NovaBay Pharmaceuticals, Inc.
Form S-1
February 14, 2007
Table of Contents

As filed with the Securities and Exchange Commission on February 14, 2007

Registration No. 333-

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

NOVABAY PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

5980 Horton Street, Suite 550

Emeryville, CA 94608

(510) 899-8800

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

Ron Najafi, Ph.D.

Chairman of the Board, Chief Executive Officer and President

NovaBay Pharmaceuticals, Inc.

5980 Horton Street, Suite 550 Emeryville, CA 94608

(510) 899-8800

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

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

(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.
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 7.

PRICE $ PER SHARE

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

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

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 developed 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. 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 it is effective against these pathogens at concentrations that are significantly lower than the concentrations at which it begins to kill human cells.

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.

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.

Table of Contents

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 will 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.

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, which would 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.

Rapidly Killing Bacteria. Our in-vitro tests indicate that our Aganocide compounds eliminate certain bacterial colonies in minutes, whereas current therapies may take hours or days at comparable therapeutic concentrations.

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.

Table of Contents

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.

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.

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.

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 February 12, 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$1.1746.

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.

Table of Contents

The Offering

Common stock offered by NovaBay	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	We intend to use the estimated net proceeds from this offering of $ for the advancement of the clinical development of our Aganocide compounds, 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. Although we currently anticipate that we will use the net proceeds of this offering as described above, there may be circumstances where, for sound business reasons, a reallocation of funds may be necessary. We may re-allocate the net proceeds from time to time depending upon the ultimate amount of net proceeds raised and upon changes in business conditions prevalent at the time. See Use of Proceeds.
Risk Factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to purchase shares of our common stock.
American Stock Exchange and Toronto Stock Exchange listings	We intend to apply to list our shares on the American Stock Exchange (AMEX) and the Toronto Stock Exchange (TSX) under the symbol NBY. Any such listing will be subject to the approval of the relevant stock exchange, and any such approval will not be given unless all of the original listing requirements are met.

The number of shares of our common stock to be outstanding following this offering is based on 31,849,813 shares of our common stock outstanding at 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 upon the completion of this offering, and does not include, as of such date:

- 4,791,259 shares of common stock issuable upon exercise of options outstanding at a weighted average exercise price of $0.42 per share; and
- 836,000 shares of common stock reserved for future grant under our 2005 Stock Option Plan.

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

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

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

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

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, 2003, 2004 and 2005 are derived from our audited financial statements. We have also included data from our unaudited financial statements for the nine months ended September 30, 2005 and 2006. Our financial statements have been prepared in accordance with United States GAAP, which differ in certain respects from Canadian GAAP.

	Year Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
	(in thousands, except share and per share data)				
Statements of Operations Data:					
Revenue	$	$	$	$	$ 208
Operating expenses:					
Research and development(1)	330	1,573	2,174	1,767	2,660
General and administrative(1)	623	1,253	1,395	993	1,730
Total operating expenses	953	2,826	3,569	2,760	4,390
Interest income (expense) and other, net	(24)	22	106	78	97
Net loss before income taxes	(977)	(2,804)	(3,463)	(2,682)	(4,085)
Provision for income taxes					
Net loss	$ (977)	$ (2,804)	$ (3,463)	$ (2,682)	$ (4,085)
Net loss per share:					
Basic and diluted	$ (0.12)	$ (0.32)	$ (0.36)	$ (0.28)	$ (0.37)
Shares used in per share calculations:					
Basic and diluted	8,087,239	8,755,418	9,704,207	9,579,761	11,051,270
Pro forma net loss per share (unaudited):					
Basic and diluted			$ (0.13)		$ (0.14)
Shares used in pro forma per share calculations (unaudited)(2):					
Basic and diluted			26,621,129		29,316,688

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
	(in thousands)				
Research and development	$ 2	$ 11	$ 55	$ 55	$ 34
General and administrative			16		138
Total stock-based compensation expense	$ 2	$ 11	$ 71	$ 55	$ 172

(2) The pro forma weighted average common shares outstanding reflects the conversion of our convertible preferred stock (using the if-converted method) into common stock as though the conversion had occurred on the original dates of issuance.

Table of Contents

The following table presents a summary of our balance sheet as of September 30, 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 September 30, 2006	
	Actual	Pro Forma As Adjusted
	(unaudited) (in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 12,990	
Working capital	9,801	
Total assets	13,479	
Deferred revenue current and non-current	9,792	
Convertible preferred stock	192	
Common stock and additional paid-in capital	14,532	
Total stockholders equity	2,854	

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, 2003, 2004 and 2005, we had net losses of approximately $1.0 million, $2.8 million and $3.5 million, respectively and for the nine months ended September 30, 2006 we had a net loss of approximately $4.1 million. Through September 30, 2006, we had an accumulated deficit of approximately $11.9 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 $0.3 million, $1.6 million and $2.2 million for the years ended December 31, 2003, 2004, and 2005, respectively and $2.7 million for the nine months ended September 30, 2006. 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. 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;