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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

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**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(f) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-50439

**NITROMED, INC.**

(Exact name of registrant as specified in its charter)

Delaware

22-3159793

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

45 Hayden Avenue, Suite 3000, Lexington, Massachusetts  
(Address of principal executive offices)

02421  
(Zip Code)

Registrant's telephone number, including area code: (781) 266-4000



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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$.01 par value per share

NASDAQ Global Market

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 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 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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of the registrant's common stock held by nonaffiliates of the registrant was approximately \$66,817,000, based on the price at which the registrant's common stock was last sold on June 29, 2007.

As of March 3, 2008, there were 46,125,976 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's proxy statement for the annual meeting of stockholders, which are to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2007, are incorporated by reference into Part III of this report.

**NITROMED, INC.  
ANNUAL REPORT  
ON FORM 10-K**

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*This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any projections of revenue, expenses, earnings or losses from operations, or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product development and commercialization timelines or outcomes; any statements of expectation or belief; and any statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described in "Item 1A—Risk Factors" and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.*

*The forward-looking statements included in this annual report represent our estimates as of the date of this annual report. We specifically disclaim any obligation to update these forward-looking statements in the future, except as specifically required by law or the rules of the Securities and Exchange Commission. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report.*

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

We are the maker of BiDil®, which is indicated for the treatment of heart failure in self-identified black patients as an adjunct to current standard therapies. BiDil is an orally administered fixed-dose combination of isosorbide dinitrate and hydralazine hydrochloride. The U.S. Food and Drug Administration, or FDA, approved BiDil in June 2005 and we commercially launched BiDil in July 2005.

#### **Recent Development—Restructuring**

Based upon our determination that the successful commercialization of BiDil requires a magnitude of resources that we cannot currently allocate to the program, as well as our plans to conserve cash in order to pursue the development of an extended release formulation of BiDil, known as BiDil XR™, in January 2008 we discontinued active promotional activities for BiDil. We concurrently implemented a restructuring plan that includes the elimination of approximately 75 positions by the end of February 2008, reducing headcount from approximately 90 to 15, with an additional reduction in headcount to approximately 10 positions anticipated by the end of April 2008. Although we have discontinued promotional activities related to BiDil, we intend to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels. In conjunction with implementing our January 2008 restructuring plan, we intend to evaluate and pursue strategic alternatives for our business which may include the divestiture of our BiDil and BiDil XR business and/or our nitric oxide patent portfolio, a merger or consolidation with another company, or other comparable arrangements.

Our January 2008 restructuring follows the elimination of our discovery research program in March 2006 and the replacement of our sales force with a small team of senior cardiovascular business managers in October 2006. The January 2008 restructuring also follows our efforts in August 2007 to deploy an expanded field organization designed to focus on selected prescriber targets.

## **BiDil XR**

BiDil is an orally-administered medicine that is presently dosed three times daily. We are seeking to develop BiDil XR as a once-daily formulation. We believe that BiDil XR could enhance the market for BiDil through improved patient convenience and treatment compliance. We commenced clinical development of BiDil XR in October 2006, and preliminary clinical studies with BiDil XR have demonstrated proof of principle. We have engaged a third party contract research organization to enroll qualified patients and conduct our clinical trials of BiDil XR. The pilot clinical trials have tested several prototypes and compared their pharmacokinetic profile with BiDil tablets. In preliminary clinical studies in healthy volunteers, we have demonstrated our ability to delay the release of isosorbide dinitrate and hydralazine hydrochloride by varying the amount of coating and ratios of different polymers on beads in capsules. We will need to conduct additional formulation studies and trials in order to finalize the formulation prior to the bioequivalence trials. We anticipate that we will finalize the BiDil XR formulation in 2009. Assuming that the BiDil XR formulation is successfully finalized, we anticipate initiating pivotal bioequivalence trials and then filing the new drug application in 2010 or 2011.

In December 2007, we met with the FDA to discuss our proposed development plan for BiDil XR. The FDA agreed that our clinical development plan to conduct bioequivalence and pharmacodynamic studies comparing BiDil XR to the current commercial immediate release formulation of BiDil is acceptable. Our proposed plan could support FDA approval to commercialize BiDil XR, if bioequivalence is demonstrated. The bioequivalence study design compares the pharmacokinetics of the BiDil XR formulation to the pharmacokinetics of BiDil. Pharmacokinetics refers to the manner in which the body absorbs, distributes, metabolizes and excretes the study drug. The adequacy of the results will ultimately be determined by the FDA during the regulatory review period.

In connection with our efforts to develop BiDil XR, in February 2007 we entered into a license agreement with Elan Pharma International Limited, or Elan, pursuant to which Elan granted to us an exclusive worldwide royalty-bearing license to import, use, offer for sale and sell an oral capsule formulation incorporating specified technology owned or controlled by Elan and containing, as its sole active combination of ingredients, the combination of the active drug substances isosorbide dinitrate and hydralazine hydrochloride, including BiDil XR. In consideration for the grant of the license, we have agreed to pay Elan royalties that are calculated by reference to annual net sales parameters set forth in the agreement. In addition, we have also agreed to pay Elan specified amounts upon the achievement of specified development and commercialization milestone events set forth in the agreement.

## **Nitric Oxide Enhancing Technologies**

We have generated significant intellectual property rights relating to our nitric-oxide enhancing technologies and we are seeking out-licensing opportunities to further exploit these proprietary technologies. We do not have any current plans to conduct any further internal research with respect to these technologies.

## **Company Information**

We were incorporated in Delaware in 1992. Our office is currently located at 45 Hayden Avenue, Suite 3000, Lexington, Massachusetts 02421, and our telephone number is (781) 266-4000. Our Internet address is [www.nitromed.com](http://www.nitromed.com). The information on our website is not incorporated by reference into this annual report on Form 10-K and should not be considered to be a part of this annual report. Our website address is included in this annual report on Form 10-K as an inactive textual reference only.

When used in this annual report on Form 10-K, the terms "NitroMed," "we," "our" and "us" refer to NitroMed, Inc., unless otherwise specified. We own the following registered U.S. trademarks:

NitroMed, BiDil, NitroMed Cares, More Life to Live, and NitroMed's logo "N." In addition, we have filed an application for BiDil XR. Other trademarks and service marks appearing in this annual report on Form 10-K are the property of their respective holders.

## **BiDil: Treatment for Heart Failure in African Americans**

### *Heart Failure in African Americans*

Heart failure, also called congestive heart failure or dilated cardiomyopathy, is a progressively worsening condition that occurs when the heart muscle weakens and cannot pump blood efficiently enough to meet the metabolic needs of the body. The loss of pump function is usually caused by an underlying condition, such as hypertension or coronary artery disease, which weakens the heart muscle and increases a person's risk of heart failure. The most common symptoms of heart failure include shortness of breath from congestion in the lungs, fatigue, sleeping problems due to the inability to lay flat, sudden awakening with shortness of breath and swelling in the feet, ankles and other parts of the body.

Heart failure affects approximately five million Americans and there is currently no cure for the disease. After a patient is diagnosed with heart failure, their prognosis is generally poor, with approximately 50 percent of patients dying within five years. Heart failure is the primary reason for hospitalizations among people over the age of 65 and is one of the most expensive diseases faced by Americans, costing more than all cancers combined.

An estimated 750,000 African Americans are currently diagnosed with heart failure. African Americans between the ages of 45 and 64 are 2.5 times more likely to die from heart failure than Caucasians in the same age range. The African American community is also more likely to be subject to the disease at a younger age than their Caucasian counterparts, resulting in earlier disability and higher rates of both hospitalization and premature death. Ethnic disparities in the prevalence of heart failure have been attributed to a variety of factors, including access to medical care, disease management, socioeconomic factors, lifestyle habits and a higher incidence of diabetes, hypertension and metabolic syndrome.

### *African American Heart Failure Trial (A-HeFT)*

In 2001, we partnered with the Association of Black Cardiologists, Inc. to conduct the African American Heart Failure Trial, or A-HeFT, the first trial conducted in a heart failure population in which all of the participants identified themselves as black. A retrospective analysis of an earlier study with a combination of isosorbide dinitrate and hydralazine hydrochloride had suggested a trend for improved survival in the subset of patients with mild to moderate heart failure who self-identified themselves as black. The randomized, double-blind, placebo-controlled A-HeFT study enrolled 1,050 self-identified black patients with New York Heart Association, or NYHA, class III or IV heart failure at 169 clinical research sites. The classification system means that patients had marked limitation of physical activity (class III) or were unable to carry out any physical activity without discomfort (class IV). Participants in A-HeFT were required to be stable while receiving standard heart failure therapy at the time of the beginning of the trial, per their physicians. The primary end point for the trial was a composite score made up of weighted values for death from any cause, a first hospitalization for heart failure, and change in the quality of life.

After a unanimous recommendation from the independent A-HeFT Data Safety Monitoring Board in July 2004, A-HeFT was halted early due to a significant survival benefit seen with the drug. Patients taking BiDil in addition to current therapies experienced a significant 43% decrease in the risk of mortality ( $p=0.012$ ) (absolute mortality rate: BiDil, 6.2% vs. placebo, 10.2%), a 39% reduction in the risk of first hospitalization for heart failure ( $p<0.001$ ) (absolute first hospitalization rate: BiDil, 16.4% vs. placebo, 24.4%) and a statistically significant improvement at most time points in response to the

Minnesota Living with Heart Failure Questionnaire, which is a self-report of the patient's functional status, versus patients taking placebo in addition to current standard therapies. Adverse events reported in the trial included symptoms of headache and dizziness, which were significantly more frequent in the group given BiDil, and exacerbations of congestive heart failure, both moderate and severe, which were significantly more frequent in the placebo group.

### *BiDil*

BiDil, an orally administered fixed-dose combination of isosorbide dinitrate and hydralazine hydrochloride, was approved by the FDA in June 2005 for the treatment of heart failure in self-identified black patients. BiDil is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status. There is little experience in patients with NYHA class IV heart failure. Most patients in the A-HeFT clinical trial received, in addition to BiDil or placebo, concomitant therapy with one or more of the following other heart failure medicines: a loop diuretic, an angiotensin converting enzyme inhibitor or an angiotensin receptor blocker, and a beta blocker. In addition, many patients also received a cardiac glycoside or an aldosterone antagonist. BiDil is a fixed-dose combination of isosorbide dinitrate, a vasodilator with effects on arteries and veins, and hydralazine hydrochloride, a predominantly arterial vasodilator. The mechanism of action underlying the beneficial effects of BiDil in the treatment of heart failure has not been established.

Based upon our determination that the successful commercialization of BiDil requires a magnitude of resources that we cannot currently allocate to the program, as well as our plans to conserve cash in order to pursue the development of BiDil XR, in January 2008 we discontinued active promotional activities for BiDil. Although we have discontinued promotional activities related to BiDil, we intend to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels.

We are party to a five-year exclusive manufacturing and supply agreement with Schwarz Pharma Manufacturing, Inc., or Schwarz Pharma, which is now a division of UCB S.A., for the three times daily immediate release dosage formulation of BiDil. Under the supply agreement, we have the right to engage a backup manufacturer. As part of the manufacturing process, we order bulk materials of hydralazine hydrochloride from Flavine International, Inc., the U.S. representative of Sumitomo Corp., and isosorbide dinitrate from Dottikon ES Holding AG.

We estimate that a substantial majority of insured African American patients over the age of 45 have access to BiDil at Tier II insurance reimbursement, a term generally used to denote a preferential level of reimbursement at which patient co-pays range from approximately \$15.00 to \$30.00 per prescription. Our estimates are drawn from published databases, subscription databases and external consultants who have expertise in this area. Due to the fact that ethnicity data is not generally collected by commercial and Medicare Part D insurers, exact figures cannot be determined.

### *BiDil XR*

The current formulation of BiDil is an immediate-release tablet that must be taken three times daily. We are currently developing an extended release formulation of BiDil, known as BiDil XR, that is designed to be taken once a day. We believe that BiDil XR could enhance the BiDil market by facilitating greater compliance by patients with their medications schedule, an issue which we believe is more pronounced in a patient population already on a substantial number of concomitant medications.

We commenced clinical development of BiDil XR in October 2006, and preliminary clinical studies with BiDil XR have demonstrated proof of principle. We have engaged a third party contract research organization to enroll qualified patients and conduct our clinical trials of BiDil XR. The pilot clinical trials have tested several prototypes and compared their pharmacokinetic profile with BiDil tablets. In

preliminary clinical studies in healthy volunteers, we have demonstrated our ability to delay the release of isosorbide dinitrate and hydralazine hydrochloride by varying the amount of coating and ratios of different polymers on beads in capsules. We will need to conduct additional formulation studies and trials in order to finalize the formulation prior to the bioequivalence trials. We anticipate that we will finalize the BiDil XR formulation in 2009. Assuming that the BiDil XR formulation is successfully finalized, we anticipate initiating pivotal bioequivalence trials and then filing the new drug application in 2010 or 2011. In December 2007, we met with the FDA to discuss our proposed development plan for the product. The FDA agreed that our clinical development plan to conduct bioequivalence and pharmacodynamic studies comparing BiDil XR to the current commercial immediate release formulation of BiDil is acceptable. Our proposed plan could support FDA approval to commercialize BiDil XR, if bioequivalence is demonstrated. The bioequivalence study design compares the pharmacokinetics of the XR formulation to the pharmacokinetics of the immediate release formulation. Pharmacokinetics refers to the manner in which the body absorbs, distributes, metabolizes and excretes the study drug. The adequacy of the results will ultimately be determined by the FDA during the regulatory review period.

In connection with our efforts to develop BiDil XR, in February 2007 we entered into a license agreement with Elan. Pursuant to the agreement, Elan granted to us an exclusive worldwide royalty-bearing license, for the term of the agreement, to certain know-how, patents and technology, and any improvements to any of the foregoing developed by either party during the term of the agreement. Pursuant to this license, we have the right to import, use, offer for sale and sell the oral capsule formulation incorporating specified technology referred to in the agreement and containing, as its sole active combination of ingredients, the combination of the active drug substances isosorbide dinitrate and hydralazine hydrochloride, including BiDil XR.

#### **Nitric Oxide Enhancing Intellectual Property**

In the 1980s, nitric oxide was identified as a significant molecule that regulates a wide range of important cellular functions. Professor Robert R. Furchgott, a member of our then-current scientific advisory board until his retirement in 2005, and two other individuals were awarded the Nobel Prize in Physiology and Medicine in 1998 for this discovery. Recent research has shown that nitric oxide also plays important biochemical and physiological roles in many diseases or medical conditions, including cardiovascular disease, gastrointestinal and inflammatory disease, central nervous system disorders, sexual dysfunction and respiratory disease.

In March 2006, we eliminated our discovery research programs, and we do not have any current plans to conduct any other discovery research efforts with respect to our nitric oxide enhancing technologies. We are currently seeking out-licensing opportunities for these technologies. We believe that we have generated significant intellectual property rights related to our nitric oxide-enhancing technology and compounds to protect our interests. We plan to continue to maintain and preserve those rights which we believe have the potential to add value to our company.

Prior to our March 2006 restructuring, we utilized our nitric oxide expertise and proprietary position to develop product candidates for a variety of medical conditions. Our previous efforts sought to produce nitric oxide-enhancing drug candidates by combining an existing, marketed medicine with a nitric oxide donor, which is a molecule capable of increasing nitric oxide levels in the body. The nitric oxide donor and the existing medicine can be combined together through either a chemical linkage to potentially create a proprietary new chemical entity or through the direct mixing of the medicine and the nitric oxide enhancing compound to potentially create a patentable new use and dosage form. We believe that the probability of clinical success for those drug candidates is increased because regulatory approvals have already been achieved for the existing medicines that we were seeking to improve. We also believe that the commercial risk associated with these drug candidates is mitigated because many of these existing medicines have already generated significant sales in their markets.

### *Nitric Oxide-Based Programs*

Set forth below is a list of classes of nitric oxide-enhancing medicines where we have created intellectual property rights and where we believe nitric oxide-enhancing drugs may offer a clinical benefit compared to existing FDA-approved medicines. Our previous efforts in these areas consisted of discovery-stage research primarily directed to establishing our intellectual property position.

- Nitric oxide-enhancing medicines for cardiovascular disease;
- Nitric oxide-based medicines for acute renal failure;
- Nitric oxide-enhancing nonsteroidal anti-inflammatory drugs;
- Nitric oxide-enhancing phosphodiesterase inhibitors;
- Nitric oxide-enhancing steroids;
- Nitric oxide-enhancing gastrointestinal protectants;
- Nitric oxide-enhancing arginines; and
- Nitric oxide-enhancing antibiotics.

### **Research and Development**

During the fiscal years ended December 31, 2007, 2006 and 2005, our total company-sponsored research and development expenses were \$12.2 million, \$17.0 million, and \$29.0 million, respectively, and our collaborator-sponsored research and development expenses were \$-0-, \$-0- and \$2.3 million, respectively.

Our internal development activities are solely directed to the continued development of BiDil XR, and we do not have any current plans to conduct any other discovery research efforts with respect to our nitric oxide enhancing technologies.

### **Proprietary Rights and Licensing**

Our policy is to prosecute and enforce our patents and proprietary technology. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

As of December 31, 2007, we have 98 issued U.S. patents and 43 pending U.S. patent applications. We also have 79 issued patents and 172 pending patent applications in certain major industrial countries, including Canada, the major European market countries, Australia and Japan. Our issued U.S. and foreign patents expire on various dates through 2027.

*BiDil.* We have three issued U.S. patents, one which expired in April 2007 and the other two expiring in 2020, and one Canadian patent expiring in 2008, which relate to co-administration of the components of BiDil. The first U.S. patent and the Canadian patent cover methods for reducing mortality associated with chronic congestive heart failure. The second U.S. patent covers methods for reducing mortality associated with chronic congestive heart failure, for improving the quality of life, for improving oxygen consumption or improving exercise tolerance in black patients. The third U.S. patent covers additional claims to specific indications and dosing ranges for the treatment of heart failure and other conditions in black patients. We have not filed any patent applications outside of the United States and Canada for BiDil, as pertains to the patent which expired in 2007. In addition, we have filed seven additional Patent Cooperation Treaty, or PCT, applications and eight U.S. patent applications and corresponding foreign patent applications that could provide additional patent protection for BiDil.



*Nitric Oxide Stents.* We have seven U.S. patents expiring on dates between 2013 and 2021 which cover the coating of medical devices with nitric oxide compounds, prevention of adverse effects associated with the use of a medical device, treatment of a damaged vessel or treatment of a damaged vascular surface in a patient by administration of a nitric oxide compound. We have three pending U.S. patent applications which, if issued, will have expiration dates between 2021 and 2025 and one pending PCT application which cover the composition of matter of specific nitric oxide donors or nitric oxide-linked compounds and their methods of use for the treatment of restenosis. We have filed additional patent applications worldwide. We have been issued one Australian patent, one European patent, and one Canadian patent, all of which expire in 2014.

*Nitric Oxide-Enhancing COX-2 Inhibitors and Nitric Oxide-Enhancing Nonsteroidal Anti-Inflammatory Drugs.* We have nine issued and six pending U.S. patent applications, which, if issued, will have expiration dates between 2020 and 2023 and which disclose and claim novel nitric oxide-enhancing COX-2 inhibitors. These applications also disclose kits and methods of use for the treatment of pain, inflammation and fever, gastrointestinal disorders, disorders resulting from elevated levels of COX-2 inhibitors, for reducing renal and respiratory toxicity, for facilitating wound healing and for improving the cardiovascular profile of COX-2 inhibitors. We have also filed additional foreign patent applications relating to this technology. We have eleven U.S. patents expiring between 2015 and 2018 which cover different compositions of matter and methods of use for the treatment of pain, inflammation, fever and gastrointestinal disorders with novel nitric oxide-enhancing nonsteroidal anti-inflammatory drugs. Three issued and two pending applications, which, if issued, will expire in 2023, disclose specific composition of matter and methods of use for the treatment of pain, inflammation and gastrointestinal disorders of novel nitric oxide-enhancing nonsteroidal anti-inflammatory drugs.

We have filed additional patent applications worldwide and have been issued five Australian patents, three of which expire in 2016 and two in 2019, and one issued Canadian patent, which expires in 2016.

*Nitric Oxide Enhancing Cardiovascular Compounds.* We have twelve pending U.S. patent applications and two pending PCT applications, which if issued, will have expiration dates between 2024 and 2026 and which disclose and claim novel nitric oxide-enhancing cardiovascular compounds. These applications also disclose kits and methods of use for the treatment of several diseases and disorders. We have also filed additional foreign patent applications related to this technology.

*Other Development Programs.* We also have a U.S. patent and a pending U.S. patent application, both of which expire in 2019, which disclose the methods of use of N-hydroxyguanidine compounds in the treatment of renal failure. We have also filed additional foreign patents applications covering this technology.

#### **Corporate Collaborations and Business Arrangements**

*Elan.* In February 2007, in connection with our efforts to develop BiDil XR, we entered into a license agreement with Elan. Pursuant to the agreement, Elan granted to us an exclusive worldwide license, for the term of the agreement, to certain know-how, patents and technology, and any improvements to any of the foregoing developed by either party during the term of the agreement. Pursuant to this license, we have the right to import, use, offer for sale and sell the oral capsule formulation incorporating specified technology referred to in the agreement and containing, as its sole active combination of ingredients, the combination of the active drug substances isosorbide dinitrate and hydralazine hydrochloride, including BiDil XR. In consideration for the grant of the license, we have agreed to pay Elan royalties that are calculated by reference to annual net sales parameters set forth in the agreement. In addition, we have also agreed to pay Elan specified amounts upon the achievement of specified development and commercialization milestone events set forth in the agreement.

The term of the agreement runs in the United States from the effective date of the agreement until the later of (a) the 20th anniversary of the date of the first sale of the product by us or a permitted sublicensee to an unaffiliated third party, which is referred to in the agreement as the first in market sale, or (b) the expiration of the last-to-expire patent for the product listed in the FDA's "Orange Book." Elsewhere in the world, the term will run on a country by country basis from the effective date of the agreement until the later of (a) the 20th anniversary of the date of the first in market sale of the product in the country concerned or (b) the expiration of the life of the last to expire patent included in the Elan intellectual property in that country. Following the expiration of the initial term, the agreement shall continue automatically for rolling 3 year periods thereafter, unless the agreement has been terminated by either of the parties by serving 1 year's written notice on the other party prior to the end of the initial term or any such additional 3 year period. Either Elan or we may terminate the agreement in the event of a material, uncured breach by the other party, or if the other party goes into liquidation or becomes bankrupt or insolvent. In addition, we may terminate the agreement in the event of a technical failure, which is defined as the inability to achieve a pharmacokinetic profile for the product consistent with that of BiDil administered three times daily (at 6 hour intervals). Elan may terminate the agreement with respect to a particular country in the territory in the event that we do not meet certain obligations set forth in the agreement with respect to such country, provided that Elan must first consult with us and, if applicable, provide us with an opportunity to meet such obligations prior to exercising Elan's termination rights.

