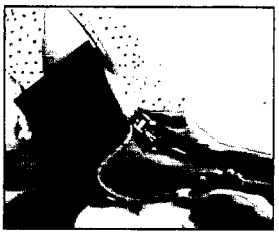
Myogen INC



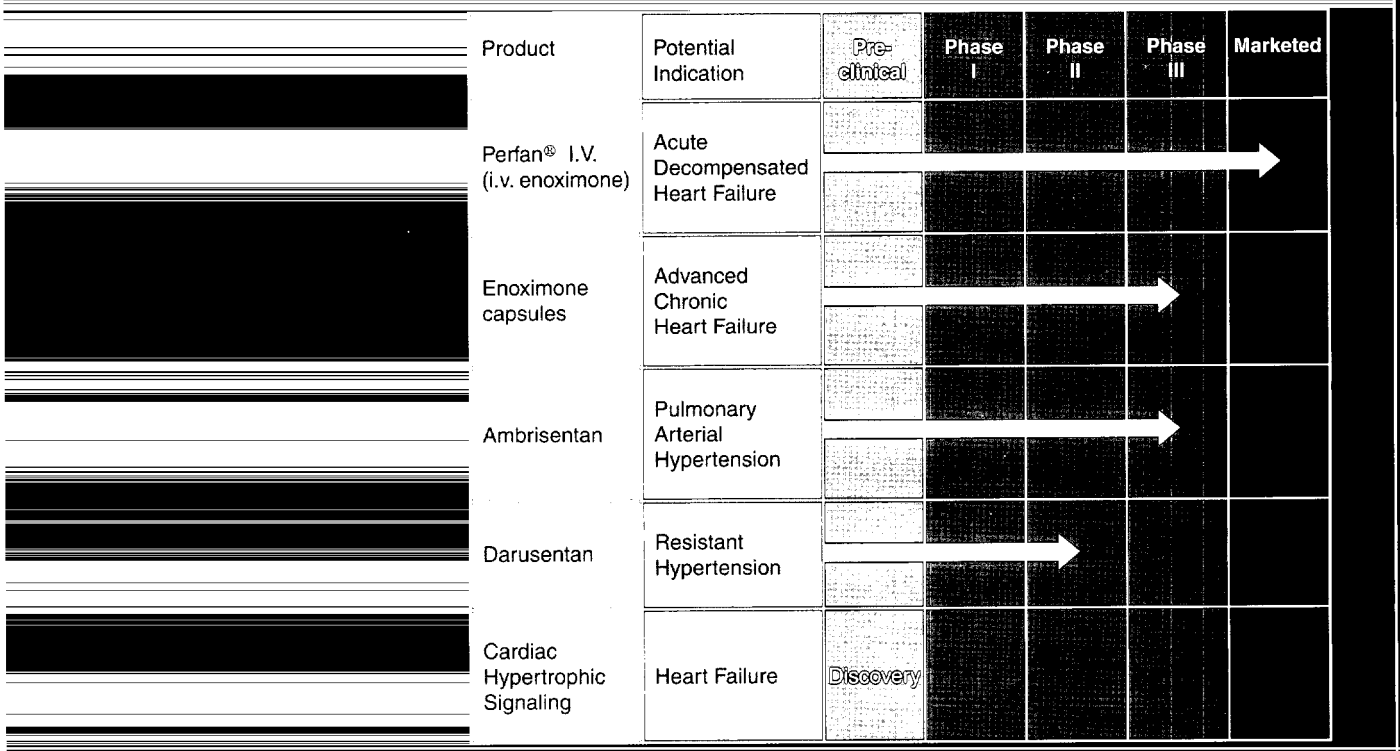
Innovative Therapies Targeting Cardiovascular Disease

2003 Annual Report

2003 Accomplishments

- Completed patient enrollment in EMOTE, our Phase III trial of enoximone capsules in patients with advanced chronic heart failure.
- In-licensed darusentan, a type-A selective endothelin receptor antagonist which showed encouraging Phase II results for treatment of essential hypertension.
- Raised net proceeds of $39.9 million through the sale of Series D preferred stock.
- Completed AMB-220, our Phase II trial of ambrisentan in pulmonary arterial hypertension, which achieved its primary endpoint.
- Established research and development collaboration with the Novartis Institutes for BioMedical Research, Inc.
- Raised net proceeds of $73.3 million through the completion of initial public offering of common stock.

