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# **NovaBay** PHARMA

2007 Annual Report

Developing  
Non-Antibiotic  
Anti-Infectives

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# Our Products Address the Growing Crisis of Antibiotic Resistant Infections

## Dear Shareholder:



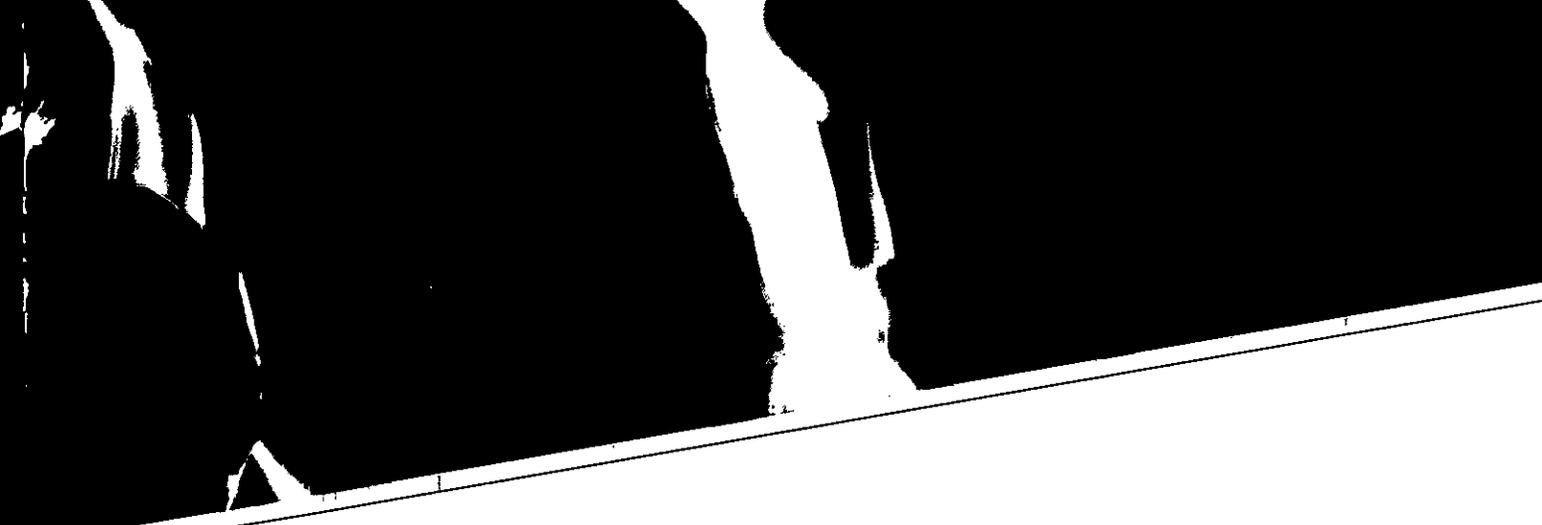
Ron Najafi, Ph.D.  
Chairman and  
Chief Executive Officer

Developing innovative product candidates targeting the prevention or treatment of hospital-acquired and non-hospital infections.

As we move forward in 2008, it is time to look back at the Company's achievements in 2007 upon which we are building. It was a year of intense activity, culminating in the completion of NovaBay's successful IPO. We raised \$20 million at a time when the market was unfavorable and many biotech companies postponed or canceled their IPOs.

During the year, we continued to work closely with Alcon, Inc. (NYSE: ACL), not only on the development of NVC-422, our lead Aganocide™ compound, for use in eye, ear, and sinus infections, but also on the development of a new molecule for use in contact lens solutions. We look forward to continued progress in 2008.

As many of our early shareholders will remember, NovaBay started its activities focused on the use of NeutroPhase™ (NVC-101) in chronic wounds. In June 2007, we advanced our commitment to wound care by entering into an exclusive, worldwide agreement with an affiliate of Kinetic Concepts, Inc. (NYSE: KCI) for the use of NeutroPhase in wound care. KCI is the premier company in the wound care market with its world-leading V.A.C.® Therapy device. In support of this effort, we obtained approval from the U.S. Food and Drug Administration for the use of NeutroPhase in a variety of wound care applications.



## Internal Programs

Indication	Market	Clinical Status
MRSA: Nasal pre-surgery preparation	27M Surgical operations	• Phase II
Catheter Associated Urinary Tract Infections	5M patients require catheters	• Phase I
Dialysis Access Associated Infections	Primary cause of death on dialysis	• Pre-clinical
Central Venous Catheter Infections	5M patients require central venous catheters	• Pre-clinical
Ventilator Associated Pneumonia	27% of all infections in ICUs	• Pre-clinical

Our clinical, regulatory, and pharmaceutical departments have been advancing the development of two in-house clinical programs. We have completed Phase I safety trials of NVC-422 (trademarked as AgaNase™). We aim to demonstrate that AgaNase can eradicate the *Staph. Aureus*, and MRSA, in the nasal passages, a major reservoir of this bacteria. Used prior to surgery, this should significantly reduce the number of patients that incur blood-borne infections that lead to prolonged hospitalization. These potentially fatal infections need to be treated with intravenous antibiotics. The safety trials demonstrated that AgaNase was well tolerated at the doses that we believe should have therapeutic efficacy.

Our second indication is the prevention and treatment of catheter-associated urinary tract infections (CAUTI). It is estimated that approximately 40% of all hospital infections are attributable to CAUTI. In March of this year, we announced the completion of dosing of the first cohort

of volunteers in a multi-cohort Phase I safety study of a bladder and catheter lavage solution of NVC-422. This clinical program is aimed at preventing the development of CAUTI. We look forward to advancing our clinical trials in this area.

The opportunity and need for these programs to prevent infections in hospital settings has been reinforced by two major policy initiatives taken in 2007. The Centers for Disease Control is leading the effort with individual States to mandate disclosure of hospital infection rates. Even more importantly, Medicare has announced that it will not reimburse hospitals for the costs incurred treating preventable hospital-acquired infections. This change should motivate hospitals to adopt new, preventive measures to avoid losing estimated tens of billions of dollars of vital revenue.



NovaBay microbiologist screening new compounds

**\$66B** in incremental costs due to hospital associated infections

**13%** of hospital ICU infections resulted in death

# Targeting Large and Diverse Healthcare Markets



NovaBay scientists working on bacterial biofilm

During 2007, we made significant breakthroughs in understanding and mastering the chemistry of Aganocide compounds. We have started patenting and publishing the results of these efforts. Our biology and analytical chemistry teams have played a critical role in evaluating the new molecules invented by our chemists. In addition

to this, they provided critical data in support of our successful applications to the FDA. We scaled up the production of NVC-422 to a multi-kilogram level to fully meet the needs for our own planned clinical trials and those that we expect Alcon to undertake during 2008.

We have put a significant effort into developing formulations for NVC-422 to extend the number of potential applications for which it can be used. We have seen progress on both gel and ointment formulations. These formulations provide us with the ability to pursue high-value dermatology opportunities for NVC-422. The most important of these is the treatment of acne, where current products are either poor in efficacy or produce toxic side effects. We are beginning a full pre-clinical program to prepare for entry into human trials. As we continue our internal progress, we see this area as an attractive segment that is open to both partnering and continued internal development.

## NVC-422 Kills Multi-Drug Resistant (MDR) Bacteria: Screening with recent ocular isolates

	Acinetobacter junii	E. coli	P. aeruginosa	S. pneumoniae	Staph epidermidis	E. faecalis	H. influenzae	Staph aureus
<b>NVC-422</b>	○	○	○	○	○	○	○	○
Tobramycin								
Gentamicin								
Neomycin								
Trimethoprim								○
Ciprofloxacin							○	○
PolymyxinB	○	○	○				○	
Moxifloxacin				○			○	
Tetracycline					○	○	○	○

○ Indicating complete eradication of bacteria on the horizontal line



### Partnered Programs

Product	Indication	Status
NVC-422	Ophthalmic (Lead indication)	• Licensed to Alcon
NVC-422	Otic	• Licensed to Alcon
NVC-422	Sinus	• Licensed to Alcon
NVC-612	Contact Lens	• Licensed to Alcon
NVC-101	Wound care	• Licensed to KCI

I would like to extend my thanks to our Board of Directors, our scientific advisors and, most of all, the employees of NovaBay who have made significant scientific advances in the development of the Aganocides as an important new non-antibiotic class of anti-microbials. We had thirty-three employees at the end of 2007, and expect to continue to add staff strategically during 2008. In 2007, NovaBay added additional scientific leadership, including the appointment of Nafsika Georgopapadakou, Ph.D. as Vice President of Research, who has many years of experience in the anti-microbial area. We are equally pleased with the recent appointment of Tom Paulson as Chief Financial Officer. Tom's significant experience working with public companies and raising capital will allow Jack O'Reilly, who was serving in that capacity, to focus on corporate and business development.

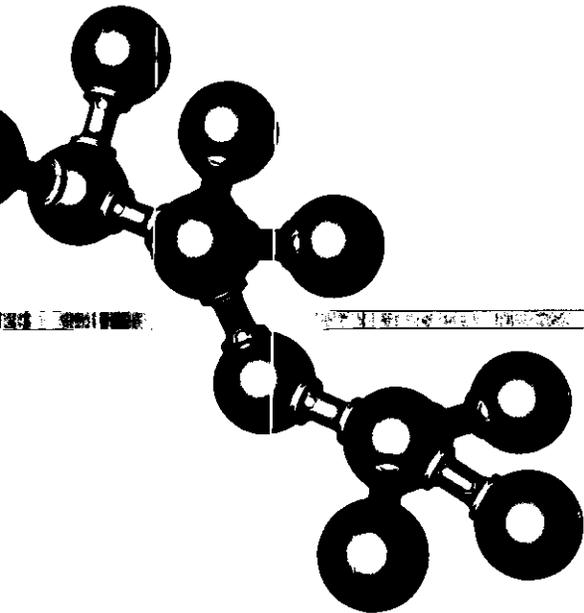
We could not have delivered these achievements without the support of our shareholders. As you know, the development of new drugs is a costly process and without investor support, we would not be able to continue with their development. In addition to saving lives and reducing suffering, it is our goal to provide a high return for all of our investors.

Sincerely yours,

Ron Najafi, Ph.D.  
Chairman and  
Chief Executive Officer  
NovaBay Pharmaceuticals, Inc.

AgaNase is being developed to clear MRSA from the nose, from which it can spread to cause surgical site infections





## About The Aganocide™ Compounds

Our Aganocide compounds are NovaBay's proprietary technology. These compounds work by mimicking our own natural defense against infections. The compounds are based upon small molecules that white blood cells naturally produce to destroy harmful microbes. Since our immune system works without ever creating resistance, NovaBay has taken the effective and rapidly acting molecules that function within our own bodies and created stable analogs of these molecules. While our lead Aganocide compound is NVC-422, additionally we have synthesized many other analogs. Our Aganocide compounds have a unique profile:

- **Fast acting:** Most antibiotics take many hours to kill certain kinds of bacteria; our Aganocide compounds can kill bacteria in minutes. *In-vitro* studies have shown 99.999% of microbes are eradicated in less than five minutes.
- **Broad spectrum of activity:** *In vitro* studies have demonstrated that our compounds kill all bacteria, viruses, yeasts and fungi against which they have been tested.
- **Effective against multi-drug resistant bacteria:** Our compounds were highly effective in *in vitro* studies against multi-drug resistant bacteria including Methicillin-Resistant Staphylococcus aureus (MRSA) and Vancomycin-Resistant Enterococcus (VRE).
- **Effective against biofilm:** Biofilm is a slimy matrix produced and inhabited by bacteria. NVC-422 has demonstrated to be highly effective against well-established biofilm grown on urinary tract catheters.
- **High therapeutic index:** Both NVC-101 and NVC-422 demonstrate greater *in vitro* therapeutic index (ratio of toxicity to efficacy) than existing topical antiseptics.