*Schwarz Pharma Manufacturing, Inc.* In February 2005, we entered into a five-year exclusive manufacturing and supply agreement with Schwarz Pharma for the three times daily immediate release dosage formulation of BiDil. Under the supply agreement, we have the right to engage a backup manufacturer but do not currently have any backup manufacturing agreement in place. The agreement renews automatically upon the expiration of the then-current term for successive one year terms unless either party provides written notice of termination at least six months prior to the expiration of the then-current term. The agreement is also terminable upon the occurrence of certain specified events. Schwarz Pharma is now a division of UCB S.A.

*Cardinal Health PTC, LLC.* In June 2005, we entered into a three-year exclusive distribution agreement with Cardinal Health for the distribution of BiDil in all formulations. We are obligated to pay Cardinal Health fees for the services provided under the agreement. Pursuant to the terms of the agreement, Cardinal Health has the right of first negotiation for any new pharmaceutical product to be sold by us during the term. The agreement renews automatically unless either party provides written notice of termination at least ninety days prior to the expiration of the then-current term. The agreement may be terminated without cause upon 120 days notice. However, we are obligated to pay certain fees if we exercise this termination right during the initial term of the agreement. The agreement is also terminable upon the occurrence of certain specified events.

*Dr. Jay N. Cohn.* In January 1999, as amended in January 2001 and March 2002, we entered into a collaboration and license agreement with Dr. Jay N. Cohn. Under the agreement, Dr. Cohn licensed to us exclusive worldwide royalty-bearing rights to technology and inventions owned or controlled by Dr. Cohn and that relate to BiDil for the treatment of cardiovascular disease. We have made milestone payments and are currently making royalty payments to Dr. Cohn upon sales of BiDil. During the years ended December 31, 2007, 2006 and 2005, we incurred royalties to Dr. Cohn in the approximate amounts of \$450,000, \$364,000, and \$134,000, respectively. The agreement imposes upon us an obligation to use reasonable best efforts to develop and, upon receipt of regulatory approval, manufacture, market and commercialize products based upon the licensed rights. If we fail to meet this obligation, Dr. Cohn has the right to terminate the agreement and the license granted to us under the agreement. Dr. Cohn also has the right to terminate the agreement if we materially breach the agreement and fail to remedy the breach within 30 days. We have the right to terminate the agreement at any time upon 30 days prior written notice. Unless earlier terminated, the agreement continues in

perpetuity. Pursuant to the agreement, Dr. Cohn was appointed to our then-current scientific advisory board, entered into a consulting agreement with us and was granted an option to purchase 10,000 shares of our common stock.

*FoxKiser.* In connection with our efforts to obtain the approval of BiDil from the FDA, we entered into an agreement with the law firm of FoxKiser LLC, which we refer to as FoxKiser, for services related to the regulatory approval process for BiDil. The agreement provided for payment of legal consulting fees upon receipt of written FDA approval of BiDil. On June 23, 2005, we received written FDA approval of BiDil, and in July 2005, we paid \$2.4 million pursuant to the terms of this agreement. In addition, the agreement requires us to pay royalties to FoxKiser on commercial sales of BiDil. The royalty term ends six months after the date of market introduction of an FDA-approved generic version of BiDil. During the years ended December 31, 2007, 2006 and 2005, we incurred royalties to FoxKiser in the approximate amounts of \$450,000, \$364,000 and \$134,000, respectively.

#### **Trademarks, Trade Secrets and Other Proprietary Information**

We own the following registered U.S. trademarks:

- BiDil;
- NitroMed;
- NitroMed Cares;
- More Life to Live; and
- NitroMed "N" logo.

We have also filed applications for BiDil XR and HeartHealthHeritage. In addition, we depend upon trade secrets, know-how and continuing technological improvements to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

#### **Competition**

We face intense competition from a wide range of pharmaceutical and life science companies, as well as academic and research institutions and government agencies. These competitors include organizations that are pursuing the same or similar technologies to those which constitute our technology platform and organizations that are developing and commercializing pharmaceutical products that may be competitive with BiDil and, if successfully developed and commercialized, BiDil XR.

We believe that competition for BiDil principally comes from companies currently marketing and selling therapeutics to treat heart failure in the general population. These competitors include GlaxoSmithKline, plc, Merck & Co., Inc., Pfizer Inc. and AstraZeneca plc. We also compete on the basis of the availability in generic form and at substantially lower prices of the individual components that constitute BiDil (isosorbide dinitrate, which is separately marketed for angina, and hydralazine hydrochloride, which is separately marketed for hypertension). Although these generic components are not bioequivalent to BiDil, physicians have, and may in the future, prescribe them in lieu of prescribing BiDil. We expect to face similar competitive factors with respect to BiDil XR to the extent that BiDil XR is successfully developed and commercialized.

We also face competition from other pharmaceutical companies seeking to develop drugs using nitric oxide technology. For example, we are aware of at least seven companies working in areas of nitric oxide based therapeutics which may overlap areas in which we have previously engaged in discovery research activities. These companies are: Angiogenix Inc., Vernalis plc, NicOx S.A., Amulet Pharmaceuticals, Inc., RenoPharm, Vasopharm BIOTECH GmbH and N30 Pharmaceuticals, LLC.

Principal competitive factors in our industry include:

- improved patient outcomes;
- cost-effectiveness;
- acceptance by patients, physicians, other health care providers and third-party public and private payors;
- the quality and breadth of an organization's technology;
- the skill of an organization's employees and its ability to recruit and retain skilled employees;
- an organization's intellectual property protection;
- development, sales and marketing capabilities; and
- the availability of substantial capital resources to fund development and commercialization activities.

Companies with which we compete generally have financial and other resources that are substantially greater than our own. Moreover, because we have discontinued all promotional activities for BiDil and we have ceased all research and development activities related to our nitric oxide based technologies, our ability to compete has been significantly adversely affected.

## **Government Regulation and Reimbursement**

### ***FDA Requirements for New Drug Compounds***

The research, testing, manufacture, import, export and marketing of drug products (including their components) are extensively regulated by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, labeling, promotion, sampling, marketing and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject us to a variety of enforcement actions all of which could have a material effect.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include pre-clinical laboratory tests, animal tests and formulation studies under the FDA's good laboratory practice regulations, or GLP; the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence; adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication for which FDA approval is sought; submission to the FDA of a new drug application, or NDA; satisfactory completion of a FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements; and FDA review and approval of the NDA. Satisfaction of FDA pre-market approval requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential product candidates for a considerable period of time and impose costly procedures upon a manufacturer's activities. Success in

early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product, including new safety risks, may result in restrictions on the product or even complete withdrawal of the product from the market.

Clinical trials to support a NDA for marketing approval are typically conducted in three phases. In phase I, the drug is tested to assess safety, including side effects associated with increasing doses, metabolism, pharmacokinetics and pharmacological actions. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied. Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population. The FDA may require bioequivalence, bioavailability, or other clinical studies to support approval of new formulations of approved products, such as BiDil XR. All clinical trials must be conducted in compliance with patient protection laws and regulations, including requirements related to informed consent and institutional review board, or IRB, review and approval.

Clinical testing of any product may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA, an IRB, or a clinical trial sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval.

After successful completion of the required clinical testing, generally a NDA or supplement to an existing NDA is prepared and submitted to the FDA. FDA approval of the NDA or the NDA supplement is required before marketing of the product may begin in the United States. The cost of preparing and submitting a NDA or NDA supplement is substantial.

Following the FDA's evaluations of the NDA or NDA supplement, including inspection of the manufacturing facilities, the FDA may issue an approval letter, an approvable letter, or a not approvable letter. A not approvable letter outlines deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval commitments, including testing and surveillance to monitor the drug's safety or efficacy, and may also impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once the NDA or NDA supplement is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports and/or supplemental NDAs for approval of changes to the originally approved prescribing information, product formulation, and manufacturing and testing requirements. Following approval, drug products are required to be manufactured and tested for compliance with NDA and/or compendial specifications prior to release for commercial distribution. The manufacture and testing must be performed in approved manufacturing and testing sites complying with current Good Manufacturing Practice, or

cGMP, requirements and subject to FDA inspection authority. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs. Accordingly, after approval manufacturers must continue to expend time, money and effort in the area of production and quality control, and employee training, to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA strictly regulates the promotional claims that may be made about prescription drug products, including direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Approved drug products must be promoted in a manner which is consistent with their terms and conditions of approval and the statutory standards of the Food, Drug, and Cosmetic Act. Failure to market consistent with the statutory and regulatory standards may result in enforcement action by the FDA, which may include product seizures, civil or criminal penalties, or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with FDA regulations can also result in Department of Justice investigation based on the False Claims Act and other federal laws governing reimbursement for drugs under the Medicare, Medicaid and other federally supported healthcare programs. Both the FDA and Department of Justice enforcement may relate to previous marketing practices that we have since suspended.

Once a NDA is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. An approved ANDA provides for marketing of a drug product that has the same conditions of use, active ingredients, strength, dosage form, route of administration, and labeling as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. There is no requirement, other than the requirement for bioequivalence testing, for an abbreviated NDA applicant to conduct or submit results of pre-clinical or clinical tests to prove the safety or efficacy of its drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Federal law provides for a period of three years of marketing exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, if the FDA deems that the approval of the drug was required to be supported by new clinical trials (other than bioequivalence studies) that were conducted by or for the sponsor. During this three-year period, the FDA cannot grant final approval of an ANDA based on that listed drug. Additionally, in the event that the sponsor of the listed drug has properly informed the FDA of patents covering its listed drug, applicants submitting an ANDA referencing that drug are required to certify whether they intend to market their generic products prior to expiration of those patents. If an ANDA applicant certifies that it believes all listed patents are invalid or not infringed, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If the patent holder then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patents in question are invalid, unenforceable or not infringed. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then the FDA cannot grant effective approval of the ANDA until those patents expire.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our product candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

### ***Foreign Regulation of New Drug Compounds***

Approval of a drug product by comparable regulatory authorities will be necessary in all or most foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ than that required for FDA approval.

### ***Hazardous Materials***

Our previous research and development processes involved the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material.

### ***Reimbursement***

Our ability to continue to generate revenue through the sale of BiDil and any future products depends in part on the extent to which reimbursement for the costs of such products will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly-approved health care products, products used for indications not approved by the FDA and products which have competitors for their approved indications. If we are unable to maintain our level of preferential reimbursement treatment for BiDil from governmental and other third-party payors, our ability to sell and/or maintain acceptable pricing schemes for BiDil may be impaired, thereby reducing our revenue.

### ***Employees***

As of December 31, 2007, we had 88 full-time employees, 64 of whom were engaged in sales and marketing and 24 of whom were engaged in management, administration, finance, and research and development. In January 2008, we implemented a restructuring plan that includes the elimination of approximately 75 positions by the end of February 2008, reducing headcount to approximately 15, with an additional reduction in headcount to approximately 10 positions anticipated by the end of April 2008. As part of this restructuring plan, we also discontinued active promotional activities related to BiDil.

None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages.

### ***Product Liability Insurance***

The administration of our products to humans, whether in clinical trials or after marketing approvals are obtained and the product is in use commercially, may expose us to liability claims. These claims might be made by customers, including corporate partners, clinical trial subjects, patients, pharmaceutical companies or others. We maintain product liability insurance coverage for claims arising from the use of our products, whether in clinical trials or approved commercial usage. However, insurance coverage is becoming increasingly expensive, and our insurance may not provide sufficient coverage to fully protect us against liability. If we are unable to maintain sufficient levels of insurance due to increased costs or if our insurance does not provide sufficient coverage against liability claims, a finding of liability could deplete our resources and reduce the assets available for our daily operations.

## Significant Customers

Our significant customers in each of the last three years, and their percentage of our total sales, are as follows:

<u>Customer</u>	<u>Year ended December 31,</u>		
	<u>2007</u>	<u>2006</u>	<u>2005</u>
McKesson Corporation . . . . .	38%	34%	44%
Cardinal Health . . . . .	36%	36%	21%
Amerisource Bergen Corporation . . . . .	17%	18%	14%

Our sales of BiDil are made to customers geographically located throughout the United States.

We recognized \$750,000 in research and development revenue from the non-exclusive licensing of certain non-strategic intellectual property in 2007, and recognized no research and development revenue in 2006. In 2005, our former collaboration activities with Boston Scientific Corporation accounted for 100% of our research and development revenues. No other company accounted for more than 10% of our total revenues in fiscal years 2007, 2006 or 2005.

## Raw Materials

The active ingredients in BiDil are hydralazine hydrochloride, which we purchase from Flavine International, Inc., the U.S. representative of Sumitomo Corp., and isosorbide dinitrate, which we purchase from Dottikon ES Holding AG. We believe that Sumitomo is currently the only supplier of hydralazine hydrochloride worldwide. We do not have any agreement with Sumitomo regarding the supply of hydralazine hydrochloride.

## Segment Information

During the three years ended December 31, 2007, 2006 and 2005, we operated in one reportable business segment, developing nitric oxide-enhancing medicines, under the management approach of Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

## Available Information

Our internet website address is <http://www.nitromed.com>. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission, or SEC. These SEC reports can be accessed through the "Investors" section of our website. We also make available on our website the charters for our audit committee, compensation committee, and nominating and corporate governance committee, as well as our code of business conduct and ethics, and such information is available in print to any stockholder of NitroMed who requests it. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the NASDAQ Global Market. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC.



## ITEM 1A. RISK FACTORS

*You should carefully consider the following risk factors, in addition to other information included in this annual report, in evaluating NitroMed and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected.*

### **Risks Relating to our Business, Strategy and Financial Condition**

**We have recently discontinued active promotional activities related to our only commercially-available product, BiDil, which could significantly adversely affect our future revenue and our ability to continue to fund our operations.**

Based upon our determination that the successful commercialization of BiDil requires a magnitude of resources that we cannot currently allocate to the program, as well as our plans to conserve cash in order to pursue the development of BiDil XR, in January 2008 we discontinued active promotional activities for BiDil. We concurrently implemented a restructuring plan that includes the elimination of approximately 75 positions by the end of February 2008, reducing headcount from approximately 90 to 15, with an additional reduction in headcount to approximately 10 positions anticipated by the end of April 2008. Although we have discontinued our promotional activities for BiDil, we intend to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels.

We expect to incur operating expenses going forward primarily related to our continued development of BiDil XR and to keeping BiDil available on the market. We expect to fund a substantial portion of these operating expenses through ongoing BiDil sales. We expect that the elimination of our sales force and discontinuation of our promotional activities for BiDil could result in a decline in BiDil prescriptions by healthcare providers and could also adversely affect third party payors' willingness to provide reimbursement at favorable levels. If physicians do not continue to prescribe BiDil in sufficient quantities, and/or if managed care providers remove BiDil from a preferential reimbursement tier on their plan formularies, then our future revenue from sales of BiDil will decline significantly, and we may not generate sufficient capital to fund our continued operations, including with respect to our planned development of BiDil XR.

**We are evaluating strategic alternatives that may involve the divestiture of some or all of our business. If we are unable to effect one or more of such strategic alternatives, we may not have sufficient capital to fund our business and may be required to substantially curtail or cease our operations.**

In conjunction with our January 2008 restructuring plan, in which we ceased active promotion of BiDil and significantly reduced our workforce, we are evaluating strategic alternatives to divest our current business in whole or in part in our effort to maximize the value of our commercial organization and product development programs for our shareholders. We have engaged an investment bank to advise us in considering these potential strategic alternatives, which may include the sale, license or divestiture of certain of our assets, including our BiDil business, the assets relating to BiDil XR and/or our nitric oxide technologies, the sale or merger of our company, or other similar strategic transactions. We do not know that our evaluation of strategic alternatives will result in one or more such transactions being successfully consummated or, if successful, that any such transaction would achieve our goal of maximizing the value of our organization and programs for our stockholders. As we evaluate strategic options intended to maximize shareholder value for our company, we intend to execute on our business strategy of ceasing active promotional efforts for BiDil while devoting substantially all of our resources to supporting ongoing BiDil prescriptions and the continued development of BiDil XR. If we are unable to successfully consummate one or more strategic transactions relating to our business, we may not have sufficient capital to execute on our current business plan and could be required to further curtail or cease our operations.

**We have a history of operating losses and we will require substantial additional amounts of cash to fund our operating plan, including our plans to support any continued sales of BiDil and seek to develop and commercialize BiDil XR. If additional capital is not available, we will need to limit, scale back or cease our operations.**

We have experienced significant operating losses since our inception in 1992. For the year ended December 31, 2007, we had a net loss of \$31.6 million. As of December 31, 2007, we had an accumulated deficit of \$345.4 million. We expect that we will continue to incur substantial losses and that our cumulative losses will increase as we continue our efforts to develop BiDil XR and support ongoing prescriptions for BiDil. We expect that the losses that we incur will fluctuate from quarter to quarter and that these fluctuations may be substantial.

In January 2008, we ceased actively promoting sales of BiDil, which is our only significant source of revenue. We intend to continue incurring costs relating to supporting ongoing BiDil prescriptions, and we also expect to incur additional expenses relating to the ongoing development of BiDil XR. We believe that our existing sources of liquidity and the cash expected to be generated from future sales of BiDil, together with the significant reduction in expenditures as a result of our January 2008 restructuring, will be sufficient to fund our operations for at least the next twelve months. However, our future capital requirements, and the period in which we expect our current cash to support our operations, may vary from what we expect due to a number of factors, including the following:

- the amount of future product sales of BiDil;
- the cost of manufacturing and selling BiDil;
- the timing of collections related to sales of BiDil;
- the time and costs involved in completing the clinical trials and further development of, and obtaining regulatory approvals for, BiDil XR, if at all;
- our ability to successfully consummate one or more strategic arrangements relating to our business and assets;
- the effect of competing technological and market developments;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; and
- the cost of maintaining licenses to use patented technologies.

Our business plan is to seek to divest all or substantially all of our business through a merger, asset sale, license, business combination or the like. However, if and for so long as we continue our current business and operations, we will require substantial additional funds, which we expect to generate through a combination of BiDil sales and one or more strategic transactions. However, we may not be able to successfully consummate a strategic transaction, and additional financing may not be available to us on acceptable terms, if at all.

If we are unable to obtain funding on a timely basis, whether through a strategic divestiture, financing or borrowing arrangements or other capital-raising transaction, we may not be able to support continued prescriptions for BiDil, we may be compelled to significantly curtail or delay our development efforts with respect to BiDil XR, and we could also be required to limit, scale back or cease our operations, any of which would have a material and adverse effect on our business, financial condition and results of operations.

**A substantial portion of our short-term investment portfolio is invested in auction rate securities which have faced recent market failures. Failures in these auctions may affect our liquidity.**

At March 3, 2008, we held approximately \$7.6 million of investments with an auction reset feature, referred to as auction rate securities. Auction rate securities are securities that are structured to allow for short-term interest rate resets, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to 35 days, investors can sell or continue to hold the securities at par. During early February 2008, the majority of auction rate securities in the marketplace failed at auction due to sell orders exceeding buy orders. In the event that we need to access our investments in these types of securities, we will not be able to do so until a future auction on these investments is successful, the issuer redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature, which could be in as much as 30 years. In the future, should we experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments.

**If we fail to achieve and maintain the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.**

On February 28, 2008, we received a letter from the NASDAQ Stock Market's Listing Qualifications Department providing notification that, for the last 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market, referred to as the minimum bid price rule. NASDAQ stated in such notification that, in accordance with the NASDAQ Marketplace Rules, we have 180 calendar days, or until August 26, 2008, to regain compliance with the minimum bid price rule.

The NASDAQ notification also states that if, at any time before August 26, 2008, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, NASDAQ will provide written notification that we have achieved compliance with the minimum bid price rule. However, NASDAQ may, in its discretion, require that we maintain a bid price of in excess of \$1.00 for a period in excess of 10 days, but generally no more than 20 days, before determining that we have demonstrated the ability to maintain long-term compliance. If we do not regain compliance with the minimum bid price rule by August 26, 2008, NASDAQ will provide written notification that our securities will be delisted from The NASDAQ Global Market. At that time, we may appeal NASDAQ's determination to delist our securities to a NASDAQ Listing Qualifications Panel. We can not assure you that any such appeal, if made, would be successful. Alternatively, in the event such delisting is based solely upon non-compliance with the minimum bid price rule, we could apply to transfer our securities to The NASDAQ Capital Market, provided that we satisfy the requirements for initial listing on such market, other than the minimum bid price rule. If such an application were approved and we otherwise maintain the listing requirements for The NASDAQ Capital Market, other than the minimum bid price requirement, we would be afforded the remainder of The NASDAQ Capital Market's second 180 calendar day grace period in order to regain compliance with the minimum bid price rule.

There are many factors that may adversely affect our minimum bid price, including those described throughout this section titled "Risk Factors." Many of these factors are outside of our control. As a result, we may not successfully regain compliance with the minimum bid price rule. Even if we regain compliance in the near term, we may not be able to sustain such compliance in the long term. If we do not regain compliance with the minimum bid price rule and elect to appeal NASDAQ's determination to delist our securities to a NASDAQ Listing Qualifications Panel, such appeal may not be successful. Furthermore, our potential inability to maintain compliance with other listing requirements between

now and August 26, 2008, or in any future period, could result in delisting even if we achieved compliance with the minimum bid price rule during such time. A delisting of our common stock from The NASDAQ Global Market would make it more difficult our stockholders to sell our common stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

**If we do not maintain an adequate level of revenue from sales of BiDil given our lack of promotional activities, the availability of cash to fund our planned development of BiDil XR will significantly decline, our BiDil XR development efforts may not be successful and our business may fail.**

Our current strategy is to continue to advance the development of BiDil XR while simultaneously seeking strategic alternatives to divest all or substantially all of our current business. We will depend upon continued sales of BiDil to fund a substantial portion of our costs and expenses to develop BiDil XR. We have recently discontinued all promotional activities relating to BiDil, and we intend only to expend the resources necessary to maintain BiDil on the market for patients through normal wholesale and retail channels. As a result of our lack of promotional efforts for BiDil, sales of BiDil may decline rapidly. Our inability to successfully generate further revenue from BiDil sales will adversely affect our ability to seek to advance the development of BiDil XR, in which case we may be required to further curtail or cease our operations.

Factors that we believe may materially adversely affect continued sales of BiDil, and may also affect sales of BiDil XR, if it is successfully developed and commercialized, include:

- the discontinuation of our promotional programs as a result of our January 2008 restructuring plan;
- the unavailability of favorable government and third-party payor reimbursement;
- our inability to manufacture and sell BiDil at a competitive price;
- the availability in generic form and at substantially lower prices of the individual components that constitute BiDil (isosorbide dinitrate, which is separately marketed for angina, and hydralazine hydrochloride, which is separately marketed for hypertension) and the misperception by physicians, patients and payors that these generic components are equivalent to BiDil;
- the requirement by potential large purchasers of BiDil, such as hospitals or health maintenance organizations, or by state formularies, other government agencies or private payors that approve reimbursement for drugs, that the generic components of BiDil be substituted for BiDil;
- the failure of physicians, third-party payors and patients to accept a product intended to improve therapeutic results based on ethnicity or to accept BiDil as being safe, effective, easy to administer and medically necessary; and
- our inability to maintain the necessary patent protection, licenses and regulatory approvals required to manufacture and sell BiDil.

