NovaBay Pharmaceuticals, Inc.
Form S-1/A
September 04, 2007
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As filed with the Securities and Exchange Commission on September 4, 2007

Registration No. 333-140714

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 6

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

NOVABAY PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

5980 Horton Street, Suite 550

Emeryville, CA 94608

(510) 899-8800

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

Ramin (Ron) Najafi, Ph.D.

Chairman of the Board, Chief Executive Officer and President

NovaBay Pharmaceuticals, Inc.

5980 Horton Street, Suite 550 Emeryville, CA 94608

(510) 899-8800

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, $0.01 par value	$34,500,000	$2,815(3)

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

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

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EXPLANATORY NOTE

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

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

Subject to completion, dated September 4, 2007

PROSPECTUS

5,000,000 Shares

Common Stock

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

We expect the public offering price to be between $4.00 and $6.00 per share. Currently, no public market exists for the shares. After pricing the offering, we expect that the common stock will be traded on the American Stock Exchange and on the Toronto Stock Exchange under the symbol NBY.

Investing in our common stock involves risks. See Risk Factors beginning on page 9.

PRICE $ PER SHARE

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

The underwriters may also purchase up to an additional 750,000 shares from us at the public offering price, less the underwriting discounts and commissions, until 30 days after the date of the closing of this offering to cover over-allotments, if any. The table above provides the maximum amount of underwriting discounts and commissions. Discounts and commissions on the sale of shares to certain investors identified by us will be 0.7% rather than 7%, and to the extent such investors purchase shares in this offering the aggregate underwriting discounts and commissions will be reduced accordingly. In addition, we have agreed to pay up to $150,000 of the underwriters expenses and to issue to the underwriters broker warrants to purchase up to 7% of the total number of shares sold in this offering, excluding pursuant to the over-allotment option.

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

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

Dundee Securities Inc. **Desjardins Securities Inc.**

Blackmont Capital Inc. **Dawson James Securities, Inc.**

The date of this prospectus is , 2007.

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

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PROSPECTUS SUMMARY

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

Our Company

Overview

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

We have discovered and are developing a class of antimicrobial compounds, which we have named Aganocide compounds, that we believe could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial infections. Our current development efforts are focused on Aganocide compounds to treat patients with infections of the eye, ear and sinus, to create an improved environment for the healing of wounds and to prevent infections that result from surgical or other hospital procedures, or that can be caused by the use of products, such as contact lens solutions, which can introduce an infection into the body. NVC-422 is our lead compound in a class of antimicrobial compounds that we call the Aganocide compounds. Our in-vitro and in-vivo animal tests have demonstrated that NVC-422 kills a wide range of bacteria as well as certain yeasts, fungi and viruses very rapidly, at concentrations that are significantly lower than the concentrations at which it begins to kill human cells. We will need to conduct Phase I, II and III human clinical trials to confirm these results in order to obtain approval of NVC-422 from the U.S. Food and Drug Administration, or FDA. Often, positive in-vitro or in-vivo animal studies are not followed by positive results in human clinical trials, and we may not be able to demonstrate that our products are safe and effective for indicated uses in humans. We estimate that the clinical trials will take three to five years to conduct for each indication and will cost between $15 million and $30 million per indication. We filed an Investigational New Drug application, or IND, in March 2007 with the FDA, and began human clinical trials in May 2007.

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

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

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or occur in a hospital or hospital-like setting, and to partner with leading companies to assist with the development of other products. Since the cost of developing each indication is likely to be in the range of $15 million to $30 million, we will require additional funds to complete the in-house development of multiple indications. In August 2006, we entered into a collaboration and licensing agreement with an affiliate of Alcon, Inc., a leading ophthalmic pharmaceutical company, to develop products incorporating Aganocide compounds for use in the eye, ear and sinus, as well as in contact lens solutions. We received $10.0 million from the Alcon affiliate in September 2006 in connection with the collaboration and licensing agreement. Other than revenues received pursuant to this agreement, and the agreement with the Kinetic Concepts affiliate, we have had no revenues since our inception. We do not expect to have any revenues from sales of our drug products until 2011 or later. Until September 2006, we funded our operations through the proceeds from private placements of our preferred stock and from the exercise of warrants that had been granted to holders of our preferred stock. Our cumulative losses through June 30, 2007 were $15.5 million.

Industry Background

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

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

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

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

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

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

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Our Solution

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

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

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

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

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

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

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

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

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

Although we have demonstrated the benefits of our antimicrobial compounds in in-vitro and in-vivo animal studies, we will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain FDA approval of our compounds. All drug development programs are subject to substantial risk. Often, positive in-vitro or in-vivo animal studies have not been followed by positive results in human clinical trials; and we may not be able to demonstrate that our products are safe and effective for indicated uses in humans. Failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies or otherwise delay development of our product candidates.

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

Our Strategy

The key elements of our strategy include:

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

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

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

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

Corporate Information

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

Presentation of Financial Information

We present our financial statements in United States dollars, which may be referenced in this prospectus as $, U.S.$, dollars or U.S. dollars . Amounts are stated in U.S. dollars unless otherwise indicated. On September 4, 2007, the noon buying rate in New York for cable transfers payable in Canadian dollars, as certified for customs purposes by the Federal Reserve Bank of New York, was U.S.$1.00 to Cdn.$1.0493.