#### Safe Harbor Statement:

This letter contains forward-looking statements, which are based upon management's current expectations, assumptions, estimates, projections and beliefs. These statements include, but are not limited to, statements regarding the development and potential benefits of, and the market opportunities for, NovaBay's product candidates. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or achievements to be materially different and adverse from those expressed in or implied by the forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, risks and uncertainties relating to difficulties or delays in discovery, development, testing, regulatory approval, production, and marketing of the Company's product candidates, unexpected adverse side effects or inadequate therapeutic efficacy of the product candidates, the uncertainty of patent protection for the Company's intellectual property or trade secrets, the Company's ability to obtain additional financing as necessary and unanticipated research and development and other costs. The forward-looking statements in this release speak only as of this date, and NovaBay disclaims any intent or obligation to revise or update publicly any forward-looking statement except as required by law.

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

SEC  
Mail Processing  
Section

MAY 06 2008

Washington, DC  
104

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2007

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-33678

**NOVABAY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

California  
(State or other jurisdiction  
of incorporation or organization)

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

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

Registrant's Telephone Number, Including Area Code: (510) 899-8800

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.01 par value per share	American Stock Exchange (also listed on the Toronto Stock Exchange)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter. The aggregate market value of the common stock held by non-affiliates of the registrant as of October 31, 2007, the date of closing of the registrant's initial public offering, was approximately \$67,948,000 (based on the closing sales price of the common stock on that date). For the purposes of this calculation, shares owned by officers, directors and 10% stockholders known to the registrant have been deemed to be owned by affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 11, 2008, there were 21,300,218 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III incorporates by reference certain information from the registrant's definitive proxy statement to be filed for the 2008 Annual Meeting of Stockholders.

**NOVABAY PHARMACEUTICALS, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007**

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Unless the context requires otherwise, all references in this report to "we," "our," "us," the "Company" and "NovaBay" refer to NovaBay Pharmaceuticals, Inc. and its subsidiaries.

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

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. These forward-looking statements include but are not limited to statements regarding our product candidates, market opportunities, competition, strategies, anticipated trends and challenges in our business and the markets in which we operate, and anticipated expenses and capital requirements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading "Risk Factors" in Item 1A of this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should read this report and the documents that we reference in this report and have filed as exhibits to the report completely and with the understanding that our actual future results may be materially different from what we expect. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this report. 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.*

### PART I

#### ITEM 1. BUSINESS

##### Overview

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

We were incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, we changed our name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, we formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which may conduct research and development in Canada, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which will explore and pursue dermatological opportunities.

##### Our Target Indications and Product Candidates

To optimize the commercial opportunities of our Aganocide compounds, we have developed a two-pronged clinical development strategy. Our first approach is to create and retain technology in indications focused on hospital-associated infections, an area that we believe presents a strategic opportunity for NovaBay. Our second approach is to partner out the Aganocide compounds for use in non-hospital applications.

## **In-House Programs**

### ***Pre-Surgical Nasal Preparation***

*Staphylococcus aureus* is a major cause of surgical site infection ("SSI"). SSI is a source of significant concern because of the risk to the patient and because of the resulting increase in the cost of post-surgical treatment. In particular, if the strain of *S. aureus* causing the SSI is an antibiotic-resistant variant known as methicillin-resistant *S. aureus* ("MRSA"), the treatment options become extremely limited and increasingly problematic. It has been shown that surgical patients that carry *S. aureus* in their nasal passages are at a significantly higher risk of developing SSIs. Conventional body washing with an antiseptic preparation does not deal with nasal passages, which are a major area of the body for *S. aureus* colonization. We have formulated NVC-422, our lead Aganocide compound, as a nasal spray and are developing it for the decolonization of *S. aureus* (including MRSA) from the nasal passages. Studies show that when combined with an antiseptic body wash, nasal decolonization leads to a significant reduction in SSIs. Our formulation of NVC-422 for nasal applications is trademarked as AgaNase and is currently in Phase II clinical trials.

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

Urinary tract catheters have become a routine part of the management of patients in intensive care and long-term care settings with an estimated five million patients undergoing catheterization each year. Catheter associated urinary tract infections ("CAUTI") are the major source of hospital-acquired infections, accounting for more than 40% of all hospital infections, or 800,000 infections per year. These infections generally prolong hospitalization, require intensive antibiotic therapy and greatly increase the cost of treatment. A contributing factor in CAUTIs is the formation of bacterial biofilm within the catheter. This biofilm provides an on-going reservoir of bacteria that can cause infection. We are developing a formulation of NVC-422 to destroy bacteria in the bladder as well as bacteria that have formed biofilm within the catheter. We are currently conducting Phase I clinical trials to establish the maximum safe dose for our CAUTI formulation.

## **Partnering Programs**

### ***Wound Care***

Wound infections are a major problem because they prevent the wounds from healing and can cause serious bloodstream infections. We have developed NVC-101, a proprietary solution of hypochlorous acid which we have trademarked as NeutroPhase, to address this challenge. We have received clearance from the U.S. Food and Drug Administration ("FDA") for the marketing of this product as a wound cleanser and debriding agent. We are currently working with our partner, an affiliate of Kinetic Concepts, Inc. ("KCI"), to optimize its use with their V.A.C.<sup>®</sup> System wound care device.

### ***Eye, Ear, Sinus and Contact Lens Solution***

We are currently working with Alcon Manufacturing Ltd. ("Alcon"), an affiliate of Alcon, Inc., to develop NVC-422 for the treatment of eye, ear and sinus infections as well as for use in contact lens solutions.

### ***Dermatology***

We are focused on developing products that will potentially eliminate the need to use antibiotic-based products in the dermatology market. In laboratory testing, we have shown that NVC-422 kills *P. Acne* and other dermal bacteria. We are currently in advanced preclinical development of a variety of formulations for use in the treatment of skin infections. If preclinical studies confirm our initial findings, we plan to bring these formulations into proof of concept clinical development in order to enhance their value as we explore partnering opportunities.

## **Our Technology and Research**

We have developed our lead compounds by understanding the nature of the molecules that are produced by our white blood cells to kill pathogens such as bacteria, viruses and fungi. Our white blood cells produce small,

highly active molecules that are extremely efficient in killing these pathogens once their entry into the body has been detected by our defense systems. However, these molecules are not readily usable as pharmaceutical products because our body produces them “on demand” and the molecules are not naturally stable. We have discovered ways to stabilize one of these naturally occurring molecules, which we call NVC-101, or NeutroPhase. Through the modification of another of these natural molecules, we have created NVC-422, which is our lead Aganocide compound. NVC-422 is a stable analog of naturally occurring N-chlorotaurine (“NCT”). We believe NVC-422 is actually safer and more potent than the NCT molecule. In addition, we have made significant discoveries over the past year that have enabled us to understand why the naturally generated molecules cannot be kept stable and used as drugs. Based on this improved understanding, we have created and expect to create additional antimicrobial compounds that have different characteristics than NVC-422, such as ability to penetrate different tissues and speed at which they kill pathogens.

In 2002, the World Health Organization predicted that within ten years we will be entering into a post-antibiotic era—meaning there will be infections for which there will be no effective antibiotic treatments. By using nature’s blueprint for the development of new anti-infective products, we start with the advantage that the natural molecules do not allow pathogens to develop resistance. Extensive laboratory studies appear to confirm that the Aganocide compounds should inherit this advantage. The ability of our Aganocide compounds to be effective without developing resistance is critical in a situation where bacteria are continuing to develop ever more sophisticated mechanisms for protecting themselves from antibiotics.

Additionally, we are continuing our work to expand our understanding of the activity of the Aganocide compounds against bacteria in biofilm. Just as bacteria are found everywhere, we now understand that biofilm is a natural, ever present defense mechanism of bacteria. Biofilm is a cocoon-like shield that forms around a colony of bacteria. Once the biofilm is formed, bacteria go into dormancy. Dormant bacteria reproduce once every few days, while an active bacteria reproduces every 30 to 60 minutes. Antibiotics are generally only effective against fast reproducing bacteria. In controlled laboratory studies, our Aganocide compounds were found to be highly effective at killing bacteria in biofilm. We believe their activity in biofilm is a critical element of their success, particularly in the prevention of catheter associated urinary tract infections.

#### **Alcon Collaboration and License Agreement**

In August 2006, we entered into a collaboration and license agreement with Alcon to license to Alcon the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solution. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. In addition to the technology access fee, we are entitled to receive semi-annual payments from Alcon to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compounds.

#### **KCI License Agreement**

In June 2007, we entered into a license agreement with KCI, under which we granted KCI the exclusive rights to develop, manufacture and commercialize NeutroPhase, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to us a non-refundable technology access fee of \$200,000. We are also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, we are entitled to receive payments of up to \$1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products.

## **Research and Development**

As of December 31, 2007, we had 28 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 2005, 2006 and 2007 were \$2.0 million, \$4.1 million and \$7.4 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 registered the Aganocide trademark in the European Community and Japan and have a trademark application allowed in the United States. We have allowed trademark applications in the United States for NeutroPhase, NovaBay and the NovaBay design, and a pending application for AgaNase. We have registered the NovaBay, AgaNase and NeutroPhase trademarks in Australia and have applications for these same trademarks pending in a number of other foreign countries.

We have one issued patent, one allowed patent application and eight pending applications in the United States. We also have four pending international applications filed under the Patent Cooperation Treaty, and one issued patent in Mexico, one issued patent in China, one allowed patent in Israel and 46 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 allowed U.S. patent application claims a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. NovaBay must pay an issue fee on or before March 27, 2008, in order for this application to issue as a U.S. patent. If NovaBay fails to timely pay this fee, no patent will issue. 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 and 2026.

## **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. 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.

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.

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.

### **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 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 regulations;
- submission to the FDA of an Investigational Drug ("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 ("NDA");
- 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.

### ***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.

### ***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 ("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.

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 QSRs and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

### ***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.

### ***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.

### ***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. 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 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.

### **Employees**

As of December 31, 2007, we had 35 full-time employees, including 16 with doctoral degrees. Of our full time workforce, 28 employees were engaged in research and development, and 7 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.

### **Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our corporate website, located at [www.novabaypharma.com](http://www.novabaypharma.com), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC").

### **ITEM 1A. RISK FACTORS**

*Our business is subject to a number of risks, some of which are discussed below. Other risks are presented elsewhere in this report and in the information incorporated by reference into this report. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC, including our subsequent reports on Forms 10-Q and 8-K, before deciding to buy, sell or hold our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently believe are not important may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment.*

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

We have incurred net losses since our inception. For the years ended December 31, 2005, 2006 and 2007 we had net losses of approximately \$3.5 million, \$5.3 million and \$5.4 million, respectively. Through December 31, 2007, we had an accumulated deficit of approximately \$18.5 million. To date, we have been, and expect to

remain for the foreseeable future, mostly in a research and development stage. Since our inception, we have not generated revenue, except for modest revenue in 2006 and 2007 relating to two research and development collaboration and license agreements. We have incurred substantial research and development expenses, which were approximately \$2.0 million, \$4.1 million and \$7.4 million for the years ended December 31, 2005, 2006 and 2007, respectively. We expect to continue to make, for at least the next several years, significant expenditures for the development of products that incorporate our Aganocide compounds, as well as continued research into the biological activities of our Aganocide compounds, which expenditures are accounted for as research and development expenses. We do not expect any of our current product candidates to be commercialized within the next several years, if at all, except as may be commercialized under our agreement with KCI, pursuant to which we granted them the exclusive rights to develop, manufacture and commercialize NVC-101, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. We expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

**Our limited operating history may make it difficult for you to evaluate our business and to assess our future viability.**

Our operations to date have been limited to organizing and staffing our company, developing our technology, researching and developing our compounds, and conducting preclinical studies and early-stage clinical trials of our compounds. We have not demonstrated the ability to succeed in achieving clinical endpoints, obtain regulatory approvals, formulate and manufacture products on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability are unlikely to be as accurate as they could be if we had a longer operating history.

**We have very limited data on the use of our products in humans and will need to perform costly and time consuming clinical trials in order to bring our products to market.**

Most of the data that we have on our products is from in-vitro (laboratory) studies or in-vivo animal studies. We will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain approval from the FDA of our compounds. Often, positive in-vitro or in-vivo animal studies are not followed by positive results in human clinical trials, and we may not be able to demonstrate that our products are safe and effective for indicated uses in humans. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials and will cost between \$15 million and \$30 million.