**If the third-party manufacturer of BiDil encounters delays or difficulties in production, we may not be able to meet demand for the product and we may lose potential revenue, which would adversely affect our financial results and our ability to execute our business plan.**

We do not physically manufacture BiDil and have no plans to do so. We have engaged Schwarz Pharma under a five-year exclusive manufacturing and supply agreement solely for the three times daily immediate release dosage formulation of BiDil. Under the supply agreement, we have the right to engage a backup manufacturer but do not currently have any backup manufacturing agreement in place. The terms of the supply agreement provide that it may be terminated by either us or Schwarz Pharma under specified circumstances, including a material breach of the supply agreement by either

party, the occurrence of a payment default by us, our material impairment of the manufacturing licenses we have granted to Schwarz Pharma or a failure of Schwarz Pharma to supply conforming products. In addition, either party may terminate the supply agreement in the event the FDA takes any action, the result of which is to permanently prohibit the manufacture, sale or use of the product.

Furthermore, Schwarz Pharma may encounter difficulties in production. These problems may include, but are not limited to:

- difficulties with production costs and yields;
- quality control and assurance;
- difficulties obtaining ingredients for our products;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations; and
- lack of capital funding.

If we are unable to maintain a commercially reasonable manufacturing agreement for the production of BiDil with Schwarz Pharma, we have no back-up manufacturing facility and thus we would not be able to manufacture and sell BiDil until another facility was qualified. The number of third-party manufacturers with the manufacturing and regulatory expertise and facilities necessary to manufacture finished products for us on a commercial scale is limited, and it would take a significant amount of time to arrange, qualify, and receive necessary regulatory approval for alternative arrangements. We may not be able to contract for alternative manufacturing on acceptable terms, if at all.

If we are unable to successfully contract for third-party manufacturing, or if Schwarz Pharma or any other third-party manufacturer of BiDil fails to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, we may be unable to meet the demand for our product and we may lose potential revenues, all of which could cause the price of our common stock to decline and would adversely affect our financial results and our ability to execute our business plan.

**We rely on a single source supplier for one of the two active ingredients in BiDil, and the loss of this supplier could prevent us from selling BiDil, which would materially harm our business.**

We rely on Sumitomo Corp. for our supply of hydralazine hydrochloride, one of the two active ingredients in BiDil. To the best of our knowledge, Sumitomo is currently the only supplier of hydralazine hydrochloride worldwide. We do not have any agreement with Sumitomo regarding the supply of hydralazine hydrochloride. If Sumitomo stops manufacturing or is unable to manufacture hydralazine hydrochloride, or if we are unable to procure hydralazine hydrochloride from Sumitomo on commercially favorable terms, we may be unable to continue to sell BiDil on commercially viable terms, if at all. Furthermore, because Sumitomo is currently the sole supplier of hydralazine hydrochloride, Sumitomo has unilateral control over the price of hydralazine hydrochloride. Any increase in the price for hydralazine hydrochloride may reduce our gross margins and adversely affect our ability to sell BiDil at a favorable price.

**BiDil is subject to ongoing regulatory review and oversight. If we fail to comply with continuing United States regulations, we could lose our approval to market BiDil and our business would be seriously harmed.**

Even after approval, any products we develop are subject to ongoing regulatory review and restrictions, including the review of new clinical results and other post-marketing data. The FDA can propose to withdraw approval or place additional restrictions on indications for which we can market the product or the manner in which we may distribute the product if new clinical data or experience shows that a product is not safe for use under the approved conditions of use.

The marketing claims we are permitted to make in labeling or advertising regarding our marketed products must comply with FDA laws and regulations and are limited to those specified in any FDA approval. Although we are not actively marketing BiDil, we could face liability for our previous marketing activities if the FDA believes that we have promoted our products for unapproved indications or otherwise failed to comply with the FDA's promotional labeling or advertising regulations, or guidelines regarding company support for continuing medical education. Based on such allegations, the FDA could issue an untitled letter or warning letter, or take other enforcement action including seizure of allegedly violative product, injunctions or civil or criminal prosecution against us and our officers or employees. In addition, the Department of Justice enforces laws prohibiting kickbacks to healthcare providers and false claims in connection with government-funded reimbursement programs for drug purchases, such as Medicare and Medicaid, and any prior off-label marketing of BiDil could subject us to civil or criminal prosecution, for which the government could seek to recover substantial monetary penalties, the imposition of restrictions on our marketing activities, and the exclusion of BiDil from eligibility for government reimbursement programs.

In addition, the manufacturer and the manufacturing facilities we use to produce BiDil are subject to periodic review and inspection by the FDA. We are required to report any serious and unexpected adverse experiences and certain quality problems with BiDil and make other periodic reports to the FDA. The discovery of any previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Certain changes to an approved product often require prior FDA approval before the product, as modified, may be marketed.

If we or our third-party manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we or they could be subject to enforcement actions which could affect our ability to develop, market and sell BiDil successfully and could harm our reputation and lead to lower acceptance of BiDil by the market. These enforcement actions include product seizures; voluntary or mandatory recalls; patient or physician notifications, including letters to healthcare professionals and corrective advertising; withdrawal of product approvals; restrictions on, or prohibitions against, marketing our products; operating restrictions; fines; restrictions on importation or exportation of our products; injunctions; debarments; civil and criminal penalties; and suspension of review of, or refusal to approve, pending applications.

**Clinical testing of BiDil XR may not be successful, in which case we may be unable to commercialize BiDil XR and the value of our business will substantially decline.**

In order to obtain regulatory approvals for the commercial sale of BiDil XR, we will be required to complete clinical trials in humans to demonstrate the safety and efficacy of BiDil XR. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials of BiDil XR can occur at any stage of testing.

We met with the FDA in December 2007, and the agency agreed that our clinical development plan to conduct bioequivalence and pharmacodynamic studies comparing BiDil XR to the current commercial immediate release formulation of BiDil is acceptable. The agency indicated that such a plan could support FDA approval to commercialize BiDil XR, if bioequivalence is demonstrated. The bioequivalence study design compares the pharmacokinetics of the XR formulation to the pharmacokinetics of the immediate release formulation. Pharmacokinetics refers to the manner in which the body absorbs, distributes, metabolizes and excretes the study drug. The adequacy of the results will ultimately be determined by the FDA during the regulatory review period. Although we are encouraged by this meeting with the FDA, we may experience numerous unforeseen events during, or

as a result of, our planned clinical trials of BiDil XR that could delay or prevent our ability to receive regulatory approval for, or commercialize, BiDil XR, including:

- conditions imposed on us by the FDA regarding the scope or design of our clinical trials;
- difficulty obtaining or maintaining IRB approval of studies;
- problems in finalizing the formulation of BiDil XR through our planned clinical studies;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, including testing alternative formulations of BiDil XR;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we currently anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate, any of which would result in significant delays and increased costs;
- our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate one or more of our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of BiDil XR or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and
- the effects of BiDil XR may not be the desired effects or may include undesirable side effects or may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of BiDil XR beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for BiDil XR;
- not be able to obtain marketing approval;
- obtain approval for an indication that is not as broad as intended; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether future clinical trials will begin as planned, will need to be redesigned or will be completed on schedule, if at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize BiDil XR, or allow our competitors to bring products to market before we do, which could impair our ability to commercialize BiDil XR and may harm our business and results of operations.

**We currently rely on a third party contract research organization to conduct our clinical trials of BiDil XR. Such third party may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.**

We do not independently conduct clinical trials for BiDil XR. We rely on a third party contract research organization to enroll qualified patients and conduct our clinical trials of BiDil XR. Our reliance on this third party for clinical development activities reduces our control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on a third party that we do not control does not relieve us of these responsibilities and requirements. Furthermore, this third party may also have relationships with other entities, some of which may be our competitors. If our third party contract research organization does not successfully carry out its contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for BiDil XR and will not be able to, or may be delayed in our efforts to, successfully commercialize BiDil XR.

**If we are not able to obtain required regulatory approvals, we will not be able to commercialize BiDil XR and our ability to generate revenue will be materially impaired.**

BiDil XR, and the activities associated with its development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by authorities in other countries. Failure to obtain regulatory approval for BiDil XR will prevent us from commercializing BiDil XR.

Securing FDA approval may require the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Our future product, BiDil XR, may not be effective, may be only moderately effective or may prove to have undesirable side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited in scope or subject to restrictions or post-approval commitments that render the product not commercially viable. If any regulatory approval that we obtain is delayed or is limited, we may decide not to commercialize BiDil XR after receiving the approval.



**The development and future commercialization of BiDil XR may be terminated or delayed, and the cost of development and future commercialization may increase, if third parties on whom we rely to manufacture BiDil XR do not fulfill their obligations.**

We do not have manufacturing capabilities for BiDil XR and have no current plans to develop any such capacity in the future. In order to continue to develop BiDil XR, apply for regulatory approvals and commercialize this product, we plan to rely on our collaborative licensor, Elan, for the production of clinical and commercial quantities of BiDil XR. In addition, contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current Good Manufacturing Practices, or cGMP, and other governmental regulations and corresponding foreign standards. The cGMP requirements govern, among other things, quality control of the manufacturing process and documentation of policies and procedures. Other than through contract, we do not have control over compliance by our contract manufacturers with these regulations and standards. Our present or future contract manufacturers may not be able to comply with cGMP and other FDA requirements or similar regulatory requirements outside the United States. Any failure by our contract manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of BiDil, delays, suspension or withdrawal of approvals, seizures or recalls of such product candidate, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our business. We will depend upon these third parties to perform their obligations in a timely manner and in accordance with applicable laws and regulations, including those related to quality control and quality assurance. To the extent that third-party manufacturers with whom we contract fail to perform their obligations in accordance with applicable laws and regulations, we may be adversely affected in a number of ways, including:

- we may not be able to initiate or continue clinical trials of BiDil XR;
- we may be delayed in submitting applications for regulatory approvals for BiDil XR; and
- even if we successfully commercialize BiDil XR, we may be required to cease distribution and/or recall some or all batches of the product and we may not be able to meet commercial demands for our products or achieve profitability.

**Currently, we are engaging in limited internal research and development activities and, accordingly, our ability to generate future revenue from our nitric oxide technology portfolio is completely dependent on our ability to enter into scientifically and commercially successful out-licensing arrangements with third parties.**

At the end of the first quarter of 2006, we scaled back our research and development staff in a restructuring of our company and have limited our internal research and development activities solely to the continued development of BiDil XR. We are currently seeking out-licensing opportunities for our other potential product candidates based on our proprietary nitric oxide technology. The application of our proprietary nitric oxide technology is unproven in humans and, as a result, we may not be able to successfully out-license any products based on this technology. Our potential product candidates include nitric oxide enhancements of existing drugs; in these cases, we have sought to modify compounds whose chemical and pharmacological profiles are well-documented and understood. Many of our potential product candidates, however, are new molecules with chemical and pharmacological profiles that differ from that of the existing drugs. These compounds may not demonstrate in patients the chemical and pharmacological properties shown in laboratory studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. In addition, it is possible that existing drugs or newly-discovered drugs may not benefit from the application of our nitric oxide technology. We may not be able to secure out-licensing arrangements for these potential product candidates. Even if we are successful in entering into out-licensing arrangements with respect

to our potential product candidates, we have no assurance that we will be able to secure such arrangements on terms completely favorable to us. If our out-licensing arrangements include unfavorable financial terms, our ability to generate revenue from our technology portfolio will be severely limited.

Additional factors that may affect the success of our potential future out-licensing arrangements include the following:

- our future licensing partners may be pursuing alternative technologies or developing alternative product candidates, either on their own or in collaboration with others, that may be competitive with the product candidate which they have licensed from us and which could affect their commitment to our program;
- future reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our licensing partners would reduce our revenues, which could be based on a percentage of net sales by the licensee;
- our future licensing partners may terminate their agreements with us, which could make it difficult for us to attract new licensees or adversely affect how we are perceived in the business and financial communities; and
- our future licensing partners may pursue higher-priority programs or change the focus of their development programs, which could affect a licensee's commitment to us.

As a result of the foregoing factors, our potential strategic licensees may not be successful in developing and commercializing any products based on our proprietary nitric oxide technology. Any failure of such potential licensees at any stage of the development or commercialization process with respect to our potential product candidates would significantly reduce the possibility that we would realize any future revenue from our technology portfolio.

#### **Risks Relating to our Intellectual Property Rights**

**Our patent protection for BiDil, the individual components of which are available in generic form, is limited, and we may be subject to generic substitution or competition and resulting pricing pressure.**

We have no composition of matter patent covering BiDil, our product for the treatment of heart failure in self-identified black patients as an adjunct to current standard therapy. BiDil is a fixed-dose combination of two individual components, isosorbide dinitrate and hydralazine hydrochloride, both of which are available in generic form, which are approved and separately marketed, in dosages similar to those we include in BiDil, for indications other than heart failure, at prices below the prices we are charging for BiDil. We have two issued method-of-use patents that expire in 2020. One patent covers the use of the combination of isosorbide dinitrate and hydralazine hydrochloride to reduce mortality associated with chronic congestive heart failure, for improving the oxygen consumption, for improving the quality of life or for improving exercise tolerance in a black patient. The other patent covers the use of the combination of isosorbide dinitrate and hydralazine hydrochloride in certain dosage amounts for reducing mortality associated with heart failure in a black patient. Our method of use patent that covered the use of the combination of isosorbide dinitrate and hydralazine hydrochloride to reduce the incidence of mortality associated with chronic congestive heart failure expired in accordance with its terms in April 2007.

We may not be able to enforce our method-of-use patents to prevent physicians from prescribing isosorbide dinitrate and hydralazine hydrochloride separately for the treatment of heart failure in black patients, even though neither drug is approved for such use. We also may not be able to enforce these method-of-use patents to prevent hospitals and pharmacies from supplying such patients with these individual components separately in lieu of BiDil.

Other factors may also adversely affect our patent protection for BiDil. If we are successful in marketing BiDil, manufacturers of generic drugs will have an incentive to challenge our patent position. The combination therapy of isosorbide dinitrate and hydralazine hydrochloride for use in heart failure was developed through lengthy, publicly-sponsored clinical trials conducted during the 1980s, prior to the filing of the patent application that resulted in the 2007 patent. The U.S. Patent and Trademark Office, or U.S. patent office, considered published reports on these clinical trials and concluded that they did not constitute prior art that would prevent the issuance of the 2007 patent. The U.S. patent office also considered the question of whether the 2007 patent constituted prior art with respect to the 2020 patents, and determined that the claims of the 2020 patents were non-obvious and patentable. A court considering the validity of the 2020 patents with respect to questions of prior art might be presented with other alleged prior art or might reach conclusions different than those reached by the U.S. patent office. If the 2020 patents were to be invalidated or if physicians were to prescribe isosorbide dinitrate and hydralazine hydrochloride separately for heart failure in black patients, our BiDil revenue could be significantly reduced, we could fail to recover the cost of developing BiDil and BiDil might not be a viable commercial product.

**If we are not able to obtain and enforce patent protection for our discoveries, our ability to secure out-licensing arrangements with respect to our potential product candidates will be harmed, and we may not be able to operate our business profitably.**

Our success depends, in part, on our ability to protect proprietary methods and technologies that we developed under the patent and other intellectual property laws of the United States and other countries, in order to prevent others from using our inventions and proprietary information. Because certain United States patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over patent applications of others.

The process of seeking patent protection for our discoveries is expensive and time consuming, and we may not be able to prosecute all necessary or desirable patent applications or maintain all issued patents at a reasonable cost. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The mere issuance of a patent does not guarantee that it is valid or enforceable; even if we have obtained patents, they may not be valid or enforceable against third parties.

The issued patents and patent applications for our potential product candidates and nitric oxide technology include claims with respect to both the composition of specific products or compounds and specific methods of using these products or compounds in therapeutic areas. In some cases, like BiDil, our only patent protection is with respect to the method of using a product or compound. Method-of-use patents may provide less protection for our product candidates and products. If another company gains FDA approval for an indication separate from the one claimed in our method-of-use patents, physicians may be able to prescribe that product for use in the approved indication. In addition, physicians may prescribe a product for which we or our potential strategic partners have obtained approval for an unapproved indication for that product. As a practical matter, we or our potential strategic partners may not be able to enforce our method-of-use patents against physicians prescribing products for such off-label use. Off-label use and any resulting off-label sales could make it more difficult to obtain the price we or our potential strategic partners would otherwise wish to achieve for, or to successfully commercialize, our potential products. In addition, in those situations where we have only method-of-use patent coverage for a product candidate, it may be more difficult to find a pharmaceutical company partner to license or support development of our potential product candidates.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the U.S. patent office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change over time. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

**If we become involved in patent litigation or other proceedings to enforce our patent rights, we would incur substantial costs and expenses, as well as substantial liability for damages, and/or we, or our strategic partners, could be required to stop product development and commercialization efforts.**

A third party may sue us or our potential strategic partners for infringing on its patent rights. Likewise, we or our potential strategic partners may need to resort to litigation to enforce a patent issued to us or to seek a declaratory judgment on the scope and validity of third-party proprietary rights. The cost to us or our potential strategic partners of any litigation or other proceedings relating to intellectual property rights, even if resolved in our or our partner's favor, could be substantial, and the litigation would divert management efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, our strategy of providing nitric oxide-enhancing versions of existing products could lead to more patent litigation due to the fact that the markets for these existing products are very large and competitive. Uncertainties resulting from litigation could limit our ability to continue our operations. For example, we filed an opposition in the European Patent Office, or EPO, to revoke NicOx S.A.'s European Patent No. 904 110, which we refer to as EP '110. This patent is directed to the use of organic compounds containing a nitrate group or inorganic compounds containing a nitric oxide group to reduce the toxicity caused by certain drugs, including non-steroidal anti-inflammatory drugs. The basis for our opposition, in part, is that the claims in EP '110 are anticipated and therefore invalid if they are construed to cover a single compound chemically linked to a nitrate moiety. In March 2007, the three-member EPO Opposition Division invalidated all of the claims of EP '110, and the official written decision revoking EP '110 was issued on June 19, 2007. Pursuant to the rules of the EPO, NicOx had an opportunity to file an appeal regarding this invalidation decision. On October 5, 2007, we received notice from the EPO Opposition Division that no appeal had been submitted within the applicable time limit, and accordingly the opposition proceedings are finally terminated.

Nevertheless, if any parties are able to successfully claim that the development or use by us or our potential strategic partners of proprietary technologies infringes upon their intellectual property rights, we or our potential strategic partners might be forced to pay damages, potentially including treble damages, if we or our potential strategic partners are found to have willfully infringed on such parties' patent rights. In addition to any damages we or our potential strategic partners might have to pay, a court could require us or our potential strategic partners to stop the infringing activity or obtain a license on terms that are unfavorable to us. In addition, some licenses may be non-exclusive, and therefore our competitors may have access to the same technology licensed to us. If we or our potential strategic partners fail to obtain a required license or are unable to design around a patent, we or our potential strategic partners may be unable to effectively market some of our technology and product candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating sufficient revenue to sustain our operations.

**We in-license a significant portion of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to commercializing BiDil and out-licensing our other product candidates.**

We are a party to a number of licenses that give us rights to third-party intellectual property that are necessary for our business. In particular, we have obtained the exclusive right to develop and commercialize BiDil pursuant to a license agreement with Dr. Jay N. Cohn, and some of our intellectual property rights relating to nitric oxide compounds have been obtained pursuant to license agreements with the Brigham and Women's Hospital and Boston University. In addition, we may enter into additional licenses in the future. These licenses impose various development, commercialization, funding, royalty, diligence, and other obligations on us. If we breach these obligations, the licensor may have the right to terminate the license or render the license non-exclusive, which would result in us being unable to develop, manufacture and sell products that are covered by the licensed technology.

### **Risks Relating to our Industry**

**We could be negatively impacted by the application or enforcement of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state anti-referral laws.**

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change or discontinue our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, we could become subject to false claims litigation under federal statutes, which can lead to treble damages based on the reimbursements by federal healthcare programs, civil money penalties (including penalties levied on a per false claim basis), restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. These false claims statutes include the False Claims Act, which allows any person to bring suit on behalf of the federal government alleging the submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against pharmaceutical and biotechnology companies have increased significantly in recent years and have increased the risk that a healthcare company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. It is possible that we could become subject to such litigation and, if we are not successful in defending against it, such litigation would have a material adverse effect on our business, financial condition and results of operations. In addition, the cost of defending claims or allegations under the False Claims Act, even if successful, would also have a material adverse effect on our business, financial condition and results of operations.

**We face significant competition, which may result in others commercializing products more successfully than ours.**

The pharmaceutical industry is highly competitive and characterized by rapid and significant technological change. Moreover, because we have discontinued all promotional activities for BiDil and we have ceased all research and development related to our nitric oxide-based product candidates, our ability to effectively compete in the marketplace has been significantly adversely affected. Our principal competitors are large, multinational pharmaceutical companies that have substantially greater financial and other resources than we do and are conducting extensive research and development activities on technologies and product candidates similar to or competitive with ours. Many of our competitors are more experienced than we are in pharmaceutical development and commercialization, obtaining regulatory approvals and product marketing and manufacturing. As a result, our competitors may:

- develop and commercialize products that render BiDil and/or BiDil XR, if successfully developed and commercialized, obsolete or non-competitive or that cause BiDil to be less desirable as a result of patent or non-patent exclusivity;
- develop product candidates and market products that are less expensive or more effective than BiDil;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of product acquisition or other opportunities more readily than we can.

There are a number of companies currently marketing and selling products to treat heart failure in the general population that will compete with BiDil. These include GlaxoSmithKline, plc, which currently markets Coreg®, Merck & Co., Inc., which currently markets Vasotec® and Astra Zeneca, plc, which currently markets Toprol XL®. We also compete on the basis of the availability in generic form and at substantially lower prices of the individual components that constitute BiDil (isosorbide dinitrate, which is separately marketed for angina, and hydralazine hydrochloride, which is separately marketed for hypertension). Although these generic components are not bioequivalent to BiDil, physicians have, and may in the future, prescribe them in lieu of prescribing BiDil.

We also face competition from other pharmaceutical companies seeking to develop drugs using nitric oxide technology. For example, we are aware of at least seven companies working in areas of nitric oxide based therapeutics which may overlap areas in which we have previously engaged in discovery research activities. These companies are: Angiogenix, Inc., Vernalis plc, NicOx S.A., Amulet Pharmaceuticals, Inc., RenoPharm, Vasopharm BIOTECH GmbH and N30 Pharmaceuticals, LLC.

We expect to face similar competitive factors with respect to BiDil XR to the extent that BiDil XR is successfully developed and commercialized.

**We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.**

Our business exposes us to the risk of product liability claims that is inherent in the clinical testing, manufacturing and marketing of human therapeutic products. Our clinical trial and commercial product liability insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain insurance on acceptable terms, if at all. Moreover, any insurance that we do obtain may not provide adequate protection against potential liabilities, and our capital resources could be depleted as a result.