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

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The Offering

Common stock offered by NovaBay	5,000,000 shares
Common stock to be outstanding after this offering	21,137,782 shares
Use of proceeds	We currently expect to use our net proceeds from this offering as follows: approximately $5 million for the Phase I and II clinical development of NVC-422 in pre-surgical nasal preparation; approximately $5 million for the pre-clinical, Phase I and initial Phase II studies of NVC-422 in the prevention of catheter associated urinary tract infections; approximately $2 million for pre-clinical studies to select among additional indications to be taken into development; and the remainder of the net proceeds for research and development, working capital and other general purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, services or technologies, or to enter into strategic marketing relationships with third parties. Although we currently anticipate that we will use the net proceeds of this offering as described above, there may be circumstances where, for sound business reasons, a reallocation of funds may be necessary. We may re-allocate the net proceeds from time to time depending upon the ultimate amount of net proceeds raised and upon changes in business conditions prevalent at the time. See Use of Proceeds.
Risk Factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to purchase shares of our common stock.
American Stock Exchange and Toronto Stock Exchange listings	We have applied to list our shares on the American Stock Exchange (AMEX) and the Toronto Stock Exchange (TSX) under the symbol NBY. The TSX has conditionally approved the listing of our shares, subject to our fulfillment of all of the requirements of the TSX on or before November 26, 2007, including distribution of our shares to a minimum number of public security holders.

The number of shares of our common stock to be outstanding following this offering is based on 16,137,782 shares of our common stock outstanding at June 30, 2007, which assumes the conversion of all of our outstanding preferred stock into an aggregate of 9,613,598 shares of common stock upon the completion of this offering, and does not include:

- 2,424,462 shares of common stock issuable upon exercise of options outstanding, as of June 30, 2007, at a weighted average exercise price of $0.99 per share;
- 203,500 shares of common stock reserved for future grant, as of June 30, 2007, under our 2005 Stock Option Plan (under which no additional grants will be made after the effective date of the registration statement for this offering);
- 2,000,000 shares of common stock reserved for future grant or issuance under our 2007 Omnibus Incentive Plan, which will become effective upon the effective date of the registration statement for this offering; and

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shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering at an exercise price equal to the initial public offering price.

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

a 1-for-2 reverse stock split effected in August 2007;

the underwriters will not exercise their over-allotment option to purchase up to 750,000 additional shares of common stock;

no exercise of the warrants to be issued to the underwriters in connection with this offering;

no exercise of any outstanding options;

the initial public offering price will be $5.00 per share, the midpoint of the range set forth on the cover page of this prospectus; and

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

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Summary Financial Data

The following table summarizes our financial data for the periods presented. You should read this data in conjunction with the information under Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes appearing elsewhere in this prospectus. The summary financial data for the years ended December 31, 2004, 2005, and 2006 are derived from our audited financial statements. We have also included data from our unaudited financial statements for the six months ended June 30, 2006 and 2007. Our financial statements have been prepared in accordance with U.S. GAAP, which differs in certain respects from Canadian GAAP.

	Year Ended December 31,			Six Months Ended June 30,	
	2004	2005	2006	2006	2007
				(unaudited)	
Statements of Operations Data:			(in thousands, except share and per share data)		
Revenue	$	$	$ 1,533	$	$ 2,948
Operating Expenses:					
Research and development(1)	1,481	1,952	4,087	1,319	3,529
General and administrative(1)	1,345	1,617	2,972	1,431	2,104
Total operating expenses	2,826	3,569	7,059	2,750	5,633
Other income, net	22	106	240	39	235
Net loss before income taxes	(2,804)	(3,463)	(5,286)	(2,711)	(2,450)
Provision for income taxes					
Net loss	$ (2,804)	$ (3,463)	$ (5,286)	$ (2,711)	$ (2,450)
Net loss per share:					
Basic and diluted	$ (0.64)	$ (0.71)	$ (0.92)	$ (0.53)	$ (0.38)
Shares used in per share calculations:					
Basic and diluted	4,377,709	4,852,103	5,714,608	5,162,806	6,457,979
Pro forma net loss per share (unaudited):					
Basic and diluted			$ (0.35)		$ (0.15)
Shares used in pro forma per share calculations (unaudited)(2):					
Basic and diluted			14,967,463		16,071,576

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

	Year Ended December 31,			Six Months Ended June 30,	
	2004	2005	2006	2006	2007
				(unaudited)	
			(in thousands)		
Stock-based compensation expense included above:					
Research and development	$ 11	$ 55	$ 86	$ 38	$ 118
General and administrative		16	281	137	226
Total stock-based compensation expense	$ 11	$ 71	$ 367	$ 175	$ 344

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

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The following table presents a summary of our balance sheet as of June 30, 2007:

- on an actual basis, and
- on a pro forma as adjusted basis to reflect the conversion into common stock of all outstanding shares of our preferred stock and the sale in this offering of 5,000,000 shares of our common stock at an assumed initial public offering price of $5.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (to the extent such expenses were not paid or accrued for as of June 30, 2007).

	As of June 30, 2007	
	Actual	Pro Forma As Adjusted
	(unaudited) (in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 8,053	$ 30,474
Working capital	4,197	26,937
Total assets	9,320	31,741