**We currently do not have any marketable products, and if we are unable to develop and obtain regulatory approval for products that we develop, we may never generate product revenues.**

To date, our revenues have been derived solely from two research and development collaboration and license agreements. We have never generated revenues from sales of products and we cannot guarantee that we will ever have marketable drugs or other products. Satisfaction of all regulatory requirements applicable to our product candidates typically takes many years, is dependent upon the type, complexity, novelty and classification of the product candidates, and requires the expenditure of substantial resources for research and development and testing. Before proceeding with clinical trials, we will conduct pre-clinical studies, which may, or may not be, valid predictors of potential outcomes in humans. If pre-clinical studies are favorable, we will then begin clinical trials. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before we can submit for and gain approval from the FDA and other regulatory authorities in the United States and in other countries. In addition, to compete effectively, our products will need to be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We cannot be certain that the clinical development of any of our current product candidates or any other product that we may develop in the future will be successful, that they will receive the regulatory approvals required to commercialize them, or that any of our other in-licensing efforts or pre-clinical testing will yield a product suitable for entry into clinical trials. Our commercial revenues from sales of products will be derived from sales of products that we 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.

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

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

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

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

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

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

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

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

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

In addition, at any time and without public notice, we and the underwriters may release, at our respective discretions, all or some of the securities subject to our respective 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.

**We must implement additional and expensive finance and accounting systems, procedures and controls in order to grow our business and organization and to satisfy new reporting requirements, which will increase our costs and require additional management resources.**

We completed our initial public offering, or IPO, in October 2007. As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC and Canadian securities regulatory authorities, including expanded disclosure and accelerated reporting requirements and more complex accounting rules. We are also required to comply with marketplace rules and the heightened corporate governance standards of the Toronto Stock Exchange, or TSX, and the American Stock Exchange, or AMEX. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, which will be required by 2009, and other requirements of the SEC, Canadian securities regulatory authorities, AMEX and the TSX will increase our costs and require additional management resources. We recently have begun upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of the first Annual Report on Form 10-K for which compliance is required, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed with the SEC and with Canadian securities regulatory authorities. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. We have also entered into a license agreement with KCI pursuant to which we granted to them the exclusive rights to develop, manufacture and commercialize our NVC-101 compound worldwide for use in wound care in humans (other than products or uses intended for the eye, ear or nose). We cannot assure you that our collaboration with Alcon or KCI or any other collaborative arrangement will be successful, or that we will receive the full amount of research funding, milestone payments or royalties, or that any commercially valuable intellectual property will be created, from these arrangements. If Alcon or KCI were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research contemplated by our collaboration with them could be delayed or terminated and our costs of performing studies may increase. We plan on entering into additional collaborations and licensing arrangements. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful. Our current and future success depends in part on our ability to enter into successful collaboration arrangements and maintain the collaboration arrangement we currently have. If we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

**We do not have our own manufacturing capacity, and we plan to rely on partnering arrangements or third-party manufacturers for the manufacture of our potential products.**

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial

partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing the potential for product revenues.

Our products, if developed and commercialized, will require precise, high quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. These manufacturers and partners are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party compliance with these regulations and standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

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

**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.

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.

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

As of December 31, 2007, our officers and directors collectively controlled approximately 18.1% of our outstanding common stock (and approximately 22.7% of our common stock when including options held by them which were exercisable as of or within 60 days of December 31, 2007). Furthermore, as of December 31, 2007, our largest shareholder, a family trust established and controlled by Dr. Ramin Najafi, our Chairman and Chief Executive Officer, beneficially owned 14.7% of our outstanding common stock. As a result, Dr. Najafi can

significantly influence the management and affairs of our company and most matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other shareholders.

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

Our success largely depends on the skills, experience and efforts of our officers, especially our Chief Executive Officer, Chief Financial Officer, Vice President of Research and Development, Vice President of Clinical Research and Development, Senior Vice President of Corporate and Business Development, and other key employees. The efforts of each of these persons is critical to us as we continue to develop our technologies and as we attempt to transition into a company with commercial products. Any of our officers and other key employees may terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our ability to compete effectively, develop our technologies and implement our business strategies.

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

**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 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 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.

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 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.

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

We have one issued patent, one allowed patent application and eight pending applications in the United States. We also have four pending international applications filed under the Patent Cooperation Treaty, or PCT, and one issued patent in Mexico, one issued patent in China, one allowed patent in Israel and 46 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. The allowed U.S. patent application claims a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. NovaBay must pay an issue fee on or before March 27, 2008, in order for this application to issue as a U.S. patent. If NovaBay fails to timely pay this fee, no patent will issue.

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 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 related international patent applications in Argentina, Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore and Taiwan. 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 two patent applications claiming various derivatives and analogs of NVC-422 Aganocide compounds and their method of use with the USPTO as well as two corresponding PCT applications. 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, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain nine months of exclusivity as a generic product under the Waxman-Hatch Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties in order to produce our products. In addition, future patents may issue to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorneys fees if we were to be found to have willfully infringed a third party's patent, to the party claiming infringement, develop non-infringing technology, stop selling any products

we develop, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

**If bacteria develop resistance to Aganocide compounds, our revenues could be significantly reduced.**

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds, we do not expect bacteria to be able to develop resistance to Aganocide compounds. However, we cannot assure you that one or more strains of bacteria will not develop resistance to our compounds, either because our hypothesis of the mechanism of action is incorrect or because a strain of bacteria undergoes some unforeseen genetic mutation that permits it to survive. Since we expect lack of resistance to be a major factor in the commercialization of our product candidates, the discovery of such resistance would have a major adverse impact on the acceptability and sales of our products.

**If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.**

Even if the FDA approves any product candidates that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- published studies demonstrating the cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

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

In addition, any revenues we receive would depend upon our partners' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, further

business combinations or other factors outside of our control. Depending upon the terms of our agreements, the remedies we have against an under-performing partner may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement partner on acceptable terms, or at all.

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

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs, devices and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete for market share against fully integrated pharmaceutical companies or other companies that develop products independently or collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater capital resources, larger research and development staffs and facilities, and greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and devices;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing, distributing and selling products.

Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than any products that we may develop;
- obtain regulatory approvals for competing products more rapidly than we will; and
- improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

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

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

Our ability to commercialize our product candidates will depend, in part, on the extent to which health insurers, government authorities and other third-party payers will reimburse the costs of products which may be developed by us or our partners. We expect that a portion of our economic return from partnering arrangements with pharmaceutical companies and other collaborators will be derived from royalties, fees or other revenues linked to final sales of products that we or our partners develop. Newly-approved pharmaceuticals and other

products which are developed by us or our partners will not necessarily be reimbursed by third-party payers or may not be reimbursed at levels sufficient to generate significant sales. Government and other third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs or medical devices. Cost control initiatives such as these could adversely affect our or our collaborators' ability to commercialize products. In addition, real or anticipated cost control initiatives for final products may reduce the willingness of pharmaceutical companies or other potential partners to collaborate with us on the development of new products.

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

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

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

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

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

- a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

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

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

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

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

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

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

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

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

#### **ITEM 2. PROPERTIES**

Our principal executive offices and our research and development and administrative operations are located in Emeryville, California. In total, we lease approximately 19,000 square feet of office space in the facility pursuant to leases with expiration dates ranging from October 2009 to May 2013. We may seek to expand our facilities to meet our operational requirements within the next twelve months.

#### **ITEM 3. 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.

#### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

In October 2007, our stockholders approved by written consent an amendment to our articles of incorporation and bylaws, to become effective after our initial public offering, to set the size of our Board at no less than nine and no more than eleven, with the exact number of directors within such range to be fixed at nine directors. The amendment was approved by the holders of 13,801,636 shares, or 85%, of our then outstanding common stock and preferred stock, voting together as a single class on an as-converted basis.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Information

Since October 25, 2007, our common stock has been listed on the American Stock Exchange and the Toronto Stock Exchange under the symbol "NBY." Prior to such time, there was no established public trading market for our common stock. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the American Stock Exchange:

	<u>High</u>	<u>Low</u>
<b>Fiscal Year 2007:</b>		
Quarter Ended December 31, 2007 .....	\$4.25	\$3.50

On March 11, 2008, the last reported sale price of our common stock on the American Stock Exchange was \$2.20.

#### Holders

As of March 11, 2008, there were approximately 442 holders of record of our common stock. This figure does not reflect persons or entities that hold their stock in nominee or "street" name through various brokerage firms.

#### 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.

#### Sales of Unregistered Securities

The following is a summary of our transactions during the year ended December 31, 2007, involving sales of our securities that were not registered under the Securities Act of 1933, as amended:

(1) In January and October 2007, prior to the filing of our registration statement on Form S-8, we granted options to purchase an aggregate of 398,125 shares of our common stock to employees and consultants at exercise prices ranging from \$2.28 to \$4.00 per share. We also granted 452 shares of common stock to our independent directors in November 2007 pursuant to the Director Compensation Plan which were issued prior to the filing of the registration statement on Form S-8.

(2) In January 2007, we granted options to purchase an aggregate of 3,707 shares of our common stock outside of our 2005 Stock Option Plan at an exercise price of \$2.28 per share as compensation for services rendered to us in connection with a private placement of our preferred stock.

(3) In February 2007, we issued 35,000 shares of common stock to one of our consultants as compensation for services rendered to us.

(4) In October 2007, we issued warrants to purchase an aggregate of 350,000 shares of our common stock to the underwriters of our IPO as part of their compensation for their services.

The issuances of securities in the transactions described in paragraph 1 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. The issuances of securities in the transactions described in paragraphs 2 and 4 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 issuance of securities in the transaction described in paragraph 3 above was 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.

### **Use of Proceeds from Sales of Registered Securities**

On October 31, 2007, we completed the initial public offering of our common stock, pursuant to which we sold 5,000,000 shares of our common stock at the initial public offering price of \$4.00 per share. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a registration statement on Form S-1 (File No. 333-140714) that was declared effective by the SEC on October 24, 2007.

The aggregate purchase price of the shares sold by us in the offering was \$20 million. We paid to the underwriters underwriting discounts and commissions totaling \$1.4 million in connection with the offering. In addition, we incurred additional expenses of approximately \$1.5 million in connection with the offering. After deducting the underwriting discounts and commissions and offering expenses, the estimated net proceeds to us from the offering were approximately \$17.1 million.

We expect to use the proceeds from our initial public offering for research and development, working capital and other general purposes. Pending such use, the net proceeds from the offering have been invested in various interest-bearing money market accounts and marketable securities. None of the net proceeds from the offering were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliate, other than in the form of wages or salaries, fees and bonuses paid out in the ordinary course of business. We will retain broad discretion over the use of the net proceeds received from our initial public offering. The timing and amount of our actual expenditures may vary significantly depending on a number of factors, including the successful early clinical development of our lead product candidates, cash flows from operations and the anticipated growth of our business.

### **Purchases of Equity Securities by the Issuer and Affiliated Purchaser**

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

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial information as of and for the dates and periods indicated have been derived from our audited consolidated financial statements. The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operation" in Part II, Item 7 of this report and our consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2003	2004	2005	2006	2007
	(in thousands, except per share data)				
<b>Statements of Operations Data:</b>					
Revenue .....	\$ —	\$ —	\$ —	\$ 1,533	\$ 5,913
Operating expenses:					
Research and development .....	270	1,481	1,952	4,087	7,421
General and administrative .....	683	1,345	1,617	2,972	4,368
Total operating expenses .....	953	2,826	3,569	7,059	11,789
Other income (expense), net .....	(24)	22	106	240	488
Net loss before income taxes .....	(977)	(2,804)	(3,463)	(5,286)	(5,388)
Provision for income taxes .....	—	—	—	—	12
Net loss .....	<u>\$ (977)</u>	<u>\$ (2,804)</u>	<u>\$ (3,463)</u>	<u>\$ (5,286)</u>	<u>\$ (5,400)</u>
Net loss per share:					
Basic and diluted .....	\$ (0.24)	\$ (0.64)	\$ (0.71)	\$ (0.92)	\$ (0.60)
Shares used in per share calculations:					
Basic and diluted .....	4,044	4,378	4,852	5,715	8,974

	December 31,				
	2003	2004	2005	2006	2007
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments .....	\$1,104	\$ 4,047	\$ 3,212	\$11,086	\$22,353
Working capital .....	631	3,908	2,985	7,926	18,194
Total assets .....	1,315	4,359	3,562	11,866	23,922
Capital lease obligation—current and non-current .....	30	20	—	—	86
Equipment loan—current and non-current .....	—	—	—	—	716
Deferred revenue—current and non-current .....	—	—	—	9,167	7,517
Convertible notes payable .....	405	—	—	—	—
Convertible preferred stock .....	65	164	175	192	—
Common stock and additional paid-in capital .....	2,258	9,127	10,869	14,683	32,797
Total stockholders' equity .....	802	4,093	3,252	1,813	14,320

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part IV, Item 15 of this report. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

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

In August 2006, we entered into a collaboration and license agreement with Alcon, to license to Alcon the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solution. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. In addition to the technology access fee, we are entitled to receive semi-annual payments from Alcon to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compounds. Alcon has the right to terminate the agreement in its entirety upon nine months' notice, or terminate portions of the agreement upon 135 days' notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

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

In June 2007, we entered into a license agreement with KCI, under which we granted KCI the exclusive rights to develop, manufacture and commercialize NeutroPhase, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to us a non-refundable technology access fee of \$200,000. We are also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, we are entitled to receive payments of up to \$1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. KCI has the right to terminate the agreement without penalty upon 60 days' notice. We have the right to terminate the agreement if

KCI has not commercially launched a product incorporating NVC-101, or any other product containing hypochlorous acid, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

We cannot control whether or when KCI will launch any products incorporating NeutroPhase, or any other products containing hypochlorous acid as the principal active ingredient, and therefore cannot predict whether or when we will receive royalties on sales of commercialized products.