## **Risks Relating to our Common Stock**

**The price of our common stock is likely to continue to be volatile in the future.**

The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In particular, the market price of our common stock, like that of the securities of other biopharmaceutical companies, has been and may continue to be highly volatile. During the period from January 1, 2005 to March 1, 2008, our stock price has ranged from a low of \$0.80 per share (on January 22, 2008) to a high of \$27.99 per share (on February 2, 2005). The following factors, among others, may affect the price of our common stock:

- fluctuations in our financial results, including with respect to sales of BiDil;
- announcements concerning fundamental or material corporate transactions, restructuring or the like;
- general market conditions;
- announcements of technological innovations or new commercial products by our competitors;
- announcements of actual or potential results relating to our BiDil XR development program;
- governmental regulations and regulatory developments in both the U.S. and foreign countries affecting us or our competitors;
- disputes relating to patents or other proprietary rights affecting us, our potential strategic partners or our competitors;
- public concern as to the safety of products developed by us, our potential strategic partners or other biotechnology and pharmaceutical companies;
- fluctuations in price and volume in the stock market in general, or in the trading of the stock of biopharmaceutical and biotechnology companies in particular, that are unrelated to our operating performance;
- issuances of securities in equity, debt or other financings;
- sales of common stock by existing stockholders; and
- the perception that such issuances or sales could occur.

**Insiders have substantial control over us and could delay or prevent a change in corporate control.**

As of March 3, 2008, our directors and executive officers, together with their affiliates, owned, in the aggregate, approximately 33.2% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, if acting together, will have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

**Provisions in our charter documents and under Delaware law may prevent or frustrate attempts by stockholders to change current management and hinder efforts to acquire a controlling interest in our company.**

Provisions of our restated certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may prevent or frustrate attempts by stockholders to replace or remove our current management. These provisions include:

- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by a majority of the board of directors, the chairman of the board or the chief executive officer;
- advance notice requirements for stockholder proposals and nominations;
- limitations on the ability of stockholders to amend, alter or repeal our certificate of incorporation or bylaws; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally defined as a person or entity which together with its affiliates owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

**Substantially all of our outstanding common stock may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.**

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 3, 2008, there were 46,125,976 shares of common stock outstanding. Substantially all of these shares may also be resold in the public market at any time. In addition, we have a significant number of shares that are subject to outstanding options and restricted stock awards. The sale of the common stock underlying these options and pursuant to these restricted stock awards after such time as the options and restricted stock awards have vested and become exercisable or free from forfeiture, as the case may be, could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

**We may incur significant costs and suffer management distraction and reputational damage from class action litigation.**

Our stock price has been, and is likely to continue to be, volatile. When the market price of a company's stock is volatile, holders of that company's stock may bring securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit was without merit, we could incur substantial costs defending the lawsuit.



**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We lease approximately 19,815 square feet of office space at a facility located at 45 Hayden Avenue in Lexington, Massachusetts. The initial term of the lease is for sixty-six months. We believe that our office space is more than adequate for our needs for the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS**

We are currently not a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders of our company, through solicitations of proxies or otherwise, during the quarter ended December 31, 2007.

**PART II**

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

**Market Price of and Dividends on NitroMed's Common Stock and Related Stockholder Matters; Recent Sales of Unregistered Securities.**

*Market Price and Dividends*

Our common stock is traded on The NASDAQ Global Market under the symbol "NTMD". The following table sets forth the high and low sale prices per share of our common stock as reported on The NASDAQ Global Market for the periods indicated.

	<u>Common stock price</u>	
	<u>High</u>	<u>Low</u>
<b>Fiscal year ended December 31, 2007</b>		
First quarter . . . . .	\$ 4.28	\$2.38
Second quarter . . . . .	\$ 3.90	\$2.16
Third quarter . . . . .	\$ 2.46	\$1.76
Fourth quarter . . . . .	\$ 1.76	\$1.01
<b>Fiscal year ended December 31, 2006</b>		
First quarter . . . . .	\$14.90	\$7.51
Second quarter . . . . .	\$ 8.86	\$3.59
Third quarter . . . . .	\$ 4.90	\$2.38
Fourth quarter . . . . .	\$ 3.20	\$2.04

On March 3, 2008, the reported last sale price of our common stock on The NASDAQ Global Market was \$1.18 per share, and we had approximately 54 holders of record of our common stock. This number does not include shareholders for whom shares are held in a "nominee" or "street" name.

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

On February 28, 2008, we received a letter from the NASDAQ Stock Market's Listing Qualifications Department providing notification that, for the previous 30 consecutive business days, the bid price our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market under NASDAQ Marketplace Rule 4450(a)(5), referred to as the minimum bid price rule. NASDAQ stated in its notification that, in accordance with NASDAQ Marketplace Rule 4450(e)(2), we have 180 calendar days, or until August 26, 2008, to regain compliance with the minimum bid price rule. The NASDAQ notification also stated that if at any time before August 26, 2008, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, NASDAQ will provide written notification that we have achieved compliance with the minimum bid price rule, although NASDAQ may, in its discretion, require that we maintain a bid price of in excess of \$1.00 for a period in excess of 10 days, but generally no more than 20 days, before determining that we have demonstrated the ability to maintain long-term compliance.

Information regarding our equity compensation plans and the securities authorized for issuance there under is set forth in Note 7 in our Notes to Financial Statements below.

### Recent Sales of Unregistered Securities

The following table sets forth information concerning the purchase of our equity securities by us during the fourth quarter of 2007. Information concerning the purchase of our equity securities during the prior quarters of 2007 has been previously included in our quarterly reports on Form 10-Q.

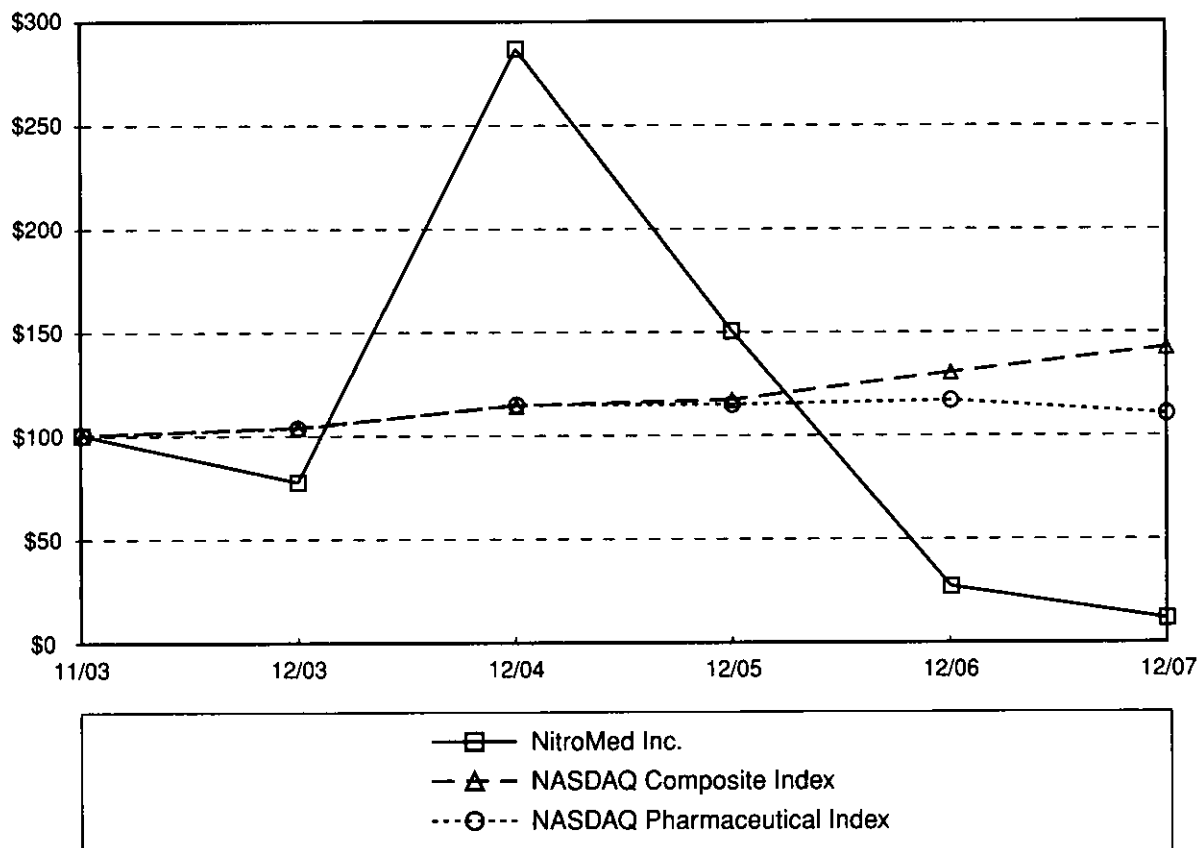
<u>Period</u>	<u>Total Number of Shares Purchased(1)</u>	<u>Average Price Per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(2)</u>	<u>Maximum Number of Shares that May Yet be Purchased Under the Plans or Programs</u>
October 1, 2007 - October 31, 2007 . . . . .	1,641	\$1.73	—	—
November 1, 2007 - November 30, 2007 . . . .	—	—	—	—
December 1, 2007 - December 31, 2007 . . . .	—	—	—	—
<b>Total . . . . .</b>	<u>1,641</u>		<u>—</u>	<u>—</u>

- (1) The amount listed in this column represents shares of common stock surrendered by certain employees to us in satisfaction of tax withholding obligations incurred upon the lapse of restrictions on shares of common stock during the period in accordance with the terms of restricted stock agreements previously entered into between us and those employees.
- (2) We currently have no plan or program to repurchase our equity securities, aside from additional shares that will be surrendered to us in satisfaction of tax withholding obligations incurred upon the future lapse of restrictions on shares of common stock in accordance with the terms of restricted stock agreements entered into between us and certain employees.

### Comparative Stock Performance Graph

The comparative stock performance graph below compares the cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing \$100 on November 6, 2003, the date on which our common stock was first publicly traded, and plotted at the close of the last trading day of the fiscal years ended December 31, 2003, 2004, 2005, 2006 and 2007, in each of (i) our common stock, (ii) The NASDAQ Global Stock Market Index of U.S. Companies, which we refer to as the NASDAQ Composite Index, and (iii) The NASDAQ Global Stock Market Pharmaceutical Index, which we refer to as the NASDAQ Pharmaceutical Index; except that, in the case of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index, the stock performance graph below reflects an investment date of October 31, 2003.

**COMPARISON OF CUMULATIVE TOTAL RETURN\***  
Among NitroMed Inc., The NASDAQ Composite Index  
And The NASDAQ Pharmaceutical Index



Measurement Period (Fiscal Year Covered)	NitroMed, Inc.	NASDAQ Composite Index	NASDAQ Pharmaceutical Index
11/6/2003 . . . . .	\$100.00	\$100.00	\$100.00
12/31/2003 . . . . .	\$ 77.34	\$103.74	\$103.28
12/31/2004 . . . . .	\$286.87	\$114.05	\$114.38
12/31/2005 . . . . .	\$150.16	\$116.80	\$114.52
12/31/2006 . . . . .	\$ 26.37	\$130.12	\$116.49
12/31/2007 . . . . .	\$ 10.87	\$142.17	\$110.11

\* \$100 invested on November 6, 2003 in our common stock and October 31, 2003 in either the NASDAQ Composite Index or the NASDAQ Pharmaceutical Index, including reinvestment of dividends.

The information included under the heading “Comparative Stock Performance Graph” in this Item 5 of our annual report on Form 10-K shall not be deemed to be “soliciting material” or subject to Regulation 14A or 14C, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

## ITEM 6. SELECTED FINANCIAL DATA

You should read carefully the financial statements included in this report, including the notes to the financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data in this section are not intended to replace the financial statements.

We derived the statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 from our audited financial statements, which are included elsewhere in this report. We derived the statement of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 from our audited financial statements which are not included herein. Historical results are not necessarily indicative of future results. See the notes to the financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per common share.

	Year Ended December 31,				
	2007(1)	2006(1)	2005	2004	2003
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenue	\$ 16,019	\$ 12,086	\$ 6,047	\$ 16,458	\$ 12,775
Cost and operating expenses:					
Cost of product sales	4,236	3,560	8,009	—	—
Research and development	12,185	17,029	31,340	27,401	18,447
Sales, general and administrative	31,358	59,403	74,596	20,185	3,574
Restructuring charges	1,004	5,283	—	—	—
Total costs and operating expenses	48,783	85,275	113,945	47,586	22,021
Loss from operations	(32,764)	(73,189)	(107,898)	(31,128)	(9,246)
Other income, net	1,190	1,852	2,046	1,355	477
Net loss	(31,574)	(71,337)	(105,852)	(29,773)	(8,769)
Deemed dividends related to beneficial conversion features of redeemable convertible preferred stock	—	—	—	—	(19,357)
Accretion of dividends and redemption value	—	—	—	—	(2,794)
Net loss attributable to common stockholders	<u>\$(31,574)</u>	<u>\$(71,337)</u>	<u>\$(105,852)</u>	<u>\$(29,773)</u>	<u>\$(30,920)</u>
Net loss per common share:					
Basic and diluted	\$ (0.75)	\$ (1.96)	\$ (3.49)	\$ (1.14)	\$ (6.95)
Weighted average basic and diluted common shares outstanding	41,997	36,399	30,355	26,152	4,447

- (1) We include the expense associated with employee stock options in the Statement of Operations effective in 2006 upon the adoption of Statement of Financial Accounting Standards No. 123R, which resulted in an aggregate of \$5.0 million and \$8.0 million recorded in the line items of research and development and sales, general and administrative expenses for the years ended December 31, 2007 and 2006, respectively.

	As of December 31,				
	2007	2006	2005	2004	2003
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities . . . . .	\$ 31,400	\$ 42,153	\$ 61,541	\$ 142,367	\$ 97,088
Working capital . . . . .	21,722	31,041	39,924	133,238	87,938
Total assets . . . . .	35,567	48,705	76,521	149,357	99,170
Long-term debt . . . . .	—	3,728	10,653	—	—
Accumulated deficit . . . . .	(345,382)	(313,808)	(242,471)	(136,619)	(106,846)
Total stockholders' equity . . . . .	\$ 22,225	\$ 29,079	\$ 33,066	\$ 137,012	\$ 81,799

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

**Overview**

We are the maker of BiDil®, which is indicated for the treatment of heart failure in self-identified black patients as an adjunct to current standard therapies. BiDil is an orally administered fixed-dose combination of isosorbide dinitrate and hydralazine hydrochloride. The FDA approved BiDil in June 2005 and we commercially launched BiDil in July 2005. We are currently a party to an exclusive five-year manufacturing and supply agreement with Schwarz Pharma Manufacturing, Inc. for the three times daily immediate release dosage formulation of BiDil.

Since our inception, we have mainly funded our operations through the sale of equity securities, debt financings, license fees, research and development funding, milestone payments from our collaborative partners, and more recently, sales of BiDil. We have never been profitable and have incurred an accumulated deficit of \$345.4 million as of December 31, 2007.

Based upon our determination that the successful commercialization of BiDil requires a magnitude of resources that we cannot currently allocate to the program, as well as our plans to conserve cash in order to pursue the development of BiDil XR™, an extended release formulation of BiDil, in January 2008 we discontinued active promotional activities for BiDil. We concurrently implemented a restructuring plan that includes the elimination of approximately 75 positions by the end of February 2008, reducing headcount from approximately 90 to 15, with an additional reduction in headcount to approximately 10 positions anticipated by the end of April 2008. Although we have discontinued promotional activities related to BiDil, we intend to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels. In conjunction with implementing our January 2008 restructuring plan, we intend to evaluate and pursue strategic alternatives for our business, which may include the divestiture of our BiDil and BiDil XR business and/or our nitric oxide patent portfolio, a merger or consolidation with another company, or other comparable arrangements.

Our January 2008 restructuring follows the elimination of our discovery research program in March 2006 and the replacement of our sales force with a small team of senior cardiovascular business managers in October 2006. The January 2008 restructuring also follows our efforts in August 2007 to deploy an expanded field organization designed to focus on selected prescriber targets.

BiDil is an orally-administered medicine that is presently dosed three times daily. We are seeking to develop BiDil XR as a once-daily formulation. Based upon discussions with the FDA, we are pursuing bioequivalence and pharmacodynamic clinical trials comparing BiDil XR formulations to BiDil. In connection with our efforts to develop BiDil XR, in February 2007 we entered into a license agreement with Elan, pursuant to which Elan granted to us an exclusive worldwide royalty-bearing license to import, use, offer for sale and sell an oral capsule formulation incorporating specified

technology owned or controlled by Elan and containing, as its sole active combination of ingredients, the combination of the active drug substances isosorbide dinitrate and hydralazine hydrochloride, including BiDil XR. In consideration for the grant of the license, we have agreed to pay Elan royalties that are calculated by reference to annual net sales parameters set forth in the agreement. In addition, we have also agreed to pay Elan specified amounts upon the achievement of specified development and commercialization milestone events set forth in the agreement.

In the near-term, the key drivers of our success will be our ability to:

- maintain sales of BiDil following our January 2008 discontinuation of promotional activities related to BiDil;
- evaluate and pursue strategic alternatives for our business which may include the divestiture of our BiDil and BiDil XR business and/or our nitric oxide patent portfolio, a merger or consolidation with another company, or other comparable arrangements; and
- successfully advance the development of BiDil XR.

As a result of our restructurings in March and October 2006, our research, development and commercialization expenses declined by approximately \$4.8 million in 2007 as compared to 2006, due primarily to a decrease in employee headcount and research and commercialization activities, partially offset by an increase in ongoing development expenses related to BiDil XR.

We estimate that we will record charges related to our January 2008 restructuring of approximately \$2.7 million in the first half of 2008. As a result of our January 2008 restructuring, we estimate that our operating expenses related to research and development and sales, general and administrative functions, excluding restructuring charges, for the year ending December 31, 2008 will be approximately \$20 million to \$22 million, excluding cost of product sales but including share-based compensation expense.

At December 31, 2007, our principal source of liquidity was \$31.4 million of cash, cash equivalents and marketable securities. We believe that our existing sources of liquidity and the cash expected to be generated from future sales of BiDil, together with the significant reduction in expenditures as a result of our January 2008 restructuring, will be sufficient to fund our operations for at least the next twelve months. We expect to incur operating expenses going forward primarily related to our continued development of BiDil XR and to keeping BiDil available on the market. We expect to fund a substantial portion of our operating expenses through ongoing BiDil sales. However, the elimination of our sales force and discontinuation of our promotional activities for BiDil could result in a decline in BiDil prescriptions by healthcare providers and could also adversely affect third party payors' willingness to provide reimbursement at favorable levels. If physicians do not continue to prescribe BiDil in sufficient quantities, and/or if managed care providers remove BiDil from a preferential reimbursement tier on their plan formularies, then our future revenue from sales of BiDil will decline significantly, and we may not achieve sufficient working capital to fund our continued operations, including with respect to our planned development of BiDil XR. As we evaluate strategic options intended to maximize shareholder value for our company, we intend to execute on our business strategy of ceasing active promotional efforts for BiDil while devoting substantially all of our resources to supporting ongoing BiDil prescriptions and the continued development of BiDil XR. If we are unable to successfully consummate one or more strategic transactions relating to our business, we may not have sufficient capital to execute on our current business plan and could be required to further curtail or cease our operations.

### **Financial Operations Overview**

*Revenue.* Our first commercial product, BiDil, was launched in July 2005, and generated product sales of \$15.3 million for the year ended December 31, 2007. Prior to the launch of BiDil, all of our

revenue had been derived from license fees, research and development payments and milestone payments that we received from our corporate collaborators. We discontinued active promotion of BiDil in January 2008.

*Research and Development.* Research and development expense consists of expenses incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities and BiDil medical support costs.

The following summarizes our primary research and development programs during the years ended December 31, 2007, 2006 and 2005. In some cases, we have not provided program costs because prior to 2000 we did not track and accumulate cost information by research program.

- *BiDil.* From May 2001 to July 2004, we enrolled 1,050 patients at 169 clinical sites in the United States in our phase III clinical trial for BiDil. We halted the trial in July 2004 due to a significant survival benefit in the preliminary data for patients taking BiDil. The FDA approved BiDil on June 23, 2005, and we launched BiDil in July 2005. The total cost for the BiDil A-HeFT trial was approximately \$43.0 million.
- *BiDil XR.* The current formulation of BiDil is an immediate-release tablet that must be taken three times daily. We are currently pursuing the development of BiDil XR, an extended release formulation of BiDil, that could be taken once a day. To date, we have incurred approximately \$9.4 million in connection with the development of BiDil XR. Preliminary clinical studies of BiDil XR demonstrated proof of principle, and we commenced clinical development of BiDil XR in October 2006. We will need to conduct additional formulation studies and trials in order to finalize the formulation prior to the bioequivalence trials. We anticipate that we will finalize the BiDil XR formulation in 2009. Assuming that the BiDil XR formulation is successfully finalized, we anticipate initiating pivotal bioequivalence trials and then filing the new drug application in 2010 or 2011. Because of its stage of development, and the uncertainties inherent in pharmaceutical development generally, we may not be able to successfully develop and commercialize BiDil XR.
- *Nitric Oxide Stents.* We formerly had a research program with Boston Scientific Corporation, or Boston Scientific, to develop cardiovascular stents enhanced with a bio-compatible polymer that is capable of releasing nitric oxide. In accordance with the terms of our agreement with Boston Scientific, the research term expired in December 2005. We are not presently engaging in any internal research and development activities with respect to cardiovascular stents.
- *Other Discovery Research.* We have used our know-how and expertise in nitric oxide to develop drug candidates that are nitric oxide-enhancing versions of existing medicines in the areas of cardiovascular, gastrointestinal/anti-inflammatory and pulmonary medicine. These studies have not progressed beyond a discovery stage of testing, and it remains speculative whether the addition of nitric oxide will result in an improved clinical profile of these medicines. We are currently seeking out-licensing opportunities for these product candidates, and are not presently engaging in any internal research and development activities with respect to these drugs. We cannot be certain if we will be able to secure out-licensing arrangements for these product candidates on favorable terms, if at all. As such, we are not able to estimate when material cash inflows from product sales, milestones and royalties could commence, if ever.

*Sales, General and Administrative.* Sales, general and administrative expense consists primarily of salaries and other related costs for personnel in sales and marketing, executive, finance, investor relations, accounting, business development and human resource functions. Other costs include facility costs not otherwise included in research and development expense; costs for public relations,



advertising and promotion services; professional fees for legal and accounting services; and costs related to our former arrangements with a contract sales organization.

*Non-Operating Income.* Non-operating income includes interest earned on our cash, cash equivalents and marketable securities, and interest expense associated with our long-term debt.

## Results of Operations

### *Years Ended December 31, 2007, 2006 and 2005*

*Revenue.* Total revenue for the year ended December 31, 2007 was \$16.0 million, compared to \$12.1 million in 2006 and \$6.0 million in 2005.

Product sales for the year ended December 31, 2007 were \$15.3 million, compared to \$12.1 million in 2006 and \$4.5 million in 2005. The increase in product sales is due to increased shipments of BiDil as BiDil has continued to gain market acceptance. We commercially launched BiDil in July 2005.

