regulation S thereunder as an offer and sale of securities that occurred outside the United States. The sale of securities was made in an offshore transaction, did not involve any directed selling efforts within the United States, and involved only purchasers who were outside the United States and were non-U.S. Persons. In addition, such securities were also exempt from registration under the Securities Act in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder based on the status of such investor as an accredited investor as defined under the Securities Act.

**Item 16. Exhibits and Financial Statement Schedules**

## (a) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
1.1*	Form of Underwriting Agreement
3.1**	Articles of Incorporation of the Registrant, as amended
3.2*	Proposed Amended and Restated Articles of Incorporation of the Registrant to be effective upon completion of this offering
3.3**	Bylaws of the Registrant, as amended
3.4*	Proposed Amended and Restated Bylaws of the Registrant to be effective upon the completion of this offering
4.1*	Specimen common stock certificate
5.1*	Opinion of Dorsey & Whitney LLP
10.1+**	2002 Stock Option Plan, and forms of agreements thereto
10.2+**	2005 Stock Option Plan, and forms of agreements thereto
10.3+*	2007 Omnibus Incentive Plan, and forms of agreements thereto
10.4+*	Employment Agreement dated 2007 by and between the Registrant and Ramin ( Ron ) Najafi
10.5+*	Employment Agreement dated 2007 by and between the Registrant and John ( Jack ) O Reilly
10.6+*	Employment Agreement dated 2007 by and between the Registrant Behzad Khosrovi
10.7+*	Employment Agreement dated 2007 by and between the Registrant and Colin Scott
10.8+**	Stock Option Grant dated May 23, 2002 by and between the Registrant and John ( Jack ) O Reilly
10.9+**	Stock Option Grant dated January 30, 2004 by and between the Registrant and Behzad Khosrovi
10.10**	Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
10.11 **	Collaboration and License Agreement dated August 29, 2006 by and between the Registrant and Alcon Manufacturing, Ltd.
10.12**	Financial Advisory and Investor Relations Consulting Agreement dated February 14, 2007 by and between the Registrant and PM Holdings Ltd.

---

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
23.1	Consent of Davidson & Company LLP
23.2*	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature pages hereto)

---

\* To be filed by amendment.

\*\* Previously filed.

Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 406 under the Securities Act. In accordance with Rule 406, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

+ Indicates management contract or compensatory plan.

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 17. Undertakings**

The registrant hereby undertakes to provide to the Underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the Underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of NovaBay pursuant to the foregoing provisions, or otherwise, NovaBay has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by NovaBay of expenses incurred or paid by a director, officer or controlling person of NovaBay in the successful defense of any action, suit, or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, NovaBay will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus as filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by NovaBay pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, NovaBay Pharmaceuticals, Inc. has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Emeryville, State of California, on the 18th day of April 2007.

NovaBay Pharmaceuticals, Inc.

By: */s/ RAMIN NAJAFI*  
**Ramin ( Ron ) Najafi**

**Chairman of the Board, Chief Executive Officer**

**and President**

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to the Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/ RAMIN NAJAFI</i> <b>Ramin ( Ron ) Najafi</b>	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	April 18, 2007
<i>/s/ JACK O REILLY</i> <b>John ( Jack ) O Reilly</b>	Senior Vice President, Corporate Development, Chief Financial Officer, Treasurer and Director (principal financial and accounting officer)	April 18, 2007
*	Director	
<b>Charles J. Cashion</b>		April 18, 2007
*	Director	
<b>Anthony Dailley, DDS</b>		April 18, 2007
*	Director	
<b>Paul E. Freiman</b>		April 18, 2007
*	Director	
<b>Alex McPherson, MD, Ph.D.</b>		April 18, 2007
*	Director	
<b>Robert R. Tufts</b>		April 18, 2007
*	Director	
<b>Tony Wicks</b>		April 18, 2007

\*By:

/s/ RAMIN NAJAFI  
**Ramin ( Ron ) Najafi**

**Attorney-in-Fact**

II-6

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
1.1*	Form of Underwriting Agreement
3.1**	Articles of Incorporation of the Registrant, as amended
3.2*	Proposed Amended and Restated Articles of Incorporation of the Registrant to be effective upon completion of this offering
3.3**	Bylaws of the Registrant, as amended
3.4*	Proposed Amended and Restated Bylaws of the Registrant to be effective upon the completion of this offering
4.1*	Specimen common stock certificate
5.1*	Opinion of Dorsey & Whitney LLP
10.1+**	2002 Stock Option Plan, and forms of agreements thereto
10.2+**	2005 Stock Option Plan, and forms of agreements thereto
10.3+*	2007 Omnibus Incentive Plan, and forms of agreements thereto
10.4+*	Employment Agreement dated 2007 by and between the Registrant and Ramin ( Ron ) Najafi
10.5+*	Employment Agreement dated 2007 by and between the Registrant and John ( Jack ) O Reilly
10.6+*	Employment Agreement dated 2007 by and between the Registrant Behzad Khosrovi
10.7+*	Employment Agreement dated 2007 by and between the Registrant and Colin Scott
10.8+**	Stock Option Grant dated May 23, 2002 by and between the Registrant and John ( Jack ) O Reilly
10.9+**	Stock Option Grant dated January 30, 2004 by and between the Registrant and Behzad Khosrovi
10.10**	Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended.
10.11 **	Collaboration and License Agreement dated August 29, 2006 by and between the Registrant and Alcon Manufacturing, Ltd.
10.12**	Financial Advisory and Investor Relations Consulting Agreement dated February 14, 2007 by and between the Registrant and PM Holdings Ltd.
23.1	Consent of Davidson & Company LLP
23.2*	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature pages hereto)

\* To be filed by amendment.

\*\* Previously filed

Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 406 under the Securities Act. In accordance with Rule 406, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

+ Indicates management contract or compensatory plan.