To date, we have generated no revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock. We have also recently begun to generate revenue under our agreements with Alcon and KCI. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of December 31, 2007, we had an accumulated deficit of \$18.5 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.

### **Recent Events**

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

In the third and fourth quarters of 2007, we completed two Phase I safety trials of NVC-422, our lead Aganocide compound, for use as a pre-surgical nasal preparation (trademarked as AgaNase). The results from these studies indicate that AgaNase is safe and well tolerated.

In November 2007, we initiated Phase II studies of AgaNase in healthy volunteers who carry *S. aureus* in their nasal passages. The purpose of these studies is to establish the efficacy of AgaNase as a pre-surgical nasal preparation. We are conducting these studies to demonstrate that AgaNase can reduce the amount of *S. aureus*, MRSA in particular, in the nasal passages. Used prior to surgery, we believe AgaNase should significantly reduce the number of patients who develop potentially life-threatening blood borne infections. These studies are currently underway.

In December 2007, we filed an IND application with the FDA to initiate Phase I human clinical trials of NVC-422 for the prevention of catheter associated urinary tract infections. In January 2008, NovaBay received clearance of the IND and the treatment phase of the study began in late February 2008.

In September 2007, we obtained approval from the FDA for the use of NeutroPhase in a variety of wound care applications and in February 2008 received a Notice of Allowance on the related patent.

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

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

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

While our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements, included in Part IV, Item 15 of this report, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

### ***Revenue Recognition***

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

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

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

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

*Milestones*—Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and a reasonable amount of time passes between the up-front license payment and the first milestone

payment as well as between each subsequent milestone payment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

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

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

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

### ***Patent Costs***

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

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

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

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

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services”, which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

The adoption of SFAS No.123R had a material effect on our financial position and results of operations. See Note 10 of the Notes to Consolidated Financial Statements, included in Part IV, Item 15 of this report, 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.

### **Recently Issued Accounting Pronouncements**

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 consolidated financial position and results of operations.

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

In June 2007, the FASB issued EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities". EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. We are currently assessing the impact of EITF No. 07-3 on our consolidated financial position and results of operations.

### **Results of Operations**

#### ***Comparison of Years Ended December 31, 2006 and December 31, 2007***

##### ***License and Collaboration Revenue***

Total license and collaboration revenue was \$1.5 million for the year ended December 31, 2006, compared to \$5.9 million for the year ended December 31, 2007. License and collaboration revenue consisted of amounts earned under the license and collaboration agreements with Alcon and KCI for amortization of the upfront technology access fees and amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The increase in revenue during 2007 as compared to 2006 is attributable to the timing of the Alcon and KCI agreements, which were entered into in August 2006 and June 2007, respectively. The upfront technology access fee of \$10.0 million from Alcon will be amortized into

revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront technology access fee from KCI of \$200,000 will be amortized on a straight-line basis over 18 months through December 2008.

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

#### *Research and Development*

Research and development expenses increased by 82% to \$7.4 million for the year ended December 31, 2007 from \$4.1 million for the year ended December 31, 2006. This increase was due in part to an increase in salary and benefits expense of \$1.5 million, as the average number of research and development personnel increased by 77% from 2006 to 2007, and included the hiring of several senior personnel. In connection with this increase in hiring, recruiting and relocation costs increased by \$110,000 due to an increased reliance on outside personnel recruitment firms and the funding of relocation benefits. Also, during the last three quarters of 2007, we conducted Phase I and Phase II clinical studies for the pre-surgical nasal preparation indication, which caused our clinical expenses for the year ended December 31, 2007 to increase by \$730,000 over the year ended December 31, 2006. Additionally, increased efforts around the chemistry, manufacturing and controls related to NVC-422 resulted in an increase of \$538,000 from the year ended December 31, 2006 to the year ended December 31, 2007 as we produced more drug substance to support our internal research programs and Alcon collaboration requirements. Costs for outside consultants increased by \$245,000 during the year ended December 31, 2007 as a result of increased regulatory activity associated with the IND filings for the pre-surgical nasal preparation and catheter associated urinary tract infection indications and the filing of the 510(k) application related to our NVC-101 compound, as well as due to increased usage of manufacturing and formulation consultants in connection with the KCI agreement. The amortization of stock-based compensation increased by \$121,000 from 2006 to 2007 as a result of an increased number of grants becoming subject to the SFAS No. 123R guidance.

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

#### *General and Administrative*

General and administrative expenses increased by 47% to \$4.4 million for the year ended December 31, 2007 from \$3.0 million for the year ended December 31, 2006. This increase was due in part to an increase in salary and benefits expense of \$494,000 as the average number of general and administrative personnel grew by 27% from 2006 to 2007. The increase in general and administrative expenses during the year ended December 31, 2007 was also attributable to the issuance of \$360,000 in cash and stock to a consultant for investor relations and financial advisory services and cash and stock payments of \$114,000 made to our non-employee directors upon the closing of the IPO and for ongoing director compensation. Rent expense increased by \$209,000 during the year ended December 31, 2007 compared to the same period in the prior year because we leased additional space in late 2006 and during the second and fourth quarters of 2007 to accommodate our increased personnel and expanded laboratory facilities. Accounting expenses increased by \$97,000 from the 2006 to the 2007 period as audit and tax activities increased in preparation for becoming a public company.

We expect that general and administrative expenses will increase during 2008 and in subsequent years due to increasing public company expenses and business development costs and our expanding operational infrastructure. In particular, we expect to incur increasing legal, accounting, investor relations, equity administration and insurance costs in order to operate as a public company.

### *Other Income, Net*

Other income, net increased to \$488,000 for the year ended December 31, 2007 from \$240,000 for the year ended December 31, 2006. This increase was primarily attributable to increased interest income earned due to higher average cash balances as a result of the \$10.0 million upfront cash amount received from Alcon in August 2006 and the \$17.1 million received upon the closing of the IPO in October 2007.

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

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

#### *License and Collaboration Revenue*

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

#### *Research and Development*

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

#### *General and Administrative*

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

### *Other Income, Net*

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

### *Liquidity and Capital Resources*

We have incurred cumulative net losses of \$18.5 million since inception through December 31, 2007. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the private placement of our preferred stock. We raised total net proceeds of \$647,000 through the sale of our Series A Preferred Stock in 2002 and 2003, \$3.0 million through the sale of our Series B Preferred Stock in 2003 and 2004, \$5.4 million through the sale of our Series C Preferred Stock in 2004 and 2005, and \$3.6 million through the sale of our Series D Preferred Stock in 2005 and 2006. In October 2007, we completed our IPO in which we raised a total of \$20.0 million, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million.

In August 2006, we entered into a collaboration and license agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of \$10.0 million in September 2006. Additionally, we are entitled to receive semi-annual payments each January and July over the four year term of the agreement to support on-going research and development efforts. In both January and July 2007, we received a payment of \$1.4 million to support the performance of research and development activities throughout 2007. The Alcon agreement also provides for milestone payments upon the achievement of specified milestones in each field of use and royalty payments upon the sale of commercialized products. The aggregate milestone payments payable in connection with the ophthalmic, otic and sinus fields are \$19 million, \$12 million and \$39 million, respectively. As of December 31, 2007, we have not achieved any milestone nor has any product been commercialized to date. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.

In June 2007, we entered into a license agreement with KCI. Under the terms of the agreement, we received an upfront technology access fee of \$200,000 in June 2007. In addition, we are entitled to receive payments of up to \$1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. As of December 31, 2007, we had not earned or received any milestone or royalty payments under the KCI agreement. We cannot control whether or when KCI will launch any products incorporating NeutroPhase, or any other products containing hypochlorous acid as the principal active ingredient, and therefore cannot predict whether or when we will receive royalties on sales of commercialized products.

During April 2007, we entered into a master security agreement to establish a \$1.0 million equipment loan facility with a financial institution. The purpose of the loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement. As of December 31, 2007, we had an outstanding equipment loan balance of \$716,000 carrying a weighted-average interest rate of 10.57%. The principal and interest due under the loan will be repaid in equal monthly installments through April 2011. As of December 31, 2007 there was \$206,000 available for borrowing under this equipment loan facility. In January 2008, we borrowed \$203,000 under this equipment loan facility at an interest rate of 10.45%. Upon the close of this funding, there was \$3,000 available for borrowing under the equipment loan facility.

In March 2008, we amended the Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 with PM Holdings Ltd. Under the terms of the original agreement, we agreed to pay PM Holdings \$28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of \$264,000 and the issuance of warrants to purchase 300,000 common shares at an exercise price of \$4.00 per share. Under the amended agreement, no further cash or equity amounts are payable during the duration of the agreement through February 2010. We expect to pay the upfront cash amount and issue the warrants during April 2008.

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

As of December 31, 2007, we had cash, cash equivalents, and short-term investments of \$22.4 million compared to \$11.1 million at December 31, 2006.

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

For the year ended December 31, 2007, cash used in operating activities of \$6.3 million was primarily attributable to our net loss of \$5.4 million, excluding the amounts recognized for stock-based compensation and depreciation, which are non-cash expenses, and excluding the amounts recognized for the accretion of discount on short-term investments, which is a non-cash revenue item. In addition, deferred revenue decreased by \$1.7 million as a result of the ongoing amortization of the upfront technology access fee received from Alcon in 2006. The cash related to this revenue item was received in 2006. Also, prepaid expenses and other assets increased by \$193,000, reflecting amounts that were paid during the period but had not yet been expensed. This amount was offset by an increase in accounts payable and accrued liabilities of \$397,000, in part due to the accrual of annual bonuses of \$572,000 which were expensed during the period but were not paid as of December 31, 2007.

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

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

For the year ended December 31, 2007, cash used in investing activities of \$5.7 million was attributable to purchases of short-term investments (net of maturities or sales) of \$5.0 million and purchases of property and equipment of \$663,000.

For the year ended December 31, 2006, cash used in investing activities of \$5.5 million was attributable to purchases of short-term investments (net of maturities or sales) of \$5.2 million and purchases of property and equipment of \$362,000.

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

Net cash provided by financing activities of \$18.0 million for the year ended December 31, 2007 was primarily attributable to the net proceeds of \$17.1 million received upon the close of the IPO and \$794,000 in proceeds from borrowings under our equipment loan.

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.