Research and development revenues were \$0.8 million for the year ended December 31, 2007, compared to \$-0- for 2006 and \$1.6 million for 2005. The \$0.8 million, or 100%, increase in research and development revenues in 2007 compared to 2006 was due to our non-exclusive licensing of certain non-strategic intellectual property in October 2007 for which we have no continuing obligation. We had \$-0- research and development revenue in 2006 due to the termination of the research term under our collaboration agreement with Boston Scientific in December 2005. All such revenue related to this collaboration agreement had been fully recognized through December 2005.

*Cost of Product Sales.* Cost of product sales for the year ended December 31, 2007 was \$4.2 million, compared to \$3.6 million in 2006 and \$8.0 million in 2005. The \$0.6 million, or 19%, increase in cost of product sales in 2007 compared to 2006 is primarily due to a \$0.8 million increase in inventory impairment charges of \$2.3 million in 2007 compared to \$1.5 million in 2006. The \$4.4 million, or 56%, decrease in cost of product sales in 2006 compared with 2005 was primarily due to a decrease of \$5.6 million in inventory impairment charges related to commercial trade and patient sample inventory, and contractual purchase commitments. The charges were due to our current estimate of inventory requirements based on our sales forecast. Offsetting the decrease in inventory impairment charges were higher product costs and higher royalty costs due to increased sales.

*Research and Development.* Research and development expense for the year ended December 31, 2007 was \$12.2 million, compared to \$17.0 million in 2006 and \$31.3 million in 2005. The \$4.8 million, or 28%, decrease in research and development expenses in 2007 compared with 2006 was primarily the result of decreased clinical and medical expenses needed to support BiDil, a decrease in payroll and benefits due to our restructuring in March 2006, and decreases in the areas of continuing medical education, clinical advisory boards, medical services fees, publications, stock-based compensation expense, and other various contracted services totaling \$8.6 million. These decreases were offset by an increase of \$3.8 million related to the development of BiDil XR. The \$14.3 million, or 46%, decrease in research and development expenses in 2006 compared with 2005 was primarily the result of decreased clinical and medical expenses needed to support BiDil, a decrease in payroll and benefits due to our restructuring in March 2006, and decreases in the areas of continuing medical education, clinical advisory boards, medical services fees, publications and other various contracted services totaling \$16.6 million. These decreases were offset by increases in the amount of \$2.9 million for stock-based compensation expense related to the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or SFAS 123R, in January 2006.

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the fiscal years ended December 31, 2007, 2006 and 2005.

Research and Development Program	December 31,		
	2007	2006	2005
BiDil . . . . .	\$ 5,339,000	\$ 9,603,000	\$19,052,000
BiDil XR . . . . .	6,581,000	2,774,000	—
Nitric oxide-enhancing cardiovascular compounds . . . . .	—	2,568,000	6,073,000
Nitric oxide stents . . . . .	—	206,000	2,279,000
Other discovery research . . . . .	265,000	1,878,000	3,936,000
Total research and development expense . . . . .	<u>\$12,185,000</u>	<u>\$17,029,000</u>	<u>\$31,340,000</u>

*Sales, General and Administrative.* Sales, general and administrative expense for the year ended December 31, 2007 was \$31.4 million, compared to \$59.4 million in 2006 and \$74.6 million in 2005. The \$28.0 million, or 47%, decrease in sales, general and administrative expense in 2007 compared to 2006 was primarily due to the following decreases: \$17.3 million reduction for lower salary and benefit costs from the restructuring of our sales force in October 2006, offset by the hiring of a smaller, more experienced sales force in mid-2007; \$5.1 million reduction in advertising and promotional services and public relations; \$1.6 million reduction in rent expenses; \$1.4 million reduction in stock-based compensation expense; and \$1.4 million reduction in consulting expenses. The \$15.2 million, or 20%, decrease in sales, general and administrative expense in 2006 compared to 2005 was primarily due to a decrease of \$11.4 million related to the restructuring of our sales force and \$7.4 million for advertising and promotional services and public relations. These decreases were offset by an increase of \$5.1 million for stock-based compensation expense related to the adoption of SFAS 123R in January 2006.

*Restructurings.* In the first quarter of 2006, we recorded a restructuring charge of \$2.0 million related to a restructuring of our discovery research operations to better align costs with revenue and operating expectations. The restructuring charges pertained to employee severance and impairment of assets and were recorded in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS 146, and Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144. In connection with the restructuring, we terminated 30 employees in our discovery research group, or approximately 30% of our workforce, resulting in a charge of \$1.4 million. All employees were terminated as of March 31, 2006. As a result of terminating these employees, we recorded an impairment charge for certain research laboratory equipment, computer equipment, and furniture and fixtures aggregating \$0.6 million, for which the future use was uncertain. These assets were written down to their fair value utilizing a third party appraiser to estimate the fair value of the assets based on current market quotes and the current condition of the equipment, furniture and fixtures.

In the fourth quarter of 2006, we recorded a restructuring charge of \$3.2 million comprised of severance benefits of \$2.5 million and impairment charges of \$0.7 million for certain research and development equipment, leasehold improvements, furniture and fixtures, and computers. The restructuring charges were recorded in accordance with SFAS 146 and SFAS 144. This restructuring program included the elimination of 120 sales personnel and eight general and administrative and research and development personnel. These employees were terminated in October 2006, and no employee remained employed at December 31, 2006. Due to these actions, certain research and development equipment, leasehold improvements, furniture and fixtures and computers became impaired. These assets were written down to the fair value based on either a third-party quote, or the estimated discounted cash flows they would generate over the remaining economic life.

In the first quarter of 2007, we recorded a restructuring charge of \$1.0 million related to vacating our former headquarters location. The charge was recorded pursuant to SFAS 146. In March 2007, we entered into an Assignment of Lease and Assumption Agreement, which we refer to as the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, pursuant to which we assigned our lease for office and laboratory space located at 125 Spring Street in Lexington, Massachusetts, which we refer to as the Spring Street Lease. Pursuant to the terms of the Assignment Agreement, we agreed to pay Shire the amount of approximately \$1.2 million as consideration for Shire's assumption of the Spring Street Lease. In addition to this charge, we incurred \$0.6 million in expenses primarily related to real estate brokerage fees and clean-up costs. Offsetting these charges was a reversal of \$0.8 million in accrued rent related to the Spring Street Lease. All amounts were paid as of June 30, 2007.

**Stock-Based Compensation Expense.** We follow the fair value recognition provisions of SFAS 123R. Compensation cost recognized subsequent to December 31, 2005 includes: (a) compensation cost for all stock-based payments granted but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock Based Compensation*, or SFAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. Such amounts have been reduced by our estimate of forfeitures of all unvested awards. Results for prior periods have not been restated.

Prior to the adoption of SFAS 123R, we accounted for share-based payments to employees using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25.

As a result of adopting SFAS 123R on January 1, 2006, our net loss and net loss per share were \$5.0 million and \$0.12 for 2007 and \$8.0 million and \$0.22 for 2006, respectively; these amounts are higher than if we had continued to account for share-based compensation under APB 25. As of December 31, 2007, the total compensation cost related to unvested stock option awards to employees not yet recognized in the statement of operations was approximately \$6.2 million, which we will recognize over a weighted average period of 1.9 years. In addition, total compensation cost related to restricted stock awards as of December 31, 2007 is \$1.2 million, which will be recognized over 1.2 years.

**Non-Operating Income.** Non-operating income decreased to \$1.2 million in 2007 compared to \$1.9 million in 2006 and \$2.0 million in 2005. The \$0.7 million, or 36%, decrease in non-operating income in 2007 compared to 2006 was primarily related to a \$1.3 million decrease in interest income due to lower average investment balances, offset by \$0.7 million in lower interest expense associated with our debt because the principal balance due on the debt was lower in 2007. The \$0.1 million, or 9%, decrease in non-operating income in 2006 compared to 2005 was primarily related to \$0.4 million in higher interest expense associated with our debt, which was outstanding during the entire 2006 period compared to six months in 2005, offset by \$0.2 million in higher interest income.

### **Liquidity and Capital Resources**

Since our inception, we have primarily funded our operations through the sale of equity securities, debt financings, license fees, research and development funding, milestone payments from our collaborative partners and, more recently, sales of BiDil. As of December 31, 2007, we have received net proceeds of \$321.1 million from the issuance of equity securities, primarily as the result of:

- the sale of \$99.1 million of our redeemable convertible preferred stock;
- net proceeds of \$60.1 million from our initial public offering in November 2003;
- net proceeds of \$81.8 million from our follow-on public offering in December 2004;

- net proceeds of \$58.5 million from our registered direct offering in January 2006; and
- net proceeds of \$18.2 million from our registered direct offering in May 2007.

At December 31, 2007, we had \$31.4 million in cash, cash equivalents and marketable securities.

During the year ended December 31, 2007, operating activities used cash of \$23.5 million, primarily due to a net loss of \$31.6 million and an increase of \$0.6 million in accounts receivable, offset by a decrease in inventory of \$1.4 million and an increase in accounts payable of \$1.3 million. In addition, we had non-cash expenses of \$5.8 million in stock-based compensation expense and \$0.3 million in depreciation and amortization. Our use of cash decreased significantly in 2007 compared to our use of cash of \$72.4 million in 2006, driven by a net loss in 2006 of \$71.4 million and \$14.5 million for payments of accounts payable and accrued expenses; this is offset by reductions to accounts receivable of \$1.2 million and \$3.3 million of prepaid expenses and non-cash charges of \$10.0 million for depreciation expense, stock-based compensation expense and fixed asset impairment charges.

During the year ended December 31, 2007, investing activities used cash of \$1.1 million primarily due to net purchases of marketable securities of \$2.1 million and capital expenditures of \$0.2 million, offset by \$0.5 million in cash received on the disposal of fixed assets and \$0.6 million of restricted cash received by us due to the assignment of the Spring Street Lease. In 2006, investing activities provided cash of \$29.3 million, primarily due to sales and maturities of marketable securities to fund operations. We do not expect to invest significant amounts in capital expenditures during 2008.

During the year ended December 31, 2007, financing activities provided cash of \$11.7 million due to net proceeds of \$18.2 million from our registered direct offering, and \$0.4 million from the issuance of common stock under our employee stock plans, offset by \$6.9 million in principal payments on long-term debt. In 2006, financing activities provided cash of \$53.0 million due to net proceeds of \$58.5 million from our registered direct offering, and \$0.8 million from the issuance of common stock under our employee stock plans, offset by \$6.3 million in principal payments on long-term debt.

On June 28, 2005, we borrowed (i) \$10.0 million from Oxford Finance Corporation, or Oxford, and (ii) \$10.0 million from General Electric Capital Corporation, or GECC, pursuant to the terms of promissory notes made by us with both Oxford and GECC, respectively. The notes bear interest at a fixed rate of 9.95% per annum and are payable in 36 consecutive monthly installments of principal and accrued interest, beginning July 1, 2005. The notes are secured by a security interest in all our personal property and fixtures with the exception of any intellectual property or products acquired, whether by purchase, license or otherwise, on or after the execution of the notes. The agreements that we entered into with each of Oxford and GECC in connection with the notes also contain a material adverse change clause with both Oxford and GECC. Under this clause, if Oxford or GECC reasonably determine that our ability to repay the notes has been materially impaired, we would be considered in default. As of December 31, 2007, we were in compliance with this clause and \$3.7 million of principal remained outstanding and unpaid. We expect that the promissory notes will be fully paid by June 30, 2008.

At March 3, 2008, we held approximately \$7.6 million of investments with an auction reset feature, referred to as auction rate securities. Auction rate securities are securities that are structured to allow for short-term interest rate resets, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to 35 days, investors can sell or continue to hold the securities at par. During early February 2008, the majority of auction rate securities in the marketplace failed at auction due to sell orders exceeding buy orders. Such failures resulted in the interest rate on these investments resetting to predetermined rates within the underlying loan agreement, which might be higher or lower than the current market rate of interest. In the event we need to access our investments in these types of securities, we will not be able to do so until a

future auction of these investments is successful, the issuer redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature, which could be in as much as 30 years. In the future, should we experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments.

On February 28, 2008, we received a letter from the NASDAQ Stock Market's Listing Qualifications Department providing notification that, for the previous 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market under NASDAQ Marketplace Rule 4450(a)(5), referred to as the minimum bid price rule. NASDAQ stated in its notification that, in accordance with NASDAQ Marketplace Rule 4450(e)(2), we have 180 calendar days, or until August 26, 2008, to regain compliance with the minimum bid price rule. The NASDAQ notification also stated that if at any time before August 26, 2008, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, NASDAQ will provide written notification that we have achieved compliance with the minimum bid price rule, although NASDAQ may, in its discretion, require that we maintain a bid price of in excess of \$1.00 for a period in excess of 10 days, but generally no more than 20 days, before determining that we have demonstrated the ability to maintain long-term compliance.

If we do not regain compliance with the minimum bid price rule by August 26, 2008, NASDAQ will provide written notification that our securities will be delisted from The NASDAQ Stock Market. At that time, we may appeal NASDAQ's determination to delist our securities to a NASDAQ Listing Qualifications Panel. Alternatively, in the event such delisting is based solely upon non-compliance with the minimum bid price rule, we could apply to transfer our securities to The NASDAQ Capital Market, provided that we satisfy the requirements for initial listing on that market set forth in NASDAQ Marketplace Rule 4310(c), other than the minimum bid price rule. If such an application were approved and we otherwise maintain the listing requirements for The NASDAQ Capital Market, other than the minimum bid price requirement, we would be afforded the remainder of The NASDAQ Capital Market's second 180 calendar day grace period in order to regain compliance with the minimum bid price rule.

The following table summarizes our contractual obligations at December 31, 2007 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

#### Payments Due by Period

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less than one year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than five years</u>
Operating lease obligation . . . . .	\$2,697,000	\$ 510,000	\$1,139,000	\$1,048,000	\$ —
Long-term debt . . . . .	3,837,000	3,837,000	—	—	—
Purchase obligations(1) . . . . .	587,000	587,000	—	—	—
License milestones(2) . . . . .	—	—	—	—	—
Total contractual cash obligations . . . . .	<u>\$7,121,000</u>	<u>\$4,934,000</u>	<u>\$1,139,000</u>	<u>\$1,048,000</u>	<u>\$ —</u>

(1) In June and October of 2007, we placed binding purchase orders totaling \$486,000 with Schwarz Pharma for production of BiDil finished goods during the first quarter of 2008. In November 2007, we placed a binding purchase order for \$101,000 for the purchase of raw materials from Flavine International, Inc. for delivery during the second quarter of 2008.

- (2) On February 9, 2007, we entered into a License Agreement with Elan, pursuant to which we may be obligated to pay certain milestone payments in the aggregate amount of \$2,500,000, of which \$250,000 has been paid to date. We are uncertain as to the timing of any future payments, if any, pursuant to the terms of the License Agreement and accordingly no amounts are included in the above table.

In January 2008, we ceased actively promoting sales of BiDil, which is our only significant source of revenue. We intend to continue incurring costs related to supporting ongoing prescriptions for BiDil, and we also expect to incur additional expenses relating to the ongoing development of BiDil XR. We believe that our existing sources of liquidity and the cash expected to be generated from future sales of BiDil, together with the significant reduction in expenditures as a result of our January 2008 restructuring, will be sufficient to fund our operations for at least the next twelve months. However, our future capital requirements, and the period in which we expect our current cash to support our operations, may vary from what we expect due to a number of factors, including the following:

- the amount of future product sales of BiDil;
- the cost of manufacturing and selling BiDil;
- the timing of collections related to sales of BiDil;
- the time and costs involved in completing the clinical trials and further development of, and obtaining regulatory approvals for, BiDil XR, if at all;
- our ability to successfully consummate one or more strategic arrangements relating to our business and assets;
- the effect of competing technological and market developments;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; and
- the cost of maintaining licenses to use patented technologies.

Our business plan is to seek to divest all or substantially all of our business through a merger, asset sale, license, business combination or the like. However, if and for so long as we continue our current business and operations, we will require substantial additional funds, which we expect to generate through a combination of BiDil sales and one or more strategic transactions. We may not be able to successfully consummate a strategic transaction, and additional financing may not be available to us on acceptable terms, if at all.

If we are unable to obtain funding on a timely basis, whether through a strategic divestiture, financing or borrowing arrangements or other capital-raising transaction, we may not be able to support continued prescriptions for BiDil, we may be compelled to significantly curtail or delay our development efforts with respect to BiDil XR, and we could also be required to limit, scale back or cease our operations, any of which would have a material and adverse effect on our business, financial condition and results of operations.

#### **Application of Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue, inventory, accrued expenses and the factors used to determine the fair value of our stock options. We base our estimates on historical experience, known trends and events and

various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

**Revenue.** Our principal source of revenue is the sale of BiDil, which began shipping in July of 2005. Other sources of revenue to date include license fees, research and development payments and milestone payments that we have received from our corporate collaborators. We exercise significant judgment in determining the amount of revenue we can recognize in connection with sales of our products and with respect to our corporate collaborations. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition could change accordingly and any such change could affect our reported operating results.

*Product Sales/Deferred Revenue.* We follow the provisions of Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*, and recognize revenue from product sales upon delivery of product to wholesalers or pharmacies when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectibility of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, wholesaler allowances, rebates, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, we defer the recognition of revenue by recording deferred revenue until such time that risk of loss has passed. In addition, we evaluate our level of shipments to wholesalers and pharmacies on a quarterly basis compared to the estimated level of inventory in the channel, remaining shelf-life of the product shipped, weekly prescription data and quarterly forecasted sales. As a result of this evaluation, we deferred \$2.1 million of revenue on shipments in December 2005 and recorded this amount in deferred revenue as of December 31, 2005. During 2006, we reversed \$1.8 million of this deferred revenue and recognized the remainder as revenue.

*Sales Returns, Allowances, Rebates and Discounts.* Our product sales are subject to returns, wholesaler allowances, rebates and cash and contract discounts that are customary in the pharmaceutical industry. A large portion of our product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to patients, who are consumers of the product. We determine the provisions for sales returns, allowances, rebates and discounts based primarily on estimates and contractual terms.

*Product Returns.* Consistent with industry practice, we offer contractual return rights that allow customers to return product only during the period that is six months prior to, and twelve months after, product expiration. Commercial product shipped during 2005 and the first half of 2006 had a shelf-life of twelve months from date of manufacture with expiration dates ranging from April 2006 to May 2007. During the third quarter of 2006, we began shipping commercial product with an expiration date of 18 months. During the second quarter of 2007, we began shipping commercial product with an expiration date of 24 months. Factors that are considered in our estimate of future product returns include an analysis of the amount of product in the wholesaler and pharmacy channels, discussions with key wholesalers and other customers regarding inventory levels and shipment trends, review of consumer consumption data, and the remaining time to expiration of our product. As a result of this ongoing evaluation, our product return reserve was \$0.9 million and \$1.3 million at December 31, 2007 and 2006, respectively. For the years ended December 31, 2007, 2006 and 2005, we recorded a reduction to revenue for product returns of \$1.0 million, \$2.6 million and \$0.1 million, respectively. The return rate and related reserve are evaluated on a quarterly basis, assessing each of the factors described above, and adjusted accordingly. In developing a reasonable estimate for the reserve for

product returns, we consider the factors in paragraph 8 of Statement of Financial Accounting Standards No. 48, *Revenue Recognition When a Right of Return Exists*. Based on the factors noted above, we believe our estimate of product returns is reasonable, and changes, if any, from this estimate would not have a material impact to our financial statements. During the first quarter of 2008, BiDil's shelf life was increased to 36 months and product bottled by our manufacturer in the first quarter of 2008 will have a 36 month shelf life.

**Sample Voucher and Co-Pay Card Program.** Beginning in the third quarter of 2005, we initiated a sample voucher program whereby we offered an incentive to patients in the form of a free 30-day trial, or approximately 100 tablets, of BiDil. We have accounted for this program in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer*, or EITF No. 01-09. Initially, these sample programs had quarterly expiration dates such that each sample voucher program was only active for one quarter at a time. As a result, at the end of each quarter we could determine the actual amount of reimbursement claims received for the vouchers distributed during the quarter. The amount of reimbursement is recorded as a reduction to revenue. During the third quarter 2006, we initiated a six month co-pay program whereby we cover the co-pay for eligible insured patients for their BiDil prescriptions, including refills. As a result of these programs, we recorded a reduction to revenue of \$0.1 million, \$0.5 million and \$0.8 million for the years ended December 31, 2007, 2006 and 2005, respectively.

**Sales Discounts, Rebates and Allowances.** Sales discounts, rebates and allowances result primarily from sales under contract with healthcare providers, wholesalers, Medicare and Medicaid programs and other governmental agencies. We estimate rebates and contractual allowances, cash and contract discounts and other rebates by considering the following factors: current contract prices and terms, sales volume, estimated customer and wholesaler inventory levels and current average rebate rates. For the years ended December 31, 2007, 2006, and 2005, we recorded cash discounts, rebates and other allowances of \$5.3 million, \$1.5 million and \$0.5 million, respectively.

**License and Collaboration Revenue.** We record collaboration revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues received in advance of performance obligations, or in cases where we have a continuing obligation to perform services, are deferred and recognized over the contractual or estimated performance period. Revenues from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved. Contract revenues are recorded as the services are performed. When we are required to defer revenue, the period over which such revenue should be recognized is subject to estimates by management and may change over the course of the collaborative agreement.

**Inventory.** We review our estimates of the net realizable value of our inventory at each reporting period. Our estimate of the net realizable value of inventory is subject to judgment and estimation. The actual net realizable value could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. On a quarterly basis, we analyze our current inventory levels and future irrevocable inventory purchase commitments and write down inventory that has become un-saleable, inventory that has a cost basis in excess of its expected net realizable value and irrevocable inventory purchase commitments that are in excess of expected future inventory requirements based on our sales forecasts. For the year ended December 31, 2007, we recorded inventory impairment charges of \$2.3 million to cost of sales related to commercial trade, patient sample inventory and excess raw materials. For the year ended December 31, 2006, we recorded inventory impairment charges of \$1.5 million to cost of sales related to commercial trade and patient sample inventory, and for contractual purchase commitments in excess of our sales forecast. For the year ended December 31, 2005, we recorded inventory impairment charges of \$7.1 million to cost of sales related to commercial trade and patient sample inventory, and for contractual purchase commitments in excess of our sales forecast.



**Accrued Expenses.** As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include fees such as amounts owed for clinical trials, sales and marketing data management, product development, contract manufacturers for the production of finished goods, marketing and medical support, such as advisory boards, and publications, marketing services and professional services, such as lawyers and accountants. In connection with such services, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we over- or under-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

**Stock-Based Compensation.** Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123R to recognize compensation cost associated with stock options issued to employees. Determining the amount of stock-based compensation expense to be recorded requires us to develop estimates to be used in calculating the grant-date fair value of a stock option. The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires us to make estimates for volatility, risk-free interest rate, expected term, and expected dividend yield. Volatility is determined exclusively using historical volatility data of our common stock based on the period of time since our common stock has been publicly traded. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of stock options granted is based exclusively on historical data and represents the weighted average period of time that stock options granted are expected to be outstanding. The expected life is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior amongst our employee population.