Myogen Product Pipeline



Focus on Cardiovascular Disease

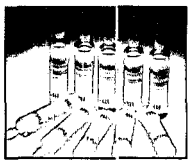
The term cardiovascular disease is used to describe a continuum of clinical conditions resulting primarily from three underlying chronic diseases: atherosclerosis, hypertension and diabetes. These underlying diseases cause permanent damage to the heart, blood vessels and kidneys, leading to progressively debilitating clinical conditions such as chronic heart failure, pulmonary arterial hypertension, systemic hypertension, chronic kidney disease, heart attack and stroke. Cardiovascular disease is the leading cause of death and disability in the U.S., accounting for approximately $300 billion in healthcare costs in 2003. Despite improved treatments and increased awareness of preventative measures, 62 million people in the U.S. currently suffer from cardiovascular disease.

Corporate Profile

Myogen is a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapeutics for the treatment of cardiovascular disorders. Myogen currently markets one product, Perfan I.V., in Europe for the treatment of acute decompensated heart failure and is developing three product candidates for three distinct cardiovascular indications: enoximone for the treatment of chronic heart failure; ambrisentan for the treatment of pulmonary arterial hypertension and darusentan for the treatment of resistant hypertension. Myogen, in partnership with Novartis, also conducts a target and drug discovery research program focused on the development of disease-modifying drugs for the treatment of chronic heart failure and related cardiovascular disorders.

Myogen's Portfolio

PERFAN I.V.



Perfan I.V. is the intravenous formulation of enoximone that is **marketed** by Myogen in eight European countries. Perfan I.V. is used in a hospital setting to treat patients with acute decompensated heart failure and to wean patients from cardiopulmonary bypass following open-heart surgery. We recorded Perfan I.V. sales of approximately $2.8 million in 2003. We believe our European sales experience helps prepare us for the potential commercial launch of future products, such as enoximone capsules, ambrisentan and darusentan.

ENOXIMONE

Enoximone is a small organic molecule that inhibits type-III phosphodiesterase, or PDE-III, an enzyme that is present in the heart and plays an important regulatory role in cardiac function. Enoximone blocks the action of this enzyme, increasing the force of contraction of the heart, thereby increasing cardiac output. We are currently conducting our **Phase III** clinical evaluation of enoximone capsules in patients with advanced chronic heart failure. If our clinical program is successful, enoximone capsules would be the first oral inhibitor of PDE-III to be commercialized for the treatment of chronic heart failure.

AMBRISENTAN

Ambrisentan is an ET_A selective endothelin receptor antagonist (ETRA). Endothelin is a small peptide hormone that is believed to play a critical role in the control of blood flow and cell growth. Elevated endothelin blood levels are associated with several cardiovascular disease conditions. We are currently conducting our **Phase III** clinical evaluation of ambrisentan in patients with pulmonary arterial hypertension. We believe the selectivity and potency of ambrisentan may offer significant advantages over non-selective ETRAs, including enhanced efficacy and a reduction in adverse side effects.

DARUSENTAN

Darusentan is an ET_A selective ETRA that has demonstrated safety and efficacy in a Phase IIa trial in essential hypertension. We are currently preparing to initiate our **Phase IIb** clinical evaluation of darusentan in patients with resistant hypertension. Hypertension affects approximately 50 million individuals in the U.S. Despite the availability and use of several classes of drugs to treat hypertension, a significant percentage of these patients do not achieve blood pressures within the recommended range, a condition described as "resistant hypertension".