We believe our cash balance at December 31, 2007 is sufficient to fund our projected operating requirements through at least the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

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

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

## Quarterly Results of Operations

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

	Three Months Ended							
	Mar. 31, 2006	June 30, 2006	Sept. 30, 2006	Dec. 31, 2006	Mar. 31, 2007	June 30, 2007	Sept. 30, 2007	Dec. 31, 2007
	(in thousands, except per share data)							
<b>Statement of Operations Data:</b>								
Revenue .....	\$ —	\$ —	\$ 208	\$ 1,325	\$ 1,483	\$ 1,465	\$ 1,444	\$ 1,521
Operating expenses:								
Research and development ...	531	788	1,122	1,646	1,463	2,066	2,051	1,841
General and administrative ...	717	714	634	907	1,035	1,069	1,021	1,243
Total operating expenses .....	1,248	1,502	1,756	2,553	2,498	3,135	3,072	3,084
Other income, net .....	30	9	58	143	122	113	72	181
Net loss before income taxes .....	(1,218)	(1,493)	(1,490)	(1,085)	(893)	(1,557)	(1,556)	(1,382)
Provision for income taxes .....	—	—	—	—	—	—	—	12
Net loss .....	<u>\$(1,218)</u>	<u>\$(1,493)</u>	<u>\$(1,490)</u>	<u>\$(1,085)</u>	<u>\$ (893)</u>	<u>\$(1,557)</u>	<u>\$(1,556)</u>	<u>\$(1,394)</u>
Net loss per share:								
Basic and diluted .....	\$ (0.24)	\$ (0.28)	\$ (0.24)	\$ (0.17)	\$ (0.14)	\$ (0.24)	\$ (0.24)	\$ (0.09)
Shares used in per share calculations:								
Basic and diluted .....	5,066	5,258	6,234	6,281	6,416	6,500	6,564	16,332

## Net Operating Losses and Tax Credit Carryforwards

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

## 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.

## Contractual Obligations

Our contractual cash commitments as of December 31, 2007 were as follows:

<u>Contractual Obligations:</u>	<u>Payment Due By Period</u>					
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>	
			(in thousands)			
Operating leases .....	\$3,121	\$ 779	\$1,334	\$864	\$144	
Capital lease .....	97	45	52	—	—	
Equipment loan .....	837	284	518	35	—	
Total .....	<u>\$4,055</u>	<u>\$1,108</u>	<u>\$1,904</u>	<u>\$899</u>	<u>\$144</u>	

Our commitments under the operating leases shown above consist of payments relating to six 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 May 31, 2013.

Our commitment under the capital lease shown above consists of the total payments due under one lease of laboratory equipment. This amount includes \$11,000 of interest payments over the remaining term of the lease.

Our commitment under the equipment loan shown above consists of the total payments due under the loan facility. This amount includes \$121,000 of interest payments over the remaining term of the loan.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

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

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 is set forth in Part IV, Item 15 of this report and is hereby incorporated into this Item 8 by reference. Our quarterly financial information is set forth in Item 7 of this report and is hereby incorporated into this Item 8 by reference.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A(T). CONTROLS AND PROCEDURES**

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

#### **Evaluation of Disclosure Controls and Procedures**

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

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

#### **Changes in Internal Control Over Financial Reporting**

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

### **ITEM 9B. OTHER INFORMATION**

On March 12, 2008, we amended the Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 with PM Holdings Ltd. Under the terms of the original agreement, we agreed to pay PM Holding \$28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of \$264,000 and the issuance of warrants to purchase 300,000 common shares at an exercise price of \$4.00 per share. Under the amended agreement, no further cash or equity amounts are payable during the duration of the agreement through February 2010. We expect to pay the upfront cash amount and issue the warrants during April 2008.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Item incorporated by reference to the definitive proxy statement to be filed relating to our 2008 Annual Meeting of Stockholders.

#### **ITEM 11. EXECUTIVE COMPENSATION**

Item incorporated by reference to the definitive proxy statement to be filed relating to our 2008 Annual Meeting of Stockholders.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Item incorporated by reference to the definitive proxy statement to be filed relating to our 2008 Annual Meeting of Stockholders.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Item incorporated by reference to the definitive proxy statement to be filed relating to our 2008 Annual Meeting of Stockholders.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Item incorporated by reference to the definitive proxy statement to be filed relating to our 2008 Annual Meeting of Stockholders.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) Documents filed as part of this report:

(1) *Financial Statements.* The following financial statements of NovaBay Pharmaceuticals, Inc. are included in a separate section of this Annual Report on Form 10-K commencing on the pages referenced below:

Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets .....	F-3
Consolidated Statements of Operations .....	F-4
Consolidated Statements of Stockholders' Equity .....	F-5
Consolidated Statements of Cash Flows .....	F-7
Notes to Consolidated Financial Statements .....	F-8

(2) *Financial Statement Schedules.*

All schedules have been omitted because they are not required or the required information is included in our consolidated financial statements and notes thereto.

(3) *Exhibits.*

The following exhibits are filed or furnished herewith or incorporated by reference to the location indicated below:

<u>Exhibit No.</u>	<u>Description</u>
3.1**	Amended and Restated Articles of Incorporation of registrant
3.2**	Amended and Restated Bylaws of registrant
4.1*	Specimen common stock certificate
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 January 1, 2007 by and between the Registrant and Ramin ("Ron") Najafi
10.5+*	Employment Agreement dated January 1, 2007 by and between the Registrant and John ("Jack") O'Reilly
10.6+*	Employment Agreement dated January 1, 2007 by and between the Registrant and Behzad Khosrovi
10.7+*	Employment Agreement dated January 1, 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

<u>Exhibit No.</u>	<u>Description</u>
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 13, 2007 by and between the Registrant and PM Holdings Ltd.
10.13*	Director Compensation Plan
10.14*	Master Security Agreement dated April 23, 2007 by and between the Registrant and General Electric Capital Corporation
10.15†*	License Agreement dated June 11, 2007 by and between us and KCI International VOF GP
10.16*	Form of Common Stock Purchase Warrant by and between the Registrant and the underwriters
10.17*	Form of Registration Rights Agreement by and between the Registrant and the underwriters
10.18+	Employment Agreement dated January 9, 2008 by and between the Registrant and Thomas J. Paulson
10.19	Amendment #1 dated March 12, 2008 to Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 by and between the Registrant and PM Holdings Ltd.
10.20	Fifth Amendment dated November 20, 2007 to Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
23.1	Consent of Davidson & Company LLP
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.

\*\* Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.

+ Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.



## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets as of December 31, 2006 and 2007 .....	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2005, 2006 and 2007 and for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2007 .....	F-4
Consolidated Statements of Stockholders' Equity as of December 31, 2002, 2003, 2004, 2005, 2006 and 2007 .....	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2006 and 2007 and for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2007 ...	F-7
Notes to Consolidated Financial Statements .....	F-8

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and the Stockholders of  
NovaBay Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of NovaBay Pharmaceuticals, Inc. (a development stage company) as at December 31, 2007 and 2006 and the related consolidated statements of operations, cash flows and stockholders' equity for the years ended December 31, 2007, 2006 and 2005 and for the period from July 1, 2002 (date of development stage inception) to December 31, 2007. 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as at December 31, 2007 and 2006 and the results of its operations and its cash flows for the years ended December 31, 2007, 2006 and 2005 and for the period from July 1, 2002 (date of development stage inception) to December 31, 2007 in conformity with generally accepted accounting principles in the United States of America.

/s/ Davidson & Company LLP

Chartered Accountants

Vancouver, Canada  
February 8, 2008

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)

**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except per share data)

	December 31,	
	2006	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 4,903	\$ 10,941
Short-term investments .....	6,183	11,412
Prepaid expenses and other current assets .....	226	419
Total current assets .....	11,312	22,772
Property and equipment, net .....	554	1,150
<b>TOTAL ASSETS</b> .....	<b>\$ 11,866</b>	<b>\$ 23,922</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Current liabilities:		
Accounts payable .....	\$ 365	\$ 142
Accrued liabilities .....	521	1,141
Capital lease obligation .....	—	37
Equipment loan .....	—	219
Deferred revenue .....	2,500	3,039
Total current liabilities .....	3,386	4,578
Capital lease obligation—non-current .....	—	49
Equipment loan—non-current .....	—	497
Deferred revenue—non-current .....	6,667	4,478
Total liabilities .....	10,053	9,602
Commitments and contingencies (note 8)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; 0 and 5,000 shares authorized at December 31, 2006 and 2007, respectively; no shares issued or outstanding at all periods .....	—	—
Convertible preferred stock		
Series A, \$0.01 par value; 4,000 and 0 shares authorized at December 31, 2006 and 2007, respectively; 3,215 and 0 shares issued and outstanding at December 31, 2006 and 2007, respectively; liquidation value of \$1,286 and \$0 at December 31, 2006 and 2007, respectively .....	32	—
Series B, \$0.01 par value; 7,000 and 0 shares authorized at December 31, 2006 and 2007, respectively; 6,865 and 0 shares issued and outstanding at December 31, 2006 and 2007, respectively; liquidation value of \$3,226 and \$0 at December 31, 2006 and 2007, respectively .....	69	—
Series C, \$0.01 par value; 8,000 and 0 shares authorized at December 31, 2006 and 2007, respectively; 6,666 and 0 shares issued and outstanding at December 31, 2006 and 2007, respectively; liquidation value of \$5,667 and \$0 at December 31, 2006 and 2007, respectively .....	67	—
Series D, \$0.01 par value; 20,000 and 0 shares authorized at December 31, 2006 and 2007, respectively; 2,481 and 0 shares issued and outstanding at December 31, 2006 and 2007, respectively; liquidation value of \$3,722 and \$0 at December 31, 2006 and 2007, respectively .....	24	—
Total convertible preferred stock .....	192	—
Common stock, \$0.01 par value; 64,000 and 65,000 shares authorized at December 31, 2006 and 2007, respectively; 6,311 and 21,269 shares issued and outstanding at December 31, 2006 and 2007, respectively .....	63	212
Additional paid-in capital .....	14,620	32,585
Accumulated other comprehensive income (loss) .....	12	(3)
Accumulated deficit during development stage .....	(13,074)	(18,474)
Total stockholders' equity .....	1,813	14,320
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b> .....	<b>\$ 11,866</b>	<b>\$ 23,922</b>

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

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share data)

	Year Ended December 31,			Cumulative
	2005	2006	2007	Period from July 1, 2002 (date of development stage inception) to December 31, 2007
<b>REVENUE</b>				
License and collaboration revenue .....	\$ —	\$ 1,533	\$ 5,913	\$ 7,446
Total revenue .....	—	1,533	5,913	7,446
<b>EXPENSES</b>				
Operating Expenses:				
Research and development .....	1,952	4,087	7,421	15,412
General and administrative .....	1,617	2,972	4,368	11,328
Total operating expenses .....	3,569	7,059	11,789	26,740
Other income, net .....	106	240	488	832
Net loss before income taxes .....	(3,463)	(5,286)	(5,388)	(18,462)
Provision for income taxes .....	—	—	12	12
Net loss .....	<u>\$(3,463)</u>	<u>\$(5,286)</u>	<u>\$(5,400)</u>	<u>\$(18,474)</u>
Net loss per share:				
Basic and diluted .....	\$ (0.71)	\$ (0.92)	\$ (0.60)	
Shares used in per share calculations:				
Basic and diluted .....	4,852	5,715	8,974	

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

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)

**CONSOLIDATED 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)
Total comprehensive loss									(544)
Issuance of Series A preferred stock and common stock for acquisition of LLC	2,723	27	3,902	39	462	—	—	—	528
Stock-based compensation expense related to non-employee stock options	—	—	—	—	15	—	—	—	15
Sale of stock warrants	—	—	—	—	10	—	—	—	10
<b>Balance at December 31, 2002</b>	<u>2,723</u>	<u>27</u>	<u>3,902</u>	<u>39</u>	<u>487</u>	<u>—</u>	<u>—</u>	<u>(544)</u>	<u>9</u>
Comprehensive loss:									
Net loss	—	—	—	—	—	—	—	(977)	(977)
Total 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	—	—	25	—	7	—	—	—	7
Issuance of stock for option exercises	—	—	40	1	7	—	—	—	8
Issuance of stock for warrant exercises	—	—	137	1	109	—	—	—	110
Stock-based compensation expense related to non-employee stock options	—	—	—	—	2	—	—	—	2
<b>Balance at December 31, 2003</b>	<u>6,473</u>	<u>65</u>	<u>4,104</u>	<u>41</u>	<u>2,217</u>	<u>—</u>	<u>—</u>	<u>(1,521)</u>	<u>802</u>
Comprehensive loss:									
Net loss	—	—	—	—	—	—	—	(2,804)	(2,804)
Total 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	—	—	5	—	1	—	—	—	1
Issuance of stock for warrant exercises	—	—	31	—	37	—	—	—	37
Issuance of stock for Series B offering costs	—	—	368	4	106	—	—	—	110
Issuance of stock for services	—	—	15	—	4	—	—	—	4
Stock-based compensation expense related to non-employee stock options	—	—	—	—	7	—	—	—	7
<b>Balance at December 31, 2004</b>	<u>16,391</u>	<u>164</u>	<u>4,523</u>	<u>45</u>	<u>9,082</u>	<u>(873)</u>	<u>—</u>	<u>(4,325)</u>	<u>4,093</u>