Accounting for equity instruments granted or sold by us under APB 25, SFAS 123 and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, requires fair value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over or under stated. For equity instruments granted or sold in exchange for the receipt of goods or services, we estimate the fair value of the equity instruments based upon consideration of factors which we deem to be relevant at that time. Because shares of our common stock were not publicly traded prior to the commencement of our public offering on November 5, 2003, market factors historically considered in valuing stock and stock option grants include comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing, pricing of private sales of our redeemable convertible preferred stock, prior valuations of stock grants and the effect of events that have occurred between the time of such grants, economic trends, and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

Prior to our initial public offering, the fair value of our common stock was determined by our board of directors contemporaneously with the grant. In the absence of a public trading market for our common stock, our board of directors considered numerous objective and subjective factors in determining the fair value of our common stock. At the time of option grants and other stock issuances, our board of directors considered the liquidation preferences, dividend rights, voting control and anti-dilution protection attributable to our then-outstanding redeemable convertible preferred stock, the status of private and public financial markets, valuations of comparable private and public companies, the likelihood of achieving a liquidity event such as an initial public offering, our existing financial resources, our anticipated continuing operating losses and increased spending levels required to complete our clinical trials, dilution to common stockholders from anticipated future financings and a general assessment of future business risks.

### **Inflation**

We believe the effects of inflation generally do not have a material adverse impact on our operations or financial condition.

### **Off-Balance Sheet Arrangements**

We do not have any material off-balance sheet arrangements.

### **Recently Issued Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those years. We do not currently believe that adoption will have a material impact on our results of operations, financial position or cash flows.

In February 2007, FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for us beginning on January 1, 2008. We do not currently believe that adoption will have a material impact on our results of operations, financial position or cash flows.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for us beginning on January 1, 2008. We do not currently believe that adoption will have a material impact on our results of operations, financial position or cash flows.

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

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of U.S. money market and high-grade corporate and U.S. government-related securities, directly or through managed funds, with maturities of two years or less. In addition, we hold auction rate securities that reset monthly, although the legal maturities of these securities at December 31, 2007 range from 2008 to 2045. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at December 31, 2007 or December 31, 2006, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We have the ability to hold our fixed income investments until maturity, and therefore we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including U.S. government agencies, municipal notes which may have an auction reset feature, corporate notes and bonds, commercial paper, and money market funds. These securities are classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We do not utilize derivative financial instruments to manage our interest rate risks.

At March 3, 2008, we held approximately \$7.6 million of investments with an auction reset feature, referred to as auction rate securities. These auctions have historically provided a liquid market for these securities. In February 2008, the majority of auction rate securities in the marketplace failed at auction due to sell orders exceeding buy orders. Our ability to liquidate our auction rate securities and fully recover the carrying value of our auction rate securities in the near term may be limited or not exist, and we may in the future be required to record an impairment charge on these investments. The vast majority of our auction rate securities, including those that have failed, were rated AAA at the time of purchase. We believe we will be able to liquidate our investments without significant loss within the next year, and we currently believe these securities are not significantly impaired, primarily due to the credit worthiness of the issuers of the underlying securities. However, it could take until the final maturity of the underlying notes (up to 30 years) to realize our investments' recorded value.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
NitroMed, Inc.

We have audited the accompanying balance sheets of NitroMed, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended 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 financial statements referred to above present fairly, in all material respects, the financial position of NitroMed, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 of the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (R), *Share-Based Payment*, using the modified-prospective transition method.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NitroMed, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2008, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 4, 2008

**NITROMED, INC.**  
**BALANCE SHEETS**

(in thousands, except par value amounts)

	December 31,	
	2007	2006
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents .....	\$ 8,167	\$ 21,074
Marketable securities .....	23,233	21,079
Accounts receivable .....	1,929	1,370
Inventories .....	1,401	2,846
Prepaid expenses and other current assets .....	334	570
Total current assets .....	35,064	46,939
Property and equipment, net .....	312	963
Restricted cash .....	191	803
Total assets .....	\$ 35,567	\$ 48,705
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable .....	\$ 3,235	\$ 1,923
Accrued expenses .....	6,379	6,545
Accrued restructuring .....	—	299
Deferred revenue .....	—	206
Current portion of long-term debt .....	3,728	6,925
Total current liabilities .....	13,342	15,898
Long-term debt .....	—	3,728
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; 5,000 shares authorized; no shares issued or outstanding .....	—	—
Common stock, \$0.01 par value; 65,000 shares authorized; 45,381 shares and 37,181 shares issued and outstanding as of December 31, 2007 and 2006, respectively .....	454	372
Additional paid-in capital .....	367,125	342,528
Accumulated deficit .....	(345,382)	(313,808)
Accumulated other comprehensive income (loss) .....	28	(13)
Total stockholders' equity .....	22,225	29,079
Total liabilities and stockholders' equity .....	\$ 35,567	\$ 48,705

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

**NITROMED, INC.**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Year Ended December 31,		
	2007	2006	2005
Revenues:			
Product sales . . . . .	\$ 15,269	\$ 12,086	\$ 4,455
License and collaboration . . . . .	750	—	1,592
Total revenues . . . . .	<u>16,019</u>	<u>12,086</u>	<u>6,047</u>
Cost and operating expenses:			
Cost of product sales . . . . .	4,236	3,560	8,009
Research and development(1) . . . . .	12,185	17,029	31,340
Sales, general and administrative(1) . . . . .	31,358	59,403	74,596
Restructuring charges . . . . .	1,004	5,283	—
Total cost and operating expenses . . . . .	<u>48,783</u>	<u>85,275</u>	<u>113,945</u>
Loss from operations . . . . .	(32,764)	(73,189)	(107,898)
Non-operating income:			
Interest income . . . . .	1,884	3,204	2,976
Interest expense . . . . .	(694)	(1,352)	(930)
	<u>1,190</u>	<u>1,852</u>	<u>2,046</u>
Net loss . . . . .	<u>(31,574)</u>	<u>(71,337)</u>	<u>(105,852)</u>
Basic and diluted net loss per share . . . . .	<u>\$ (0.75)</u>	<u>\$ (1.96)</u>	<u>\$ (3.49)</u>
Shares used in computing basic and diluted net loss per share . . . . .	<u>41,997</u>	<u>36,399</u>	<u>30,355</u>

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

Research and development . . . . .	\$ 2,005	\$ 2,795	\$ 298
Sales, general and administrative . . . . .	\$ 3,763	\$ 5,119	\$ 195

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

**NITROMED, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands)

	Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Par Value					
Balance at December 31, 2004	30,124	\$301	\$275,727	\$(2,095)	\$(136,619)	\$(302)	\$ 137,012
Exercise of stock options	339	3	653				656
Exercise of stock purchase warrants	12	—	1				1
Amortization of deferred stock compensation				887			887
Reversal of compensation expense associated with options issued to non-employees and performance options issued to employees			(394)				(394)
Issuance of stock under employee stock purchase plan	37	1	523				524
Unrealized gains on marketable securities						232	232
Net loss					(105,852)		(105,852)
Comprehensive loss							(105,620)
Balance at December 31, 2005	30,512	\$305	\$276,510	\$(1,208)	\$(242,471)	\$(70)	\$ 33,066

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



**NITROMED, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**

(in thousands)

	Common Stock Shares	Par Value	Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2005	30,512	\$305	\$276,510	\$(1,208)	\$(242,471)	\$(70)	\$ 33,066
Elimination of deferred stock compensation in accordance with the adoption of SFAS 123R			(1,208)	1,208			—
Exercise of stock options	461	5	688				693
Compensation expense associated with options issued to employees			8,042				8,042
Reversal of compensation expense associated with options issued to non-employees			(239)				(239)
Issuance of stock under employee stock purchase plan	32	—	93				93
Issuance of stock in connection with employee benefit plan	78	1	198				199
Sale of common stock in public offering (net of issuance costs of \$4,056)	6,098	61	58,444			57	58,505
Unrealized gains on marketable securities					(71,337)		57
Net loss							(71,337)
Comprehensive loss							(71,280)
Balance at December 31, 2006	37,181	\$372	\$342,528	\$ —	\$(313,808)	\$(13)	\$ 29,079

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

**NITROMED, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2006	37,181	\$372	\$342,528	\$(313,808)	\$(13)	\$ 29,079
Exercise of stock options	273	3	309			312
Compensation expense associated with options issued to employees			4,993			4,993
Reversal of compensation expense associated with options issued to non-employees			(26)			(26)
Issuance of stock under employee stock purchase plan	74	1	78			79
Issuance of stock in connection with employee benefit plan	87	1	279			280
Issuance of common stock and related stock compensation expense in connection with restricted stock plan	166	1	800			801
Sale of common stock in public offering (net of issuance costs of \$1,485)	7,600	76	18,164			18,240
Unrealized gains on marketable securities					41	41
Net loss				(31,574)		(31,574)
Comprehensive loss						
Balance at December 31, 2007	45,381	\$454	\$367,125	\$(345,382)	\$ 28	\$ 22,225

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

**NITROMED, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2007	2006	2005
Cash flows from operating activities:			
Net loss	\$(31,574)	\$ (71,337)	\$(105,852)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	285	798	896
Stock-based compensation expense	5,768	7,914	493
Non-cash restructuring charges	—	1,342	—
Changes in operating assets and liabilities:			
Accounts receivable	(559)	1,236	(4,078)
Inventories	1,445	401	(3,247)
Prepaid expenses and other current assets	236	3,290	(644)
Accounts payable	1,312	(9,887)	9,148
Accrued expenses	114	(4,636)	3,178
Accrued restructuring charge	(299)	299	—
Deferred revenue	(206)	(1,773)	1,859
Net cash used in operating activities	<u>(23,478)</u>	<u>(72,353)</u>	<u>(98,247)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(162)	(111)	(925)
Proceeds from sale of equipment	528	—	—
Purchases of marketable securities	(69,020)	(150,092)	(126,159)
Sales of marketable securities	66,907	179,520	182,426
Restricted cash	612	—	8
Net cash (used in) provided by investing activities	<u>(1,135)</u>	<u>29,317</u>	<u>55,350</u>
Cash flows from financing activities:			
Proceeds from sale of common stock	18,240	58,505	—
Proceeds from long-term debt	—	—	20,000
Principal payments on long-term debt	(6,925)	(6,272)	(3,075)
Proceeds from employee stock plans	391	786	1,181
Net cash provided by financing activities	<u>11,706</u>	<u>53,019</u>	<u>18,106</u>
Net (decrease) increase in cash and cash equivalents	(12,907)	9,983	(24,791)
Cash and cash equivalents, beginning balance	21,074	11,091	35,882
Cash and cash equivalents, ending balance	<u>\$ 8,167</u>	<u>\$ 21,074</u>	<u>\$ 11,091</u>
Supplemental disclosure:			
Cash paid during the year for interest	<u>\$ 751</u>	<u>\$ 1,403</u>	<u>\$ 790</u>

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

## NITROMED, INC.

### NOTES TO FINANCIAL STATEMENTS

(all tabular amounts in thousands except per share amounts)

#### 1. The Company

NitroMed, Inc. (the "Company") is the maker of BiDil®. Since its inception, the Company has funded its operations mainly through the sale of equity securities, debt financings, license fees, research and development funding, milestone payments from its collaborative partners, and more recently, sales of BiDil. In June 2005, the U.S. Food and Drug Administration ("FDA") approved the Company's product, BiDil, for the treatment of heart failure in self-identified black patients as an adjunct to current standard therapies. BiDil is an orally administered fixed-dose combination of isosorbide dinitrate and hydralazine hydrochloride. The Company commercially launched BiDil in July 2005, and has since generated approximately \$31.8 million in product sales, including product sales of \$4.2 million during the fourth quarter of 2007, and total product sales of \$15.3 million during the year ended December 31, 2007.

Based upon the Company's determination that the successful commercialization of BiDil requires a magnitude of resources that it cannot currently allocate to the program, as well as the Company's plans to conserve cash in order to pursue the development of an extended release formulation of BiDil, known as BiDil XR™, in January 2008 the Company discontinued active promotional activities for BiDil. The Company concurrently implemented a restructuring plan in which the Company significantly reduced its workforce immediately. The Company is evaluating strategic alternatives to divest its current business in whole or in part in an effort to maximize the value of its commercial organization and product development programs for its shareholders. The Company has engaged an investment bank to advise it in considering these potential strategic alternatives, which may include the sale, license or divestiture of certain of its assets, including its BiDil business, the assets relating to BiDil XR, and/or its nitric oxide technologies, the sale or merger of the Company, or other similar strategic transactions.

The Company's business plan is to seek to divest all or substantially all of its business through a merger, asset sale, license, business combination or the like. Although the Company has discontinued promotional activities related to BiDil, the Company intends to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels. The Company also expects to incur additional expenses related to the ongoing development of BiDil XR. If and for so long as the Company continues its current business and operations, the Company will require substantial additional funds, which it expects to generate through a combination of BiDil sales and one or more strategic transactions. The Company may not be able to successfully consummate a strategic transaction, and additional financing may not be available to the Company on acceptable terms, if at all. If the Company is unable to obtain funding on a timely basis, whether through a strategic divestiture, financing or borrowing arrangements or other capital-raising transaction, the Company may not be able to support continued prescriptions for BiDil, may be compelled to significantly curtail or delay its development efforts with respect to BiDil XR, and the Company could also be required to limit, scale back or cease its operations. Currently, the Company believes that its existing sources of liquidity and the cash expected to be generated from future sales of BiDil, together with the significant reduction in expenditures as a result of its January 2008 restructuring, will be sufficient to fund the Company's operations for at least the next twelve months.

## NITROMED, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

(all tabular amounts in thousands except per share amounts)

#### 2. Summary of Significant Accounting Policies

##### Cash Equivalents and Marketable Securities

Cash equivalents are short-term, highly liquid investments with maturities of three months or less at the time of acquisition. Investments with maturities in excess of three months at the time of acquisition are classified as marketable securities and designated as available-for-sale. Cash equivalents consist of institutional money market funds. Available-for-sale securities are carried at fair market value, as reported by the custodian, and unrealized gains and losses are reported as a separate component of accumulated other comprehensive income (loss) within stockholders' equity. Realized gains and losses were not material for the years ended December 31, 2007, 2006 and 2005.

##### Fair Value of Financial Instruments

Financial instruments mainly consist of cash, cash equivalents, marketable securities and the current portion of long-term debt. The carrying amounts of cash, cash equivalents, and marketable securities approximate their fair values. The fair value of long-term debt approximates its carrying value due to its remaining term to maturity.

##### Research and Development Expenses

Research and development expenses primarily consist of salaries and related expenses for research and development personnel, fees paid to consultants and outside service providers, materials used in clinical trials and research and development, and medical support costs related to the launch and commercialization of BiDil. The Company charges research and development expenses, including costs associated with acquiring patents, to operations as incurred.

The Company enters into contracts with professional service providers to conduct clinical trials and related services. These professional service providers render services over an extended period of time, generally one to three years. Typically, the Company enters into two types of vendor contracts, patient-based or time-based. Under a patient-based contract, the Company first determines an appropriate per patient cost using critical factors contained within the contract, which include the estimated number of patients, the cost assigned to each patient based on a patient's number of visits and the total dollar value of the contract. The Company then records the expense based upon the total number of patients enrolled during the period and the status of each patient. Under a time-based contract, using critical factors contained within the contract such as the stated duration of the contract and the timing of services provided, the Company records the contractual expense for each service provided ratably over the period during which the Company estimates the service will be performed. On a monthly basis, the Company reviews both the timetable of services to be rendered and the timing of services actually received based on regular communications with its vendors in order to evaluate the reasonableness of its estimates. Based upon this review, revisions may be made to the forecasted timetable or the extent of services performed, or both, in order to reflect the Company's most current estimate of the contract.

##### Revenue Recognition

The Company's principal source of revenue is the sale of BiDil, which began shipping in July of 2005. Other sources of revenue to date include license fees, research and development payments and milestone payments that the Company has received from its corporate collaborators.

NITROMED, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

*Product Sales/Deferred Revenue.* The Company follows the provisions of Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*, and recognizes revenue from product sales upon delivery of product to wholesalers or pharmacies when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler or pharmacy and collectibility of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, wholesaler allowances, rebates, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, the Company defers the recognition of revenue by recording deferred revenue until such time that risk of loss has passed. In addition, the Company evaluates its level of shipments to wholesalers and pharmacies on a quarterly basis compared to the estimated level of inventory in the channel, remaining shelf-life of the product shipped, weekly prescription data and quarterly forecasted sales. As a result of this evaluation, the Company deferred \$2.1 million of revenue from shipments in December 2005 and recorded this amount in deferred revenue as of December 31, 2005. During 2006, the Company reversed \$1.8 million of this deferred revenue and recognized the remainder as revenue.

*Sales Returns, Allowances, Rebates and Discounts.* The Company's product sales are subject to returns, wholesaler allowances, rebates and cash and contract discounts that are customary in the pharmaceutical industry. A large portion of the Company's product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to patients, who are consumers of the product. The Company determines the provisions for sales returns, allowances, rebates and discounts based primarily on historical experience, known trends and events, and contractual terms.

*Product Returns.* Consistent with industry practice, the Company offers contractual return rights that allow customers to return product only during the period that is six months prior to, and twelve months after, product expiration. Commercial product shipped during 2005 and the first half of 2006 had a shelf-life of twelve months from date of manufacture with expiration dates ranging from April 2006 to May 2007. During the third quarter of 2006, the Company began shipping commercial product with an expiration date of 18 months. During the second quarter of 2007, the Company began shipping commercial product with an expiration date of 24 months. Factors that are considered in the Company's estimate of future product returns include an analysis of the amount of product in the wholesaler and pharmacy channels, discussions with key wholesalers and other customers regarding inventory levels and shipment trends, review of consumer consumption data, and the remaining time to expiration of the Company's product. As a result of this ongoing evaluation, the Company's product return reserve was \$0.9 million and \$1.3 million for the years ended December 31, 2007 and 2006, respectively. For the years ended December 31, 2007, 2006 and 2005, the Company recorded a reduction to revenue for product returns of \$1.0 million, \$2.6 million and \$0.1 million, respectively. This return rate and related reserve are evaluated on a quarterly basis, assessing each of the factors described above, and adjusted accordingly. In developing a reasonable estimate for the reserve for product returns, the Company considers the factors in paragraph 8 of Statement of Financial Accounting Standards No. 48, *Revenue Recognition When a Right of Return Exists*. Based on the factors noted above, the Company believes its estimate of product returns is reasonable, and changes, if any, from this estimate would not have a material impact to the Company's financial statements. During the

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**2. Summary of Significant Accounting Policies (Continued)**

first quarter of 2008, BiDil's shelf life was increased to 36 months and product bottled by the Company's manufacturer in the first quarter of 2008 will have a 36 month shelf life.

*Sample Voucher and Co-Pay Card Program.* Beginning in the third quarter of 2005, the Company initiated a sample voucher program whereby the Company offered an incentive to patients in the form of a free 30-day trial of BiDil. The Company accounts for this program in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* ("EITF No. 01-09"). Initially, these sample programs had quarterly expiration dates such that each sample voucher program was only active for one quarter at a time. As a result, at the end of each quarter the Company could determine the actual amount of reimbursement claims received for the vouchers distributed during the quarter. The amount of reimbursement is recorded as a reduction to revenue. During the third quarter of 2006, the Company initiated a six month co-pay program whereby the Company covers the co-pay for eligible insured patients for their BiDil prescriptions, including refills. As a result of these programs, the Company recorded a reduction to revenue of \$0.1 million, \$0.5 million and \$0.8 million for the years ended December 31, 2007, 2006 and 2005, respectively.

*Sales Discounts, Rebates and Allowances.* Sales discounts, rebates and allowances result primarily from sales under contract with healthcare providers, wholesalers, Medicare and Medicaid programs and other governmental agencies. The Company estimates rebates and contractual allowances, cash and contract discounts and other rebates by considering the following factors: current contract prices and terms, sales volume, and current actual average rebate rates. For the years ended December 31, 2007, 2006 and 2005, the Company recorded rebates, cash discounts, and other allowances of \$5.3 million, \$1.5 million and \$0.5 million, respectively.

*License and Collaboration Revenue.* The Company records collaboration revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues received in advance of performance obligations, or in cases where the Company has a continuing obligation to perform services, are deferred and recognized over the contractual or estimated performance period. Revenues from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved. Contract revenues are recorded as the services are performed. When the Company is required to defer revenue, the period over which such revenue should be recognized is subject to estimates by management and may change over the course of the collaborative agreement. In October 2007, the Company entered into a License Agreement pursuant to which the Company granted the licensee a non-exclusive license under certain non-strategic patent rights owned and/or licensed by the Company. In consideration of this license, the licensee paid the Company an upfront fee of \$750,000, which the Company recognized as revenue in the fourth quarter of 2007 because the Company had no remaining deliverable at December 31, 2007.

**Accounts Receivable**

Accounts receivable consist of amounts due from wholesalers and pharmacies for the purchase of BiDil. Ongoing evaluations of customer payment histories are performed and collateral is generally not required. As of December 31, 2007, the Company has not reserved any amount for bad debts related to the sale of BiDil. The Company continuously reviews all customer accounts to determine if an allowance for uncollectible accounts is necessary. The Company currently provides substantially all of

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

its customers with payment terms of net 30 days. Through December 31, 2007, payments have generally been made in a timely manner.

**Property and Equipment**

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives, which range between three to five years. Leasehold improvements are amortized based upon the lesser of the term of the lease or the useful life of the asset. The Company reviews its property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable and recognizes an impairment loss when the estimated undiscounted cash flows are less than the carrying value of the asset. The asset is written down to its fair value, determined by either a quoted market price or by a discounted cash flow technique, whichever is more appropriate under the circumstances. During 2006, the Company recorded impairment charges of \$1.3 million (See Note 6). There were no impairment charges recorded during 2007. Property and equipment consist of the following:

	December 31,	
	2007	2006
Laboratory furniture, fixtures and equipment . . . . .	\$ 362	\$ 2,343
Office furniture, fixtures and equipment . . . . .	162	903
Leasehold improvements . . . . .	—	221
	524	3,467
Less accumulated depreciation and amortization . . . . .	(212)	(2,504)
Total . . . . .	\$ 312	\$ 963

In February 2007, the Company sold certain equipment previously used in research and development activities and received proceeds in the amount of \$528,000, which approximated the equipment's net book value.

**Inventories**

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventories consisted of the following:

	December 31,	
	2007	2006
Raw materials . . . . .	\$ 349	\$2,123
Finished goods . . . . .	1,052	723
Total . . . . .	\$1,401	\$2,846

On a quarterly basis, the Company analyzes its current inventory levels and writes down inventory that has become un-saleable or has a cost basis in excess of its expected net realizable value. In addition, the Company evaluates its future irrevocable inventory purchase commitments compared to forecasted product sales, the current level of inventory, and its related product dating. For the year



**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

ended December 31, 2007, the Company recorded inventory impairment charges of \$2.3 million to cost of sales for excess quantities comprised of commercial trade, patient sample inventory product and raw materials. For the year ended December 31, 2006, the Company recorded inventory impairment charges of \$1.5 million to cost of sales comprised of \$1.1 million for commercial trade and patient sample inventory product, and \$0.4 million for contractual purchase commitments in excess of expected future inventory requirements based on the Company's sales forecast. For the year ended December 31, 2005, the Company recorded an inventory impairment charge of \$5.6 million to cost of sales related to commercial trade and patient sample inventory product, and a \$1.5 million charge to cost of sales for contractual purchase commitments in excess of expected future inventory requirements based on the Company's sales forecast.

**Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options and restricted stock. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share is the same. Options to purchase 4,747,755, 4,935,930 and 3,819,676 shares of common stock for the years ended December 31, 2007, 2006 and 2005, respectively, have been excluded from the computation of diluted net loss per share as their effects would have been antidilutive. In addition, 451,778 shares of restricted stock issued and outstanding as of December 31, 2007 are also not included.

**Concentration of Credit Risk**

Statement of Financial Accounting Standards No. 105, *Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk*, requires disclosure of any significant off-balance-sheet and credit risk concentrations. Financial instruments that potentially subject the Company to concentration of credit risk consist principally of marketable securities and accounts receivable. The Company has no off-balance-sheet or concentrations of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company maintains its cash, cash equivalents and marketable securities balances with several high credit quality financial institutions.

The following table summarizes the number of trade customers that individually comprise greater than 10% of product revenues and their respective percentage of the Company's total product revenues on a gross basis:

Year ended:	Number of Significant Customers	Percentage of Total Product Revenues by Customer		
		A	B	C
December 31, 2007	3	38%	36%	17%
December 31, 2006	3	34%	36%	18%
December 31, 2005	3	44%	21%	14%

**NITROMED, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

The table above excludes revenues from license and collaboration agreements. The Company recognized revenue in 2007 and 2005 from two different collaborative partners.

The following table summarizes the number of customers that individually comprise greater than 10% of total accounts receivable and their respective percentage of the Company's total accounts receivable:

As of:	Number of Significant Customers	Percentage of Total Accounts Receivables by Customer		
		A	B	C
December 31, 2007.....	3	38%	34%	17%
December 31, 2006.....	3	37%	30%	16%

**Concentration of Other Risks**

The Company currently obtains one of the key active pharmaceutical ingredients for its commercial requirements for BiDil from a single source. The Company also utilizes one manufacturer to produce BiDil. The disruption or termination of the contract with the manufacturer of BiDil or of the supply of the commercial requirement for BiDil or a significant increase in the cost of the key active pharmaceutical ingredient from this single source could have a material adverse effect on the Company's business, financial position and results of operations.

**Advertising Costs**

All advertising costs are expensed as incurred. Advertising expenses were \$7.7 million, \$12.8 million and \$20.1 million for the years ended December 31, 2007, 2006 and 2005, respectively.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Such estimates relate to product returns rates, contract rebates, the net realizable value of inventory, useful lives of fixed assets, accrued liabilities, and stock-based compensation. Actual results could differ from those estimates, and such differences may be material to the financial statements.

**Accumulated Other Comprehensive Income (Loss)**

The Company presents comprehensive income (loss) in accordance with Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income*. Accumulated other comprehensive income (loss) is comprised entirely of unrealized gains and losses on available-for-sale marketable securities.

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

**Income Taxes**

Deferred tax assets and liabilities are determined based on differences between the financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards and tax credits, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

**Segment Information**

During the three years ended December 31, 2007, 2006 and 2005, the Company operated in one reportable business segment, developing nitric oxide-enhancing medicines, under the management approach of Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

**Stock-Based Compensation**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment* ("SFAS 123R"), using the modified prospective transition method as permitted under SFAS 123R. Under this transition method, compensation cost recognized for the years ending December 31, 2007 and 2006 is comprised of: (a) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock Based Compensation* ("SFAS 123"), and (b) compensation cost for all share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. In accordance with the modified prospective method of adoption, the Company's results of operations and financial position for prior periods has not been restated.

See Note 7 for additional information relating to stock-based compensation.

**New Accounting Standards**

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those years. The Company does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In February 2007, FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**2. Summary of Significant Accounting Policies (Continued)**

provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for the Company beginning on January 1, 2008. The Company does not believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In June 2007, the Emerging Issues Task Force issued EITF Issue 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF No. 07-03"). EITF No. 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF No. 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF No. 07-03 is effective for the Company beginning on January 1, 2008. The Company does not expect the adoption of EITF No. 07-03 to have a material impact on its results of operations, financial position or cash flows.

**3. Cash Equivalents and Marketable Securities**

The following is a summary of the fair market value of available-for-sale money market funds and marketable securities the Company held at December 31, 2007 and 2006:

<u>December 31, 2007</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash and money market funds .....	\$ 8,167	\$ —	\$ —	\$ 8,167
U.S. Government agencies				
Due in one year or less .....	799	—	(3)	796
Taxable auction securities .....	9,575	—	—	9,575
Tax-free auction securities .....	700	—	—	700
Corporate securities				
Due in one year or less .....	9,897	28	(1)	9,924
Due in one to three years .....	2,234	4	—	2,238
Total marketable securities .....	<u>\$23,205</u>	<u>\$ 32</u>	<u>\$ (4)</u>	<u>\$23,233</u>

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**3. Cash Equivalents and Marketable Securities (Continued)**

<u>December 31, 2006</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash and money market funds .....	\$21,074	\$ —	\$ —	\$21,074
U.S. Government agencies				
Due in one year or less .....	\$ —	\$ —	\$ —	\$ —
Due in one to three years .....	1,000	—	(13)	987
Taxable auction securities .....	18,400	—	—	18,400
Corporate securities				
Due in one to three years .....	1,692	—	—	1,692
Total marketable securities .....	<u>\$21,092</u>	<u>\$ —</u>	<u>\$(13)</u>	<u>\$21,079</u>

As of December 31, 2007, auction securities have maturity dates that range from 2008 to 2045. Marketable securities with maturity dates in excess of one year are classified as short term because they are designated as available-for-sale securities and are available to be used in current operations.

The primary objective of the Company's investment activities is to preserve principal while at the same time maximizing the income the Company receives from the Company's investments without significantly increasing risk. To achieve this objective, the Company maintains its portfolio of cash equivalents and marketable securities in a variety of securities, including U.S. government agencies, municipal notes which may have an auction reset feature, corporate notes and bonds, commercial paper, and money market funds. These securities are classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). If interest rates rise, the market value of the Company's investments may decline, which could result in a realized loss if the Company is forced to sell an investment before its scheduled maturity. The Company does not utilize derivative financial instruments to manage its interest rate risks.

At March 3, 2008, the Company held approximately \$7.6 million of investments with an auction reset feature, referred to as auction rate securities. These auctions have historically provided a liquid market for these securities. In February 2008, the majority of auction rate securities in the marketplace failed at auction due to sell orders exceeding buy orders. The Company's ability to liquidate its auction rate securities and fully recover the carrying value of its auction rate securities in the near term may be limited or not exist, and the Company may in the future be required to record an impairment charge on these investments. The vast majority of the Company's auction rate securities, including those that have failed, were rated AAA at the time of purchase. The Company believes it will be able to liquidate its investments without significant loss within the next year, and the Company currently believes these securities are not significantly impaired, primarily due to the credit worthiness of the issuers of the underlying securities. However, it could take until the final maturity of the underlying notes (up to 30 years) to realize its investments' recorded value.

**NITROMED, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
(all tabular amounts in thousands except per share amounts)

**4. Accrued Expenses**

Accrued expenses consist of the following:

	December 31,	
	2007	2006
Sales and marketing . . . . .	\$ 304	\$ 817
Compensation and related benefits . . . . .	1,955	1,425
Reimbursements and rebates related to managed care organizations . . . . .	1,800	448
Product returns reserve . . . . .	946	1,339
Other . . . . .	1,374	2,516
Total . . . . .	\$6,379	\$6,545

**5. Long-Term Debt**

On June 28, 2005, the Company borrowed (i) \$10.0 million from Oxford Finance Corporation (“Oxford”), and (ii) \$10.0 million from General Electric Capital Corporation (“GECC”) pursuant to the terms of Promissory Notes (“the Notes”). The Notes bear interest at a fixed rate of 9.95% per annum and are payable in 36 consecutive monthly installments of principal and accrued interest, beginning on July 1, 2005. Also on June 28, 2005, the Company entered into Master Security Agreements with both Oxford and GECC (“the Agreements”). Under the terms of these Agreements, the Company granted to both Oxford and GECC a security interest in and against all of the property of the Company and in and against all additions, attachments, accessories and accessions to such property, all substitutions, replacements or exchanges, and all insurance and/or other proceeds (“the Collateral”). The Collateral comprises all of the Company’s personal property and fixtures including, but not limited to, all inventory, equipment, fixtures, accounts, deposit accounts, documents, investment property, instruments, general intangibles, chattel paper and any and all proceeds (but excluding intellectual property). The Collateral does not include any intellectual property or products (or interests in any intellectual property or products (including any royalties)) acquired, whether by purchase, license or otherwise, on or after the execution of the Agreements (collectively, “New Property”), nor do the Agreements limit any indebtedness secured by any New Property provided that debt or non-cash equity (e.g., stock) is used to acquire New Property. In the event that the Company uses cash to purchase New Property, Oxford’s and GECC’s existing liens will extend to such New Property. The Agreements also contain a Material Adverse Change clause with both Oxford and GECC. Under this clause, if Oxford or GECC reasonably determine that the Company’s ability to repay the Notes has been materially impaired, the Company would be considered in default. As of December 31, 2007, the Company was in compliance with this clause. At December 31, 2007, the total principal payments due were \$3.7 million, which the Company expects will be fully paid by June 30, 2008.

**6. Restructuring Actions**

On March 31, 2006, the Company recorded charges of \$2.0 million related to a restructuring of its discovery research operations to better align its costs with revenue and operating expectations. The restructuring charges pertained to employee severance and impairment of assets and were recorded in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated*

NITROMED, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(all tabular amounts in thousands except per share amounts)

6. Restructuring Actions (Continued)

with *Exit or Disposal Activities* ("SFAS 146"), and Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS 144"). In connection with the March 2006 restructuring, the Company terminated 30 employees in its research and development group, or approximately 30% of the Company's workforce, resulting in a charge of \$1.4 million. All such employees were terminated as of March 31, 2006.

As a result of terminating these employees, the Company recorded an impairment charge for certain research laboratory equipment, computer equipment, and furniture and fixtures in an aggregate amount of \$0.6 million due to the fact that these assets would no longer be utilized. These assets were written down to their fair value utilizing a third party appraiser to estimate the fair value of the assets based on current market quotes and the current condition of the equipment, furniture and fixtures.

The following table summarizes the March 2006 restructuring plan activity as of December 31, 2007:

	Charge	Cash Payments and Write-offs	Accrued at December 31, 2006	Cash Payments	Accrued at December 31, 2007
Workforce reduction . . . . .	\$1,441	\$(1,371)	\$70	\$(70)	\$ —
Impairment . . . . .	597	(597)	—	—	—
Total . . . . .	<u>\$2,038</u>	<u>\$(1,968)</u>	<u>\$70</u>	<u>\$(70)</u>	<u>\$ —</u>

On October 10, 2006, the Company recorded a restructuring charge of \$3.2 million, which was comprised of severance benefits of \$2.5 million and impairment charges of \$0.7 million for certain research and development equipment, leasehold improvements, furniture and fixtures, and computers. The restructuring charges were recorded in accordance with SFAS 146 and SFAS 144. The October 2006 restructuring program included the elimination of 120 sales personnel and eight general and administrative and research and development personnel. None of these employees remained employed as of December 31, 2006. As a result of these terminations, the Company's decision to no longer pursue research and development internally, and the Company's decision to move to a smaller facility, certain research and development equipment, leasehold improvements, furniture and fixtures, and computers became impaired. These assets were written down to the fair value based on either a third-party quote or the estimated discounted cash flows they would generate over their estimated remaining economic life to the Company.

The following table summarizes the restructuring activity as of December 31, 2007 related to the October 2006 restructuring plan:

	Charge	Cash Payments and Write-offs	Accrued at December 31, 2006	Cash Payments	Accrued at December 31, 2007
Workforce reduction . . . . .	\$2,500	\$(2,271)	\$229	\$(229)	\$ —
Impairment . . . . .	745	(745)	—	—	—
Total . . . . .	<u>\$3,245</u>	<u>\$(3,016)</u>	<u>\$229</u>	<u>\$(229)</u>	<u>\$ —</u>

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**6. Restructuring Actions (Continued)**

In the first quarter of 2007, the Company recorded a restructuring charge of \$1.0 million related to vacating its former headquarters location. The charge was recorded pursuant to SFAS 146. In March 2007, the Company entered into an Assignment of Lease and Assumption Agreement (the "Assignment Agreement") with Shire Human Genetic Therapies, Inc. ("Shire"), pursuant to which the Company assigned its lease for office and laboratory space located at 125 Spring Street in Lexington, Massachusetts (the "Spring Street Lease"). Pursuant to the terms of the Assignment Agreement, the Company agreed to pay Shire the amount of \$1.2 million as consideration for Shire's assumption of the Spring Street Lease. In addition to this charge, the Company incurred \$0.6 million in expenses primarily related to real estate brokerage fees and clean-up costs. Offsetting these charges was a reversal of \$0.8 million in accrued rent related to the Spring Street Lease. All amounts were paid as of March 31, 2007, and the Company has no further obligations related to this lease.

In January 2008, the Company implemented a restructuring plan that includes the elimination of approximately 75 positions by the end of February 2008, reducing headcount from approximately 90 to 15, with an additional reduction in headcount to approximately 10 positions anticipated by the end of April 2008. In conjunction with the January 2008 restructuring, the Company discontinued active promotional activities for BiDil, although the Company intends to continue to manufacture and sell BiDil and maintain the product on the market for patients through normal wholesale and retail channels. The Company estimates that it will record charges related to the January 2008 restructuring of approximately \$2.7 million in the first half of 2008, reflecting costs associated with one-time termination benefits.

**7. Stockholders' Equity**

**Stockholders' Equity**

*Public Offerings*

In May 2007, the Company completed a direct offering of shares of its common stock previously registered under its effective shelf registration statement. Pursuant to this offering, the Company sold 7.6 million shares of its common stock to selected institutional investors at a price of \$2.60 per share. Proceeds to the Company from this registered direct offering, net of offering expenses and placement agency fees, totaled \$18.2 million.

In January 2006, the Company completed a direct offering of shares of its common stock previously registered under its effective shelf registration statement. Pursuant to this offering, the Company sold approximately 6.1 million shares of its common stock to selected institutional investors at a price of \$10.25 per share. Proceeds to the Company from this offering, net of offering expenses and placement agency fees, totaled \$58.5 million.

**Stock-Based Compensation**

The Company follows the fair value recognition provisions of SFAS 123R. Compensation cost recognized subsequent to December 31, 2005 includes: (a) compensation cost for all stock-based payments granted but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all stock-based



**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**7. Stockholders' Equity (Continued)**

payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. Such amounts have been reduced by the Company's estimate of forfeitures of all unvested awards.

For stock options granted to non-employees, the Company recognizes compensation expense in accordance with the requirements of Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). EITF 96-18 requires companies to recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the service period. The fair value of unvested non-employee stock awards is re-measured at each reporting period.

*Stock Option Plans.* The Company's Restated 1993 Equity Incentive Plan (the "1993 Plan"), which expired in accordance with its terms in 2003, provided for the grant of incentive stock options, nonstatutory stock options and restricted stock awards to purchase up to 2,288,200 shares of the Company's common stock. Officers, employees, directors, consultants and advisors of the Company were eligible to receive grants of options under the 1993 Plan at a price not less than 100% (or 110% in the case of incentive stock options granted to 10% or greater stockholders) of the fair market value of the Company's common stock, as determined by the Company's Board of Directors, at the time the option was granted. In May 2003, the Company's stockholders approved the 2003 Stock Incentive Plan (the "2003 Plan"), under which 800,000 shares of common stock were authorized for issuance. In October 2003, the stockholders of the Company approved an amended and restated 2003 Plan which provided, among other things, for an increase of shares authorized for issuance under the 2003 Plan to 2,500,000. In May 2005, the stockholders of the Company approved an amendment to the 2003 Plan which provided for an increase of shares authorized for issuance under the 2003 Plan to 3,500,000, and the adoption of an "evergreen" provision that allows for an annual increase in the number of shares of the Company's common stock available for issuance under the 2003 Plan. The evergreen provision provides for an annual increase to be added on the first day of each fiscal year of the Company during the period beginning in fiscal year 2006 and ending on the second day of fiscal year 2013. The increase provided by the evergreen provision is equal to the lesser of (i) 1,400,000 shares of the Company's common stock, (ii) 4% of the outstanding shares on that date or (iii) an amount determined by the Company's Board of Directors. Pursuant to the evergreen provision, an additional 1,219,679 shares of common stock were authorized for issuance under the 2003 Plan in January 2006 and an additional 1,400,000 shares of common stock were authorized for issuance under the 2003 Plan in each of January 2007 and January 2008.

While the Company may grant options to employees that become exercisable at different times or within different periods, the Company generally has granted options to employees that are exercisable in equal annual installments of 25% on each of the first four anniversary dates of the grant.

*Employee Stock Purchase Plan.* On August 18, 2003, the Board of Directors adopted the 2003 Employee Stock Purchase Plan (the "ESPP"), which allows eligible employees to purchase common stock at a price per share equal to 85% of the lower of the fair market value of the common stock at the beginning or end of each six month period during the term of the ESPP. The first offering period began on January 1, 2004. In May 2006, the stockholders of the Company approved an amendment to

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**7. Stockholders' Equity (Continued)**

the ESPP, which provided for an increase of shares available for issuance under the ESPP to 150,000, and the adoption of an "evergreen" provision that allows for an annual increase in the number of shares of the Company's common stock available for issuance under the ESPP. The evergreen provision provides for an annual increase to be added on the first day of each fiscal year of the Company during the period beginning in fiscal year 2007 and ending on the last day of fiscal year 2010, such increase to be equal to the lesser of (i) 150,000 shares of the Company's common stock or (ii) a lesser amount determined by the Company's Board of Directors. Pursuant to the evergreen provision, an additional 150,000 shares of common stock were authorized for issuance under the ESPP in each of January 2007 and January 2008.

*Grant-date Fair Value.* The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. Information pertaining to stock options and related assumptions are noted in the following table:

	December 31,		
	2007	2006	2005
Options granted (in thousands) . . . . .	960	3,833	984
Weighted-average exercise price of stock options . . . . .	\$ 2.62	\$ 6.65	\$ 16.43
Weighted-average grant date fair-value of stock options . . . . .	\$ 1.61	\$ 4.14	\$ 11.51
Assumptions:			
Volatility . . . . .	76%	74%	73%
Risk-free interest rate . . . . .	4.8%	4.7%	4.0%
Expected lives . . . . .	4.4 years	5.4 years	6.0 years
Dividend . . . . .	—	—	—

Volatility is determined exclusively using historical volatility data of the Company's common stock based on the period of time since the Company's common stock has been publicly traded. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of stock options granted is based exclusively on historical data and represents the weighted average period of time that stock options granted are expected to be outstanding. The expected life is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population.

*Stock-Based Compensation Expense.* The Company is using the straight-line attribution method to recognize stock-based compensation expense. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option. The Company has applied an annual forfeiture rate of 5.6% to all unvested options as of December 31, 2007. This analysis will be re-evaluated quarterly and the forfeiture rate will be

NITROMED, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(all tabular amounts in thousands except per share amounts)

7. Stockholders' Equity (Continued)

adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

The adoption of SFAS 123R on January 1, 2006 had the following impact: net loss was higher by \$5.0 million, and net loss per share was higher by \$0.12 for fiscal 2007 and net loss was higher by \$8.0 million, and net loss per share was higher by \$0.22 for fiscal 2006 than if the Company had continued to account for stock-based compensation under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

The following table illustrates the effect on net loss and net loss per share had the Company applied the fair value recognition provisions of SFAS 123R for the year ended 2005.

	December 31, 2005
Net loss as reported	\$(105,852)
Add: Stock-based employee compensation expense included in reported net loss	626
Deduct: Stock-based employee compensation expense determined under fair value based method	<u>(5,961)</u>
Pro forma net loss	<u>\$(111,187)</u>
Basic and diluted net loss per share	
As reported	<u>\$ (3.49)</u>
Pro forma	<u>\$ (3.66)</u>

*Stock-Based Compensation Activity*

A summary of the activity under the Company's stock options plans as of December 31, 2007 and changes during the year then ended is presented below:

	Number of Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Options outstanding at December 31, 2006	4,936	\$6.90		
Options granted	960	\$2.62		
Options exercised	(273)	\$1.14		
Options canceled	<u>(875)</u>	\$7.37		
Options outstanding at December 31, 2007	<u>4,748</u>	\$6.28		\$33
Options vested or expected to vest at December 31, 2007(1)	<u>4,496</u>	\$6.36	7.4	\$33
Options exercisable at December 31, 2007	<u>2,493</u>	\$7.15	6.5	\$33

(1) Options expected to vest is calculated by applying an estimated forfeiture rate to unvested options.

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**7. Stockholders' Equity (Continued)**

During the year ended December 31, 2007, the total intrinsic value of options exercised (i.e., the difference between the market price at exercise and the price paid by the employee to exercise the options) was \$525,000, and the total amount of cash received from exercise of these options was \$311,000. The total grant-date fair value of stock options that vested during the year ended December 31, 2007 was \$5.7 million.

During the year ended December 31, 2006, the total intrinsic value of options exercised (i.e., the difference between the market price at exercise and the price paid by the employee to exercise the options) was \$1,887,000, and the total amount of cash received from exercise of these options was \$693,000. The total grant-date fair value of stock options that vested during the year ended December 31, 2006 was \$3.7 million.

As of December 31, 2007, there was \$6.2 million of total unrecognized compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted average period of 1.9 years.

During 1999 and 2000, the Company granted performance-based options to purchase 75,100 and 100,000 shares of common stock, respectively, with an exercise price of \$1.30, to certain employees, which allow for acceleration of the vesting period upon the occurrence of certain defined events. Of the 100,000 options granted in 2000, 5,000 options were forfeited in 2002. Based on the terms of the arrangements, the awards were required to be accounted for as variable, and compensation expense was measured as the difference between the fair market value of the Company's common stock at the reporting period date and the exercise price of the award. Compensation expense is recognized over the vesting period. The Company recognized a reversal of stock based compensation expense of \$261,000 for the year ended December 31, 2005. In connection with the adoption of SFAS 123R, these awards became fixed and their associated expense is included in stock-based compensation expense for the years ended December 31, 2007 and 2006.

During 2003 and 2002, the Company granted options to purchase 413,250 and 241,000 shares of common stock, respectively, to employees at exercise prices below the deemed fair value for accounting purposes of the Company's common stock. The weighted average exercise price of these options is \$2.00 per share. The Company recorded deferred stock compensation expense related to these grants of \$3,317,000 and \$566,000 for the years ended December 31, 2003 and 2002, respectively. These amounts were being recognized as stock-based compensation expense ratably over the vesting period of four years. Included in the results of operations for the year ended December 31, 2005 is stock based compensation expense of \$887,000. In connection with the adoption of SFAS 123R in January 2006, the Company reversed the remaining deferred stock compensation balance of \$1,208,000. The fair value of these awards is accounted for in accordance with SFAS 123R, and related stock compensation expense is included in the statement of operations for the years ended December 31, 2007 and 2006.