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

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)

**CONSOLIDATED 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					
<b>Comprehensive loss:</b>									
Net loss	—	—	—	—	—	—	(3,463)	(3,463)	
Change in unrealized gains (losses) on investments	—	—	—	—	—	—	(4)	—	(4)
Total 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	—	—	50	—	12	—	—	—	12
Issuance of stock for warrant exercises	—	—	292	3	324	—	—	—	327
Issuance of stock and options for Series C offering costs	—	—	164	2	101	—	—	—	103
Issuance of stock for services	—	—	20	—	17	—	—	—	17
Stock-based compensation expense related to non-employee stock options	—	—	—	—	55	—	—	—	55
Proceeds from stock subscription receivable	—	—	—	—	—	873	—	—	873
<b>Balance at December 31, 2005</b>	<u>17,488</u>	<u>175</u>	<u>5,049</u>	<u>50</u>	<u>10,819</u>	<u>—</u>	<u>(4)</u>	<u>(7,788)</u>	<u>3,252</u>
<b>Comprehensive loss:</b>									
Net loss	—	—	—	—	—	—	(5,286)	(5,286)	(5,286)
Change in unrealized gains (losses) on investments	—	—	—	—	—	—	16	—	16
Total 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	—	—	80	1	22	—	—	—	23
Issuance of stock for warrant exercises	—	—	1,148	12	964	—	—	—	976
Issuance of stock and options for Series D offering costs	—	—	31	—	64	—	—	—	64
Issuance of stock for services	—	—	3	—	5	—	—	—	5
Initial public offering costs	—	—	—	—	(93)	—	—	—	(93)
Stock-based compensation expense related to employee and director stock options	—	—	—	—	313	—	—	—	313
Stock-based compensation expense related to non-employee stock options	—	—	—	—	49	—	—	—	49
<b>Balance at December 31, 2006</b>	<u>19,227</u>	<u>192</u>	<u>6,311</u>	<u>63</u>	<u>14,620</u>	<u>—</u>	<u>12</u>	<u>(13,074)</u>	<u>1,813</u>
<b>Comprehensive loss:</b>									
Net loss	—	—	—	—	—	—	(5,400)	(5,400)	(5,400)
Change in unrealized gains (losses) on investments	—	—	—	—	—	—	(15)	—	(15)
Total comprehensive loss									(5,415)
Conversion of preferred stock to common stock in connection with IPO	(19,227)	(192)	9,614	96	96	—	—	—	—
Issuance of stock and warrants in connection with IPO, net of offering costs	—	—	5,000	50	17,120	—	—	—	17,170
Issuance of stock for option exercises	—	—	298	3	111	—	—	—	114
Issuance of stock for services	—	—	38	—	92	—	—	—	92
Issuance of stock for director compensation	—	—	8	—	29	—	—	—	29
Stock-based compensation expense related to employee and director stock options	—	—	—	—	399	—	—	—	399
Stock-based compensation expense related to non-employee stock options	—	—	—	—	118	—	—	—	118
<b>Balance at December 31, 2007</b>	<u>—</u>	<u>\$ —</u>	<u>21,269</u>	<u>\$212</u>	<u>\$32,585</u>	<u>\$—</u>	<u>\$ (3)</u>	<u>\$(18,474)</u>	<u>\$14,320</u>

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

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,			Cumulative Period from July 1, 2002 (date of development stage inception) to December 31, 2007
	2005	2006	2007	2007
<b>Cash flows from operating activities:</b>				
Net loss	\$(3,463)	\$ (5,286)	\$ (5,400)	\$(18,474)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation	48	74	183	400
Accretion of discount on short-term investments	—	(32)	(246)	(278)
Net realized loss on sales of short-term investments	12	20	—	32
Loss on disposal of property and equipment	—	1	—	121
Stock-based compensation expense for options and stock issued to employees and directors	—	313	428	741
Stock-based compensation expense for options and stock issued to non-employees	71	54	210	363
Taxes paid by LLC	—	—	—	1
Net change in assets and liabilities:				
(Increase) decrease in prepaid expenses and other assets	38	(143)	(193)	(414)
Increase in accounts payable and accrued liabilities	64	576	397	1,308
Increase (decrease) in deferred revenue	—	9,167	(1,650)	7,517
Net cash provided by (used in) operating activities	<u>(3,230)</u>	<u>4,744</u>	<u>(6,271)</u>	<u>(8,683)</u>
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(123)	(362)	(663)	(1,550)
Proceeds from disposal of property and equipment	1	1	1	44
Purchases of short-term investments	(1,957)	(11,293)	(49,197)	(62,447)
Proceeds from maturities and sales of short-term investments	936	6,141	44,199	51,276
Cash acquired in purchase of LLC	—	—	—	516
Net cash used in investing activities	<u>(1,143)</u>	<u>(5,513)</u>	<u>(5,660)</u>	<u>(12,161)</u>
<b>Cash flows from financing activities:</b>				
Proceeds from preferred stock issuances, net of offering costs	1,342	2,558	—	11,160
Proceeds from sales of common stock and warrants	—	—	—	17
Proceeds from exercise of options and warrants	339	999	114	1,608
Proceeds from initial public offering, net of offering costs	—	(93)	17,170	17,077
Proceeds from stock subscription receivable	873	—	—	873
Proceeds from issuance of notes	—	—	—	405
Principal payments on capital lease obligation	(20)	—	(31)	(71)
Proceeds from borrowings under equipment loan	—	—	794	794
Principal payments on equipment loan	—	—	(78)	(78)
Net cash provided by financing activities	<u>2,534</u>	<u>3,464</u>	<u>17,969</u>	<u>31,785</u>
Net increase (decrease) in cash and cash equivalents	<u>(1,839)</u>	<u>2,695</u>	<u>6,038</u>	<u>10,941</u>
Cash and cash equivalents, beginning of period	4,047	2,208	4,903	—
Cash and cash equivalents, end of period	<u>\$ 2,208</u>	<u>\$ 4,903</u>	<u>\$ 10,941</u>	<u>\$ 10,941</u>
<b>Supplemental disclosure of cash flow information:</b>				
Interest paid	\$ 1	\$ 2	\$ 34	\$ 44
Income taxes paid	\$ —	\$ —	\$ —	\$ —
<b>Non-cash activities:</b>				
Conversion of notes and accrued interest to preferred stock	\$ —	\$ —	\$ —	\$ 429
Issuance of stock for subscription receivable	\$ —	\$ —	\$ —	\$ 873
Issuance of stock, options and warrants for stock offering costs	\$ 103	\$ 64	\$ 524	\$ 801
Current assets and property and equipment acquired in acquisition of LLC	\$ —	\$ —	\$ —	\$ 11
Property and equipment acquired under capital lease obligations	\$ —	\$ —	\$ 117	\$ 157

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

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1. ORGANIZATION**

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

We were incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, we changed our name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, we formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which may conduct research and development in Canada, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which will explore and pursue dermatological opportunities. We currently operate in one business segment.

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

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

***Basis of Presentation***

The consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries. Intercompany transactions and balances have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars. The financial statements have been prepared under the guidelines of Statement of Financial Accounting Standard ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises". A development stage enterprise is one in which planned principal operations have not commenced, or if its operations have commenced, there have been no significant revenues therefrom. As of December 31, 2007, we had not commenced our planned principal operations.

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

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, NovaBay Pharmaceuticals Canada, Inc. and DermaBay, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

***Reverse Stock Split***

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

***Use of Estimates***

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

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

We consider all highly liquid instruments with a stated maturity of three months or less to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximate their fair value. As of December 31, 2007, our cash and cash equivalents were held in financial institutions in the United States and include deposits in money market funds, which were unrestricted as to withdrawal or use.

We classify all highly liquid investments with a stated maturity of greater than three months as short-term investments. Short-term investments generally consist of United States government, municipal and corporate debt securities. We have classified our short-term investments as available-for-sale. We do not intend to hold securities with stated maturities greater than twelve months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we occasionally sell these securities prior to their stated maturities. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other than temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. The amortization and accretion, interest income and realized gains and losses are included in other income, net within the consolidated statements of operations. Interest income is recognized when earned.

***Concentrations of Credit Risk***

Financial instruments which potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. We maintain deposits of cash, cash equivalents and short-term investments with three highly-rated, major financial institutions in the United States.

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. We do not believe we are exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, we have established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

***Fair Value of Financial Instruments***

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of capital lease obligations and equipment loans approximates its carrying amounts as a market rate of interest is attached to their repayment.

***Property and Equipment***

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

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

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

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

***Accumulated Other Comprehensive Income***

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

***Revenue Recognition***

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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.

***Advertising Costs***

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

***Research and Development Costs***

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

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

***Patent Costs***

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

***Stock-Based Compensation***

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

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

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

***Income Taxes***

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

**NOVABAY PHARMACEUTICALS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

***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. There is no difference between basic and diluted net loss per share for all periods presented due to the Company's net losses.

The following outstanding preferred stock, stock options and stock warrants were excluded from the diluted EPS computation as their effect would have been anti-dilutive:

<u>(in thousands)</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2006</u>	<u>2007</u>
Convertible preferred stock .....	8,744	9,614	—
Stock options .....	1,782	2,401	2,896
Stock warrants .....	1,328	—	350

***Recently Issued Accounting Pronouncements***

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 consolidated financial position and results of operations.

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

In June 2007, the FASB issued EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities". EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. We are currently assessing the impact of EITF No. 07-3 on our consolidated financial position and results of operations.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**NOTE 3. SHORT-TERM INVESTMENTS**

Short-term investments at December 31, 2006 and 2007 consisted of the following:

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

<u>(in thousands)</u>	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Corporate bonds .....	\$ 5,362	\$—	\$ (4)	\$ 5,358
U.S. Agencies .....	5,553	1	—	5,554
Municipal bonds .....	500	—	—	500
Total .....	<u>\$11,415</u>	<u>\$ 1</u>	<u>\$ (4)</u>	<u>\$11,412</u>

Contractual maturities of short-term investments as of December 31, 2007 were as follows:

<u>(in thousands)</u>	December 31, 2007	
	Amortized Cost	Market Value
Due in one year or less .....	\$ 9,915	\$ 9,912
Due after ten years .....	1,500	1,500
Total .....	<u>\$11,415</u>	<u>\$11,412</u>

During the years ended December 31, 2005 and 2006, we recognized a net realized loss of \$12,000 and \$20,000, respectively. We did not recognize any realized gains or losses for the year ended December 31, 2007. For the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2007, we recognized a net realized loss of \$32,000.

**NOTE 4. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

<u>(in thousands)</u>	December 31,	
	2006	2007
Office and laboratory equipment .....	\$ 550	\$1,243
Furniture and fixtures .....	88	96
Software .....	31	72
Leasehold improvements .....	36	73
Total property and equipment, cost .....	705	1,484
Less: accumulated depreciation .....	(151)	(334)
Total property and equipment, net .....	<u>\$ 554</u>	<u>\$1,150</u>

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Depreciation expense was \$48,000, \$74,000 and \$183,000 for the years ended December 31, 2005, 2006 and 2007, respectively and \$400,000 for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2007.

**NOTE 5. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following:

<u>(in thousands)</u>	<u>December 31,</u>	
	<u>2006</u>	<u>2007</u>
Research and development .....	\$225	\$ 178
Employee payroll and benefits .....	119	688
Professional fees .....	143	197
Other .....	34	78
Total accrued liabilities .....	<u>\$521</u>	<u>\$1,141</u>

**NOTE 6. CAPITAL LEASE OBLIGATION**

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

<u>(in thousands)</u>	<u>December 31,</u> <u>2007</u>
Office and laboratory equipment .....	\$166
Less: accumulated depreciation .....	(19)
Capital lease assets, net .....	<u>\$147</u>

Future minimum lease payments under capital leases were as follows at December 31, 2007:

<u>(in thousands)</u>	<u>Lease</u> <u>Commitment</u>
Year ending December 31:	
2008 .....	\$ 45
2009 .....	45
2010 .....	7
Total minimum lease payments .....	97
Less: amount representing interest .....	(11)
Present value of minimum lease payments .....	<u>\$ 86</u>

**NOTE 7. EQUIPMENT LOAN**

During April 2007, we entered into a master security agreement to establish a \$1.0 million equipment loan facility with a financial institution. The purpose of this loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement.

As of December 31, 2007, we had an outstanding equipment loan balance of \$716,000 carrying a weighted-average interest rate of 10.57%. At December 31, 2007, there was \$206,000 available for borrowing under this equipment loan facility.

Future minimum loan payments under equipment loans were as follows at December 31, 2007:

<u>(in thousands)</u>	<u>Loan Commitment</u>
Year ending December 31:	
2008 .....	\$ 284
2009 .....	281
2010 .....	237
2011 .....	<u>35</u>
Total minimum loan payments .....	837
Less: amount representing interest .....	<u>(121)</u>
Present value of minimum loan payments .....	<u>\$ 716</u>

**NOTE 8. COMMITMENTS AND CONTINGENCIES**

*Operating Leases*

We lease laboratory facilities and office space under operating leases which expire at various dates through 2013. Rent expense was \$270,000, \$317,000 and \$526,000 for the years ended December 31, 2005, 2006 and 2007, respectively, and \$1,321,000 for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2007.

The future minimum lease payments under non-cancellable operating leases were as follows as of December 31, 2007:

<u>(in thousands)</u>	<u>Lease Commitment</u>
Year ending December 31:	
2008 .....	\$ 779
2009 .....	824
2010 .....	510
2011 .....	531
2012 .....	333
2013 .....	<u>144</u>
Total lease commitment .....	<u>\$3,121</u>

*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, 2007 that, in the opinion of management, would have a material adverse effect on our financial position, results of operations or cash flows.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**NOTE 9. STOCKHOLDERS' EQUITY**

*Preferred Stock*

In 2002 and 2003, we issued 3.2 million shares of Series A Convertible Preferred Stock for net proceeds of \$647,000. In 2003 and 2004, we issued 6.9 million shares of Series B Convertible Preferred Stock for net proceeds of \$3.0 million. In 2004 and 2005, we issued 6.7 million shares of Series C Convertible Preferred Stock for net proceeds of \$5.4 million. In 2005 and 2006, we issued 2.5 million shares of Series D Convertible Preferred Stock for net proceeds of \$3.6 million. All outstanding shares of convertible preferred stock automatically converted into 9.6 million shares of common stock upon the closing of our IPO in October 2007.

In connection with the IPO, the Company amended its articles of incorporation to provide for the issuance of up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the board of directors. As of December 31, 2007, there were no shares of preferred stock outstanding.

*Common Stock*

Under our amended articles of incorporation and bylaws, we are authorized to issue 65,000,000 shares of \$0.01 par value common stock. Each holder of common stock has the right to one vote but does not have cumulative voting rights. Shares of common stock are not subject to any redemption or sinking fund provisions, nor do they have any preemptive, subscription or conversion rights. Holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared or paid as of December 31, 2007.

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

In October 2007, we completed an initial public offering of our common stock in which we sold and issued 5,000,000 shares of our common stock at a price to the public of \$4.00 per share. We raised a total of \$20.0 million from the IPO, or approximately \$17.1 million in net cash proceeds after deducting underwriting discounts and commissions of \$1.4 million and other offering costs of \$1.5 million.

*Stock Warrants*

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

- *Series A Warrants*—The warrants issued with the sale of Series A were issued on the basis of 0.20 of a warrant for every share of Series A purchased. The exercise price of these warrants was \$1.20. We extended a limited-time offer to holders of the warrants to exercise them at a price of \$0.80. The warrants expired on July 1, 2005, except for later purchases for which the expiration date was extended to July 1, 2006.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

- *Series B Warrants*—The warrants issued with the sale of Series B were issued on the basis of 0.175 of a warrant for every share of Series B purchased. The exercise price of these warrants was \$0.80. The warrants expired on June 30, 2006.
- *Note Warrants*—Stock warrants were granted in connection with promissory notes issued to certain of our shareholders in 2002 and 2003. The warrants issued to these shareholders had an exercise price of \$1.20. The warrants expired on June 30, 2006.
- *Underwriter Warrants*—In connection with the IPO, we issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of \$4.00 per share. The warrants are exercisable on or after October 31, 2008 and expire on October 31, 2010. The warrants were valued at approximately \$524,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 50.0%, (2) a risk-free interest rate of 3.94% and (3) a contractual life of 3 years. We accounted for the fair value of the Underwriter Warrants as an expense of the IPO resulting in a charge to stockholders' equity.

At December 31, 2007, there were 350,000 warrants outstanding at a weighted-average exercise price of \$4.00 per share. None of the warrants were exercisable at December 31, 2007.

**NOTE 10. EQUITY-BASED COMPENSATION**

*Equity Compensation Plans*

Prior to the IPO, we had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, we adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the Board of Directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. At the inception of the 2007 Plan, 2,000,000 shares were reserved for issuance under the Plan. As of December 31, 2007, there were 1,399,000 shares available for future grants under the 2007 Plan.

Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and the exercise price of non-statutory stock options may be not less than 85% of the fair market value on the date of grant. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years while options granted to directors and consultants typically vest over a shorter period, subject to continued service. All of the options granted prior to October 2007 include early exercise provisions that allow for full exercise of the option prior to the option vesting, subject to certain repurchase provisions. We issue new shares to satisfy option exercises under the plans.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

*Stock Option Summary*

The following table summarizes information about our stock options outstanding at December 31, 2007 and activity during the year then ended:

<u>(in thousands, except per share data)</u>	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (yrs)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at December 31, 2006 .....	2,401	\$0.83		
Options granted .....	814	\$3.31		
Options exercised .....	(298)	\$0.38		
Options forfeited/cancelled .....	(21)	\$1.52		
Outstanding at December 31, 2007 .....	<u>2,896</u>	\$1.57	7.31	\$6,386
Vested and expected to vest at December 31, 2007 .....	<u>2,753</u>	\$1.51	7.21	\$6,246
Vested at December 31, 2007 .....	<u>1,926</u>	\$0.89	6.27	\$5,528
Exercisable at December 31, 2007 .....	<u>2,320</u>	\$1.04	6.66	\$6,305

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as quoted on the American Stock Exchange as of December 31, 2007. We received cash payments in the amount of \$12,000, \$23,000 and \$114,000 for the exercise of stock options during the years ended December 31, 2005, 2006 and 2007, respectively. The aggregate intrinsic value of stock option awards exercised was \$16,000, \$126,000 and \$571,000 for the years ended December 31, 2005, 2006 and 2007, respectively, as determined at the date of option exercise.

The options outstanding and vested by exercise price at December 31, 2007 were as follows (number of options in thousands):

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Vested</u>	
	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life (yrs)</u>	<u>Weighted Average Exercise Price</u>	<u>Number Vested</u>	<u>Weighted Average Exercise Price</u>
\$0.20 .....	544	4.15	\$0.20	544	\$0.20
\$0.30 .....	337	5.92	\$0.30	337	\$0.30
\$0.56 .....	211	6.45	\$0.56	204	\$0.56
\$0.94 - \$1.20 .....	305	6.79	\$1.15	199	\$1.13
\$1.70 - \$1.87 .....	652	8.15	\$1.70	550	\$1.70
\$2.00 - \$2.28 .....	257	9.00	\$2.24	78	\$2.23
\$3.56 - \$4.00 .....	590	9.91	\$3.70	14	\$4.00
	<u>2,896</u>	7.31	\$1.57	<u>1,926</u>	\$0.89

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

*Stock Option Awards to Employees and Directors*

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

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

Assumption	Year Ended December 31,		
	2005	2006	2007
Expected price volatility . . . . .	0.0%	74.0%	68.9%
Expected term (in years) . . . . .	10.0	5.7	6.0
Risk-free interest rate . . . . .	4.2%	4.8%	4.1%
Dividend yield . . . . .	0.0%	0.0%	0.0%
Weighted-average fair value of options granted during the period . . . . .	\$0.22	\$1.06	\$2.17

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

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

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

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

Under SFAS No. 123R, forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. For the years ended December 31, 2006 and 2007, we applied an estimated forfeiture rate of 5% to employee grants and 0% to director grants. For the year ended December 31, 2005, we accounted for forfeitures as they occurred.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

For the years ended December 31, 2006 and 2007, we recognized stock-based compensation expense of \$313,000 and \$399,000, respectively, for option awards to employees and directors. As of December 31, 2007, total unrecognized compensation cost related to unvested stock options granted or modified on or after January 1, 2006 was \$1.5 million. This amount is expected to be recognized as stock-based compensation expense in our statements of operations over the remaining weighted average vesting period of 3.28 years.

*Common Stock Awards to Directors*

In connection with the close of the IPO in October 2007, we adopted a new plan to compensate the independent members of the Board of Directors for their services. Under the terms of the Director Compensation Plan, each independent member is entitled to a combination of cash and unrestricted common stock for each board and committee meeting attended, up to specified annual maximums. In accordance with these provisions, we issued 7,831 shares of common stock to independent directors during the year ended December 31, 2007. These shares were issued out of the 2007 Plan. The fair market value of the stock issued to directors was recorded as an operating expense in the period in which the meeting occurred, resulting in total compensation expense of \$29,000 for common stock awards to directors during the year ended December 31, 2007.

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

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

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

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	2006	2007
Research and development .....	\$227	\$206
General and administrative .....	86	222
Total stock-based compensation expense .....	\$313	\$428

*Stock-Based Awards to Non-Employees*

During the years ended December 31, 2005, 2006 and 2007, we granted options to purchase an aggregate of 175,000, 58,000 and 69,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

<u>Assumption</u>	<u>Year Ended December 31,</u>		
	2005	2006	2007
Expected price volatility .....	0.0%	74.0%	71.0%
Expected term (in years) .....	10.0	5.3	5.3
Risk-free interest rate .....	4.2%	4.4%	4.7%
Dividend yield .....	0.0%	0.0%	0.0%

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Stock-based compensation expense recognized for the years ended December 31, 2005, 2006 and 2007 related to non-employee option grants was \$55,000, \$49,000 and \$118,000, respectively.

We also granted 20,000, 3,000 and 38,289 shares of unrestricted common stock to non-employees during the years ended December 31, 2005, 2006 and 2007, respectively. The fair market value of the stock issued to non-employees was recorded as an expense, resulting in total compensation expense of \$16,000, \$5,000 and \$92,000 for common stock awards to non-employees during the years ended December 31, 2005, 2006 and 2007, respectively.

**NOTE 11. COLLABORATION AND LICENSE AGREEMENTS**

*Alcon Manufacturing, Ltd.*

In August 2006, we entered into a collaboration and license agreement with Alcon Manufacturing, Ltd. ("Alcon") to license to Alcon the exclusive rights to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solution. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of \$10.0 million upon the effective date of the agreement. This up-front fee was recorded as deferred revenue and is being amortized into revenue on a straight-line basis over the four-year funding term of the agreement, through August 2010. Additionally, we will receive semi-annual payments to support on-going research and development activities over the four year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. Our obligation to perform research and development activities under the agreement expires at the end of the four year funding term. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compound. Alcon has the right to terminate the agreement in its entirety upon nine months' notice, or terminate portions of the agreement upon 135 days' notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

For the years ended December 31, 2006 and 2007, we recognized revenue of \$0.8 million and \$2.5 million, respectively, for amortization of the upfront technology access fee. We also recognized \$0.7 million and \$2.7 million, respectively, for the on-going research and development activities performed during the 2006 and 2007 periods. During the year ended December 31, 2007, we recognized \$0.6 million for materials, equipment and contract study costs which have been or will be reimbursed by Alcon. In total, we recognized revenue of \$1.5 million and \$5.8 million for the years ended December 31, 2006 and 2007, respectively, in connection with the Alcon collaboration and license agreement. At December 31, 2007, we had a deferred revenue balance of \$7.4 million related to the Alcon agreement which was comprised of \$6.7 million for the upfront technology access fee and \$0.7 million for other prepaid reimbursements. As of December 31, 2007, we had not earned or received any milestone or royalty payments under the Alcon agreement.