Since 1999, the Company has granted options to purchase a total of 201,000 shares of common stock to nonemployees at a weighted-average exercise price of \$3.50 per share, of which 125,000 remained outstanding at December 31, 2007. The Company has applied the recognition provisions of EITF 96-18 related to these stock options and utilized the Black-Scholes option pricing model to determine the fair value of these stock options at each reporting date. In connection with these awards,

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**7. Stockholders' Equity (Continued)**

the Company recognized a reversal of stock based compensation expense of \$26,000, \$239,000, and \$133,000 for the years ended December 31, 2007, 2006, and 2005, respectively.

In January 2007, the Company modified the terms of certain vested stock option awards previously granted to the Company's former interim president and chief executive officer in order to extend the term of the exercisability of the vested portion of the options from three months following the cessation of employment to five years following the cessation of employment. As a result of this modification in January 2007, the Company recorded a stock-based compensation charge of \$459,000 in the first quarter of 2007.

In May 2007, the Company entered into a Transition Agreement with L. Gordon Letts, Ph.D., the Company's former Chief Scientific Officer and Senior Vice President of Research and Development. Pursuant to the terms of the Transition Agreement, options previously granted by the Company to Dr. Letts will continue to vest during a one-year transition period, during which time Dr. Letts will continue to be an employee of the Company. Pursuant to the terms of the Transition Agreement, the terms of stock option awards granted to Dr. Letts were modified in order to extend the term of the exercisability of the options from three months following the cessation of employment to two years following the cessation of the one-year transition period. As a result of this modification, the Company incurred a stock-based compensation charge of \$168,000 for the year ended December 31, 2007, and will continue to recognize additional amounts as the options vest.

In March and April 2007, the Company entered into restricted stock agreements with certain executive officers and employees of the Company, pursuant to which these individuals were granted an aggregate of 734,790 shares of the Company's common stock under the Company's Amended and Restated 2003 Stock Incentive Plan, which are subject to forfeiture to the Company prior to vesting under certain circumstances, including voluntary separation or termination of employment for cause. The forfeiture provision lapses as follows: 25% of the shares are no longer subject to forfeiture to the Company, or "vest," on the date that is six months after the grant date; 25% vest on the first anniversary of the grant date; and 50% vest on the second anniversary of the grant date. Upon a change in control of the Company or upon termination of the employee's employment without cause, all unvested restricted shares shall immediately vest in full. The Company recognized \$801,000 of stock-based compensation expense related to these restricted stock awards for the year ended December 31, 2007. On the accompanying balance sheets the number of shares of the Company's common stock outstanding as of December 31, 2007 does not include 451,778 shares of unvested restricted common stock.

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**7. Stockholders' Equity (Continued)**

A summary of the Company's restricted stock award activity as of December 31, 2007 and changes during the year then ended is presented below:

	Restricted Shares Outstanding	Weighted- Average Grant Date Fair Value Per Share
<b>Non-vested shares outstanding at December 31, 2006</b> .....	—	\$ —
Awards granted .....	735	\$3.22
Restrictions lapsed .....	(166)	\$3.22
Awards forfeited .....	(117)	\$3.22
<b>Non-vested shares outstanding at December 31, 2007</b> .....	452	\$3.22

As of December 31, 2007, there was \$1.2 million of total unrecognized compensation cost related to unvested restricted shares, which will be recognized over the remaining vesting term of 1.2 years.

**8. Operating Lease**

On February 23, 2007, the Company entered into a lease pursuant to which the Company agreed to lease 19,815 square feet at a facility located in Lexington, Massachusetts to accommodate its reduced workforce. The term of this lease is for sixty-six months. At December 31, 2007, the expected minimum rental commitments under the lease agreement are \$510,000 for 2008, \$560,000 for 2009, \$580,000 for 2010, \$592,000 for 2011 and \$456,000 for 2012. In addition, the Company is obligated to pay a certain portion of the operating expenses and the real property taxes associated with the premises. Under the lease, a security deposit in the amount of \$190,000 is required to be held in escrow for the term of the lease, which has been recorded as restricted cash on the balance sheet at December 31, 2007. Rent expense for the years ended December 31, 2007, 2006 and 2005 was \$0.8 million, \$1.7 million and \$1.7 million, respectively.

**9. License, Manufacturing and Commercialization Agreements**

The Company has entered into various research, license and commercialization agreements to support its research and development and commercialization activities.

*Elan.* In February 2007, in connection with the Company's efforts to develop BiDil XR, the Company entered into a license agreement with Elan Pharma International Limited ("Elan"). Pursuant to the agreement, Elan granted to the Company an exclusive worldwide license, for the term of the agreement, to certain know-how, patents and technology, and any improvements to any of the foregoing developed by either party during the term of the agreement. Pursuant to this license, the Company has the right to import, use, offer for sale and sell the oral capsule formulation incorporating specified technology referred to in the agreement and containing, as its sole active combination of ingredients, the combination of the active drug substances isosorbide dinitrate and hydralazine hydrochloride, including BiDil XR. In consideration for the grant of the license, the Company has agreed to pay Elan royalties that are calculated by reference to annual net sales parameters set forth in the agreement. In addition, the Company has also agreed to pay Elan specified amounts upon the

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**9. License, Manufacturing and Commercialization Agreements (Continued)**

achievement of specified development and commercialization milestone events of up to \$2.5 million of which \$250,000 was paid in 2007.

The term of the agreement runs in the United States from the effective date of the agreement until the later of (a) the 20th anniversary of the date of the first sale of the product by us or a permitted sublicensee to an unaffiliated third party, which is referred to in the agreement as the first in market sale, or (b) the expiration of the last-to-expire patent for the product listed in the FDA's "Orange Book." Elsewhere in the world, the term will run on a country by country basis from the effective date of the agreement until the later of (a) the 20th anniversary of the date of the first in market sale of the product in the country concerned or (b) the expiration of the life of the last to expire patent included in the Elan intellectual property in that country. Following the expiration of the initial term, the agreement shall continue automatically for rolling 3 year periods thereafter, unless the agreement has been terminated by either of the parties by serving 1 year's written notice on the other party prior to the end of the initial term or any such additional 3 year period. Either Elan or the Company may terminate the agreement in the event of a material, uncured breach by the other party, or if the other party goes into liquidation or becomes bankrupt or insolvent. In addition, the Company may terminate the agreement in the event of a technical failure, which is defined as the inability to achieve a pharmacokinetic profile for the product consistent with that of BiDil administered three times daily (at 6 hour intervals). Elan may terminate the agreement with respect to a particular country in the territory in the event that the Company does not meet certain obligations set forth in the agreement with respect to such country, provided that Elan must first consult with the Company and, if applicable, provide the Company with an opportunity to meet such obligations prior to exercising Elan's termination rights.

*Boston Scientific Collaboration.* In November 2001, the Company entered into a research, development and license agreement with Boston Scientific Corporation ("Boston Scientific") in the field of restenosis. The Company granted Boston Scientific an exclusive worldwide license to develop and commercialize nitric oxide-enhancing cardiovascular stents. The Company also granted to Boston Scientific a right of first refusal to obtain an exclusive license under the Company's nitric oxide technologies to commercialize products for restenosis, which right of first refusal is for a period of three years after the end of the research term. In December 2003, the Company agreed to extend the agreement to continue the research and development collaboration through December 2005. The research term of the Boston Scientific agreement expired on December 31, 2005. Boston Scientific made an up-front license payment of \$1.5 million to the Company in 2001, and made an additional payment of \$3.0 million in December 2003 in connection with the extension of the research and development collaboration. The Company was recognizing the up-front license payments ratably over the term of the contractual performance obligation. For the year ended December 31, 2005, the Company recognized revenue of \$1.6 million. Boston Scientific also made a \$3.5 million equity investment in the Company's stock in 2001. In August 2003, in connection with a private placement, Boston Scientific made an additional \$500,000 equity investment the Company's stock.

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(all tabular amounts in thousands except per share amounts)

**9. License, Manufacturing and Commercialization Agreements (Continued)**

*Dr. Jay N. Cohn.* In January 1999, as amended in January 2001 and March 2002, the Company entered into a collaboration and license agreement with Dr. Jay N. Cohn. Under the agreement, Dr. Cohn licensed to the Company an exclusive worldwide royalty-bearing license to technology and inventions owned or controlled by Dr. Cohn and that relate to BiDil for the treatment of cardiovascular disease. Upon achieving certain developmental events, the Company was required to make milestone payments totaling \$1.0 million, which were recorded as a charge to research and development expenses in 2004. Upon commercial sale of BiDil, the Company is required to make royalty payments based on net sales at varying rates depending on sales volume. The royalty term expires upon the later of the expiration of the patent rights or ten years from the first commercial sale. During the years ended December 31, 2007, 2006 and 2005, the Company incurred royalty expenses of \$450,000, \$364,000 and \$134,000, respectively. The agreement imposes upon the Company an obligation to use reasonable best efforts to develop and, upon receipt of regulatory approval, manufacture, market and commercialize products based upon the licensed rights. If the Company fails to meet this obligation, Dr. Cohn has the right to terminate the agreement and the license granted to the Company under the agreement. Dr. Cohn also has the right to terminate the agreement if the Company materially breaches the agreement and fails to remedy the breach within 30 days. The Company has the right to terminate the agreement at any time upon 30 days' prior written notice. Unless earlier terminated, the agreement continues in perpetuity. Pursuant to the agreement, Dr. Cohn was appointed to the Company's then-current scientific advisory board, entered into a consulting agreement with the Company and was granted an option to purchase 10,000 shares of the Company's common stock.

**10. Income Taxes**

A reconciliation of federal statutory income tax provision to the Company's actual provision is as follows:

	Year Ended December 31,		
	2007	2006	2005
Benefit at federal statutory tax rate . . . . .	\$(10,735)	\$(24,255)	\$(35,990)
State taxes, net of federal benefit . . . . .	(1,980)	(4,473)	(6,637)
Non-deductible expenses . . . . .	37	910	254
Unbenefited operating losses . . . . .	12,678	27,818	42,373
Income tax provision . . . . .	\$ —	\$ —	\$ —



**NITROMED, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
(all tabular amounts in thousands except per share amounts)

**10. Income Taxes (Continued)**

The significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 93,535	\$ 81,642
Capitalized research costs, net of amortization . . . . .	27,049	27,386
Tax credit carryforwards . . . . .	7,509	6,663
Deferred revenue . . . . .	—	83
Depreciation . . . . .	(30)	422
Accrued expenses . . . . .	410	218
Other . . . . .	5,571	3,979
	134,044	120,393
Valuation allowance . . . . .	(134,044)	(120,393)
Net deferred tax assets . . . . .	\$ —	\$ —

The Company has increased its valuation allowance by approximately \$13.7 million in 2007 to provide a full valuation allowance for deferred tax assets since the realization of these benefits is not considered more likely than not. At December 31, 2007, the Company had unused net operating loss carryforwards of approximately \$237 million available to reduce federal taxable income expiring in 2010 through 2025 and approximately \$209 million available to reduce state taxable income expiring in 2008 through 2010. The Company also has federal and state research tax credits of approximately \$8.7 million available to offset federal and state income taxes, both of which expire beginning in 2010. No income tax payments were made in 2007, 2006 or 2005.

Utilization of the net operating losses, ("NOLs") and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOLs and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not currently completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since its formation, due to the significant complexity and related cost associated with such study. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOLs and credits.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109* ("FIN 48"). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. The Company adopted FIN 48 on January 1, 2007. The implementation of FIN 48 did not have a material impact on the Company's consolidated financial statements, results of operations or cash flows. At the adoption date of January 1, 2007, and also at December 31, 2007, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an increase or decrease to the

**NITROMED, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(all tabular amounts in thousands except per share amounts)**

**10. Income Taxes (Continued)**

Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN 48. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the consolidated balance sheet, statement of operations or cash flows if an adjustment were required.

**11. Commitments and Contingencies**

In connection with the Company's efforts to obtain the approval of BiDil from the FDA, the Company contracted with the law firm of FoxKiser LLC ("FoxKiser") for services related to the regulatory approval process for BiDil. The agreement provided for payment of legal consulting fees upon receipt of written FDA approval of BiDil. In addition, the agreement requires the Company to pay royalties to FoxKiser on commercial sales of BiDil. The royalty term ends six months after the date of market introduction of an FDA-approved generic version of BiDil. During the years ended December 31, 2007, 2006 and 2005, the Company recorded charges of \$-0-, \$0.9 million, and \$1.6 million, respectively, pertaining to the legal consulting fees, and \$450,000, \$364,000, and \$134,000, respectively, pertaining to royalty expenses related to this agreement.

On February 16, 2005, the Company engaged Schwarz Pharma Manufacturing, Inc. ("Schwarz Pharma") under a five-year exclusive manufacturing and supply agreement solely for the three times daily immediate release dosage formulation of BiDil. Schwarz Pharma is now a division of UCB S.A. Under the supply agreement, the Company has the right to engage a backup manufacturer. At December 31, 2007, the Company has outstanding binding purchase orders of \$0.5 million for production of BiDil finished goods.

**12. Retirement Plan**

The Company sponsors a 401(k) plan covering substantially all employees. The plan provides for salary deferral contributions by participants of up to 75% of eligible wages not to exceed Federal requirements. Those employees over 50 years old are permitted to contribute an additional amount per Federal limits (\$5,000 per year for 2007). In October 2005, the Board of Directors approved an employee match in the form of shares of the Company's common stock equal to 50% of employee contributions, limited to the first 6% of salary contributed to the 401(k) plan. For the years ended December 31, 2007, 2006, and 2005, the Company recorded expenses of \$189,000, \$411,000 and \$88,000, respectively, related to the plan.

**NITROMED, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
(all tabular amounts in thousands except per share amounts)

**13. Quarterly Results of Operations (Unaudited)**

The following table presents unaudited quarterly financial data of the Company:

	Year Ended December 31, 2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net revenues .....	\$ 3,568	\$ 3,715	\$ 3,759	\$ 4,977
Gross profit .....	2,614	3,078	3,199	2,892
Net loss .....	(10,114)	(6,236)	(8,354)	(6,870)
Basic and diluted net loss per share .....	\$ (0.27)	\$ (0.16)	\$ (0.18)	\$ (0.15)
Weighted average common shares used to compute net loss per share .....	37,263	40,100	45,180	45,322

	Year Ended December 31, 2006			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net revenues .....	\$ 2,316	\$ 2,855	\$ 3,427	\$ 3,488
Gross profit .....	1,420	2,234	\$ 2,117	\$ 2,755
Net loss .....	(25,924)	(18,280)	(16,520)	(10,613)
Basic and diluted net loss per share .....	\$ (0.75)	\$ (0.50)	\$ (0.45)	\$ (0.29)
Weighted average common shares used to compute net loss per share .....	34,597	36,724	37,090	37,147

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

None.

### ITEM 9A. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Management’s Report on Internal Control Over Financial Reporting.*

#### **Management’s Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company’s principal executive and principal financial officers and effected by the company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, the company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on this assessment, our management concluded that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm has issued an audit report on our assessment of our internal control over financial reporting. This report appears below.

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
NitroMed, Inc.

We have audited NitroMed, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NitroMed, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, NitroMed, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of NitroMed, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of NitroMed, Inc. and our report dated March 4, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 4, 2008

*(c) Changes in Internal Controls.*

No change in our internal control over financial reporting occurred during the fiscal year ending December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

**Directors and Executive Officers**

Information regarding our directors and executive officers may be found under the captions "Election of Directors," "Executive Officers" and "Corporate Governance" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

**Audit Committee**

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions "Board of Directors Meetings, Committees and Attendance" and "Report of the Audit Committee" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

**Audit Committee Financial Expert**

The Board of Directors has determined that it has at least one "Audit Committee Financial Expert" (as defined by Item 407(d)(5) of Regulation S-K of the Exchange Act) on the Audit Committee of the Board of Directors, Davey S. Scoon. The Board of Directors has further determined that Mr. Scoon is "independent" from management within the meaning of Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Information regarding Section 16(a) Beneficial Ownership Reporting Compliance may be found under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics, which applies to all of our officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics was filed with the SEC as an exhibit to our annual report on Form 10-K for the fiscal year ended December 31, 2003. In addition, we intend to post on our website, which is located at [www.nitromed.com](http://www.nitromed.com), all disclosures that are required by law or NASDAQ Stock Market listing standards concerning any amendments to, or waivers from, any provision of our code of business conduct and ethics.

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

Information with respect to this item may be found under the caption "Compensation of Executive Officers and Directors," including but not limited to the sub-captions "Compensation Discussion and Analysis," "Compensation of Directors," and "Compensation Committee Interlocks and Insider Participation," in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the caption "Stock Ownership of Certain Beneficial Owners and Management" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions "Transactions with Related Persons," "Policies and Procedures for Related Person Transactions," and "Board Determination of Independence" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the caption "Audit Fees" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

### **PART IV**

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

(a)(1) Financial Statements.

For a list of the financial information included herein, see "Index to Financial Statements" on page 50.

(a)(2) Financial Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or Notes thereto.

(a)(3) Exhibits. The list of Exhibits filed as a part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by this reference.



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

NITROMED, INC.

Date: March 6, 2008

By: /s/ KENNETH M. BATE

Kenneth M. Bate  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this report has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ KENNETH M. BATE</u> Kenneth M. Bate	President and Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2008
<u>/s/ JAMES G. HAM, III</u> James G. Ham, III	Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 6, 2008
<u>/s/ ROBERT S. COHEN</u> Robert S. Cohen	Director	March 6, 2008
<u>/s/ FRANK L. DOUGLAS, M.D., PH.D.</u> Frank L. Douglas, M.D., Ph.D.	Director	March 6, 2008
<u>/s/ ZOLA HOROVITZ, PH.D.</u> Zola Horovitz, Ph.D.	Director	March 6, 2008
<u>/s/ ARGERIS KARABELAS, PH.D.</u> Argeris Karabelas, Ph.D.	Director	March 6, 2008
<u>/s/ MARK LESCHLY</u> Mark Leschly	Director	March 6, 2008
<u>/s/ JOHN W. LITTLECHILD</u> John W. Littlechild	Director	March 6, 2008
<u>/s/ JOSEPH LOSCALZO, M.D., PH.D.</u> Joseph Loscalzo, M.D., Ph.D.	Director	March 6, 2008
<u>/s/ DAVEY S. SCOON</u> Davey S. Scoon	Director	March 6, 2008
<u>/s/ CHRISTOPHER J. SOBECKI</u> Christopher J. Sobecki	Director	March 6, 2008

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of the Company (Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-108104))
3.2	Amended and Restated Bylaws of the Company (Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-108104))
*10.1	Restated 1993 Equity Incentive Plan (Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-108104))
*10.2	Amended and Restated 2003 Stock Incentive Plan, as amended (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 000-50439))
*10.3	Form of Incentive Stock Option Agreement Granted Under Amended and Restated 2003 Stock Incentive Plan (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 (File No. 000-50439))
*10.4	Form of Nonstatutory Stock Option Agreement Granted Under Amended and Restated 2003 Stock Incentive Plan (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 (File No. 000-50439))
*10.5	Form of Restricted Stock Agreement Granted Under Amended and Restated 2003 Stock Incentive Plan entered into between the Company and certain of the Company's executive officers, together with a schedule of such officers (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on March 22, 2007 (File No. 000-50439))
*10.6	2003 Employee Stock Purchase Plan, as amended (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 000-50439))
10.7†	Collaboration and License Agreement between the Company and Professor Jay N. Cohn dated January 22, 1999, as amended January 29, 2001 and March 15, 2002 (Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-108104))
10.8	Amendment No. 1 to Collaboration and License Agreement between the Company and Professor Jay N. Cohn dated August 10, 2000 (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 (File No. 000-50439))
10.9†	Agreement between the Company and FoxKiser dated April 26, 2001 (Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-108104))
10.10†	Supply Agreement between the Company and Schwarz Pharma Manufacturing, Inc. dated as of February 16, 2005 (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 (File No. 000-50439))

Exhibit No.	Description
10.11	Master Security Agreement (including Collateral Schedule No. 001) and Financial Covenants Addendum No. 001, each dated as of June 28, 2005, between the Company and Oxford Finance Corporation and Promissory Note, dated as of June 28, 2005, made by the Company for the benefit of Oxford Finance Corporation (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on July 5, 2005 (File No. 000-50439))
10.12	Master Security Agreement (including Collateral Schedule No. 001) and Financial Covenants Addendum No. 001, each dated as of June 28, 2005, between the Company and General Electric Capital Corporation and Promissory Note, dated as of June 28, 2005, made by the Company for the benefit of General Electric Capital Corporation (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on July 5, 2005 (File No. 000-50439))
*10.13	Executive Severance Benefit Plan (Incorporated by reference to the exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006 (File No. 000-50439))
*10.14	Amendment No. 1 to Executive Severance Benefit Plan (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on August 22, 2006 (File No. 000-50439))
*10.15	Form of Agreement entered into by and between the Company and certain of its executive officers, together with a schedule of such officers (Incorporated by reference to the exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006 (File No. 000-50439))
*10.16	Form of Amendment No. 1 to Agreement entered into by and between the Company and certain of its executive officers, together with a schedule of such officers (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on August 22, 2006 (File No. 000-50439))
*10.17	Employment Offer Letter between the Company and Kenneth M. Bate, dated as of January 19, 2007 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 25, 2007 (File No. 000-50439))
*10.18	Retention Agreement between the Company and Kenneth M. Bate, dated as of January 23, 2007 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 25, 2007 (File No. 000-50439))
*10.19	Severance Agreement between the Company and Kenneth M. Bate, dated as of January 23, 2007 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 25, 2007 (File No. 000-50439))
*10.20	Retention Agreement between the Company and Kenneth M. Bate, dated as of January 15, 2008 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 17, 2008 (File No. 000-50439))
*10.21	Letter Agreement between the Company and James G. Ham, III, dated as of September 3, 2004 (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 (File No. 000-50439))
*10.22	Retention Agreement between the Company and James G. Ham, III, dated as of January 15, 2008 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 17, 2008 (File No. 000-50439))

<u>Exhibit No.</u>	<u>Description</u>
*10.23	Retention and Separation Agreement between the Company and Jane A. Kramer, dated as of January 17, 2008 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on January 17, 2008 (File No. 000-50439))
*10.24	Separation Agreement between the Company and Gerald Bruce, dated as of February 21, 2008
*10.25	Transition Agreement between the Company and L. Gordon Letts, Ph.D., dated as of May 21, 2007 (Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on May 22, 2007 (File No. 000-50439))
10.26†	License Agreement between the Company and Elan Pharma International Limited, dated as of February 9, 2007 (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 000-50439))
10.27	Lease between the Company and The Realty Associates Fund VI, L.P., dated as of February 23, 2007 (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 000-50439))
14.1	Code of Business Conduct and Ethics (Incorporated by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2003 (File No. 000-50439))
21.1	Subsidiaries of the Company
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Management contract or compensation plan or arrangement required to be filed as an exhibit pursuant to Item 15(c) of Form 10-K

† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission

END