*KCI International VOF GP*

In June 2007, we entered into a license agreement with an affiliate of Kinetic Concepts, Inc. ("KCI"), under which we granted KCI the exclusive rights to develop, manufacture and commercialize NVC-101, or NeutroPhase, as well as other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to us a non-refundable technology access fee of \$200,000. The up-front

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

technology access fee was recorded as deferred revenue and is being amortized into revenue on a straight-line basis over the 18-month performance obligation period, through December 2008. Under the agreement, we are also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, we are entitled to receive payments of up to \$1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. KCI has the right to terminate the agreement without penalty upon 60 days' notice. We have the right to terminate the agreement if KCI has not commercially launched a product incorporating NVC-101, or any other product containing hypochlorous acid, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

For the year ended December 31, 2007, we recognized revenue of \$72,000 for amortization of the upfront technology access fee and \$29,000 for consulting and materials costs which have been or will be reimbursed by KCI. In total, we recognized revenue of \$101,000 for the year ended December 31, 2007, in connection with the KCI agreement. At December 31, 2007, \$9,000 of reimbursable expenses were recorded as a receivable and included in prepaid expenses and other current assets on our balance sheet. We had a deferred revenue balance of \$128,000 at December 31, 2007 related to the KCI agreement, which consisted of the remaining amount to be amortized for the upfront technology access fee. As of December 31, 2007, we had not earned or received any milestone or royalty payments under the KCI agreement.

**NOTE 12. EMPLOYEE BENEFIT PLAN**

We have a 401(k) plan covering all eligible employees. We are not required to contribute to the plan and have made no contributions through December 31, 2007.

**NOTE 13. INCOME TAXES**

The provision for income tax expense consists of the following.

<u>(in thousands)</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2006</u>	<u>2007</u>
Current:			
Federal .....	\$—	\$—	\$—
State .....	—	—	12
Total current .....	—	—	12
Deferred:			
Federal .....	—	—	—
State .....	—	—	—
Total deferred .....	—	—	—
Provision for income taxes .....	\$—	\$—	\$ 12

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

**NOVABAY PHARMACEUTICALS, INC.**  
(a development stage company)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The effective tax rate of our provision for income taxes differs from the federal statutory rate as follows:

<u>(in thousands)</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2006</u>	<u>2007</u>
Federal tax at statutory rate .....	\$(1,177)	\$(1,743)	\$(1,832)
State taxes net of federal benefit .....	(201)	(297)	(274)
ISO-related expense for GAAP .....	—	—	81
Change in valuation allowance .....	1,347	2,111	1,997
Other .....	31	(71)	40
Actual provision for income taxes .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 12</u>

The tax effects of the deferred tax assets and liabilities are as follows:

<u>(in thousands)</u>	<u>December 31,</u>	
	<u>2006</u>	<u>2007</u>
Deferred tax assets:		
Net operating losses .....	\$ 2,550	\$ 4,040
Deferred revenue .....	2,655	2,655
Accruals .....	22	264
Stock options .....	—	310
Other .....	12	25
Total deferred tax assets .....	<u>5,239</u>	<u>7,294</u>
Deferred tax liabilities:		
Depreciation .....	(30)	(88)
Total deferred tax liabilities .....	<u>(30)</u>	<u>(88)</u>
Valuation allowance .....	(5,209)	(7,206)
Net deferred taxes .....	<u>\$ —</u>	<u>\$ —</u>

SFAS No. 109 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not”. Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our recent history of operating losses, 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. The valuation allowance increased by \$1.3 million, \$2.1 million and \$2.0 million during the years ended December 31, 2005, 2006 and 2007, respectively.

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

We track the portion of our federal and state net operating loss carryforwards attributable to stock option benefits in a separate memo account pursuant to SFAS No. 123R. Therefore, these amounts are not included in

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

gross or net deferred tax assets. Pursuant to SFAS No. 123R, the benefit of these net operating loss carryforwards will only be recorded to equity when they reduce cash taxes payable. We elected to use the “with-and-without” approach for utilizing the tax benefits of stock option exercises under SFAS No. 123R. These benefits would result in a credit to additional paid-in-capital when they reduce income taxes payable.

*Uncertain Income Tax Positions*

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

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

**NOTE 14. SUBSEQUENT EVENTS**

*Equipment Financing*

In January 2008, we borrowed \$203,000 under our equipment loan facility. This amount will be repaid over 40 months through May 2011 at an interest rate of 10.45%. Upon the close of this funding, there was \$3,000 available for borrowing under the equipment loan facility.

*Amendment to Financial Advisory and Investor Relations Consulting Agreement*

In March 2008, we amended the Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 with PM Holdings Ltd. Under the terms of the original agreement, we agreed to pay PM Holdings \$28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of \$264,000 and the issuance of warrants to purchase 300,000 common shares at an exercise price of \$4.00 per share. Under the amended agreement, no further cash or equity amounts are payable during the duration of the agreement through February 2010. We expect to pay the upfront cash amount and issue the warrants during April 2008.

<u>Exhibit No.</u>	<u>Description</u>
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-138379) initially filed with the Securities and Exchange Commission on November 2, 2006, as amended.

\*\* Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.

+ Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

**NOVABAY PHARMACEUTICALS, INC.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1**	Amended and Restated Articles of Incorporation of registrant
3.2**	Amended and Restated Bylaws of registrant
4.1*	Specimen common stock certificate
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 January 1, 2007 by and between the Registrant and Ramin ("Ron") Najafi
10.5+*	Employment Agreement dated January 1, 2007 by and between the Registrant and John ("Jack") O'Reilly
10.6+*	Employment Agreement dated January 1, 2007 by and between the Registrant and Behzad Khosrovi
10.7+*	Employment Agreement dated January 1, 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 13, 2007 by and between the Registrant and PM Holdings Ltd.
10.13*	Director Compensation Plan
10.14*	Master Security Agreement dated April 23, 2007 by and between the Registrant and General Electric Capital Corporation
10.15+*	License Agreement dated June 11, 2007 by and between us and KCI International VOF GP
10.16*	Form of Common Stock Purchase Warrant by and between the Registrant and the underwriters
10.17*	Form of Registration Rights Agreement by and between the Registrant and the underwriters
10.18+	Employment Agreement dated January 9, 2008 by and between the Registrant and Thomas J. Paulson
10.19	Amendment #1 dated March 12, 2008 to Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 by and between the Registrant and PM Holdings Ltd.
10.20	Fifth Amendment dated November 20, 2007 to Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
23.1	Consent of Davidson & Company LLP
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

<u>Exhibit No.</u>	<u>Description</u>
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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\* Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-138379) initially filed with the Securities and Exchange Commission on November 2, 2006, as amended.

\*\* Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.

+ Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

**CERTIFICATION PURSUANT TO EXCHANGE ACT  
RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ramin ("Ron") Najafi, certify that:

1. I have reviewed this annual report on Form 10-K of NovaBay Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008

/s/ RAMIN NAJAFI

---

**Ramin ("Ron") Najafi**  
**Chief Executive Officer and President**  
**(principal executive officer)**

**CERTIFICATION PURSUANT TO EXCHANGE ACT  
RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thomas J. Paulson, certify that:

1. I have reviewed this annual report on Form 10-K of NovaBay Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008

/s/ THOMAS J. PAULSON

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**Thomas J. Paulson**  
**Chief Financial Officer and Treasurer**  
**(principal financial and accounting officer)**

**CERTIFICATION PURSUANT TO 18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of NovaBay Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ramin ("Ron") Najafi, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008

*/s/* RAMIN NAJAFI

---

Ramin ("Ron") Najafi  
Chief Executive Officer and President

**CERTIFICATION PURSUANT TO 18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of NovaBay Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas J. Paulson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008

/s/ THOMAS J. PAULSON

---

Thomas J. Paulson  
Chief Financial Officer and Treasurer

## BOARD OF DIRECTORS

**Ron Najafi, Ph.D.**  
Chairman and Chief Executive Officer

**Charles Cashion**  
Co-founder, Senior Vice President  
and Chief Financial Officer of  
Conatus Pharmaceuticals, Inc.

**Anthony Dailley, D.D.S.**  
Private Investor  
Co-founder 1-800-DENTIST

**Paul E. Freiman**  
President and Chief Executive Officer  
of Neurobiological Technologies, Inc.  
Former Chief Executive Officer of  
Syntex Corporation

**T. Alex McPherson, M.D., Ph.D.**  
Former President and  
Chief Executive Officer of Biomira, Inc.

**Jack O'Reilly, M.B.A.**  
Senior Vice President,  
Business and Corporate Development

**Robert R. Tufts, Esq.**  
Founding law partner of  
Tufts Stephenson & Kasper, LLP

**Tony Wicks**  
Former Chief Executive Officer of  
American Resource Corporation Inc.

## OFFICERS

**Ron Najafi, Ph.D.**  
Chairman and Chief Executive Officer

**Thomas Paulson, M.B.A.**  
Chief Financial Officer

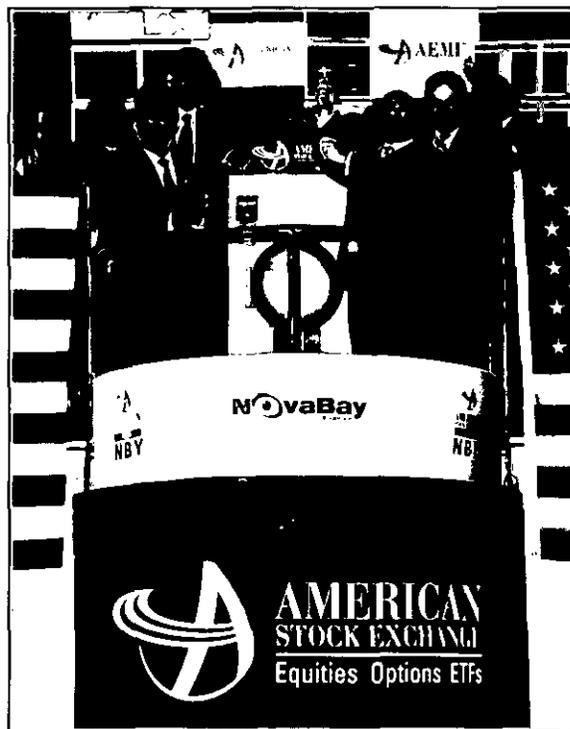
**Jack O'Reilly, M.B.A.**  
Senior Vice President, Business  
and Corporate Development

**Behzad ("Bez") Khosrovi, M.A., Ph.D.**  
Vice President,  
Research and Development

**Colin Scott, M.B., Ch.B.**  
Vice President, Clinical Research  
and Development

**Ken Krantz, M.D., Ph.D.**  
Vice President, Medical Affairs

**Nafsika Dakou ("Georgopapadakou"), Ph.D.**  
Vice President, Research



## SCIENTIFIC ADVISORY BOARD

**Bernard Churchill, M.D.**  
Professor, Urology, UCLA

**William Costerton, Ph.D.**  
Director of Biofilm Engineering,  
University of Southern California

**Fred Hawthorne, Ph.D.**  
Director, International Institute  
for Nano and Molecular Biology,  
University of Missouri—Columbia

**Larry Truesdale, Ph.D.**  
Senior Director, Pfizer, Inc.

**Roger Whiting, Ph.D.**  
President and Chief Scientific Officer,  
Roxro Pharma, Inc.

## SHAREHOLDER INFORMATION

**Corporate Headquarters**  
Novabay Pharmaceuticals, Inc.  
5980 Horton Street, Suite 550  
Emeryville, CA 94608  
(510) 899-8800

**Corporate Website**  
[www.novabaypharma.com](http://www.novabaypharma.com)

**Transfer Agent & Registrar**  
Computershare Trust Company, Inc.  
350 Indiana Street, Suite 800  
Golden, CO 80401  
(303) 262-0600

**Corporate Counsel**  
Dorsey & Whitney  
Irvine, CA

**Independent Accountants**  
Davidson & Company LLP  
Vancouver BC, Canada

**Stock Listing**  
American Stock Exchange  
AMEX: NBY

Toronto Stock Exchange  
TSX: NBY



NovaBay Team, April 2008



Novabay Pharmaceuticals, Inc.  
5980 Horton Street, Suite 550  
Emeryville, CA 94608  
(510) 899-8800  
[www.ncvabaypharma.com](http://www.ncvabaypharma.com)

**END**