Letter to Shareholders—J. William Freytag, Ph.D.

To Our Shareholders:

Seven years ago our founders had a vision of building a company recognized for its important contributions to the treatment of cardiovascular disease. I believe that we have made tremendous progress toward achieving this vision and 2003 was a particularly rewarding year. From a nearly virtual company with an idea, Myogen has grown to become a publicly traded company with a product marketed in Europe, three product candidates in late-stage clinical evaluation and a vigorous research and development program that we partnered last year with one of the largest pharmaceutical companies in the world. Our success thus far did not happen by chance. These successes are the direct result of the hard work of the dedicated team of employees and a steadfast focus on scientific understanding at Myogen.

We believe our scientific foundation is the fundamental strength of Myogen. Our understanding of the biology of cardiovascular disease combined with our clinical development expertise provide us with the capability to discover novel therapies and identify, license or acquire products that address serious, debilitating cardiovascular disorders. This fundamental scientific understanding has guided our strategy along two business initiatives:

- Selectively in-license and acquire drugs in clinical development for which we have a unique ability to add value, and
- Leverage our understanding of cardiovascular disease at the molecular level in the discovery and development of disease-modifying therapeutics.

Many current therapies for cardiovascular disease do not adequately address the underlying molecular mechanisms of the disorders that make up the disease. We believe that our strategy provides an opportunity to improve on existing therapies and to discover and develop new therapeutics to address patients' symptoms and, perhaps, to slow or reverse the progression of cardiovascular disorders. Our progress to date reinforces our belief in this strategy.

In 2003, we achieved several major goals. We expanded our product portfolio with the in-licensing of our third product candidate, darusentan. We continued the clinical development of

"We have adopted a bold vision: to develop and commercialize disease-modifying cardiovascular therapeutics. We intend to impact cardiovascular disorders rather than merely treating their symptoms."

enoximone and ambrisentan, including: the completion of AMB-220, our Phase II study of ambrisentan in pulmonary arterial hypertension; the completion of patient enrollment in EMOTE, our Phase III study of enoximone capsules in patients with advanced chronic heart failure; and, continued patient enrollment in ESSENTIAL I & II, our pivotal Phase III studies of enoximone capsules in chronic heart failure. We also were able to accelerate and strengthen our research and development efforts through a partnership with the Novartis Institutes for BioMedical Research, Inc., an affiliate of Novartis AG. And lastly, we raised approximately $120 million of additional financing which we believe will fund the Company through the middle of next year, when we expect to have reached several additional development milestones.

The drug development process is not an easy one. These accomplishments required the commitment and teamwork of our entire staff. We believe our corporate culture promotes the initiative and creativity of individuals in support of the overall team's objectives. The collaborative interaction among our various departments enables the organization to identify, set and achieve strategic value-creating objectives.

While I am proud of our accomplishments this past year, I am equally excited by Myogen's future. We have adopted a bold vision: to develop and commercialize disease-modifying cardiovascular therapeutics. We intend to impact cardiovascular disorders rather than merely treating their symptoms. This will not be an easy task, but rather one with many risks and uncertainties. We will attempt to mitigate those risks with a strategy we believe will enhance both the long-term growth of the Company and value for our shareholders. In 2004, we will focus on continuing progress with the clinical development of our product candidates, including: initiating the Phase III studies of ambrisentan, ARIES-1&-2; completing EMOTE; completing patient enrollment and drug treatment in ESSENTIAL I & II; and initiating a Phase IIb study of darusentan in resistant hypertension.

Seven years ago we were just beginning as a new company. Now, we are starting as a public company. This is the next appropriate phase as Myogen continues its evolution toward becoming a fully integrated biopharmaceutical company with unique discovery, development and commercialization capabilities. I would like to thank all of our staff for their hard work in getting us to this point.

I look forward to updating you on our progress during the year. Thank you for your continued support.

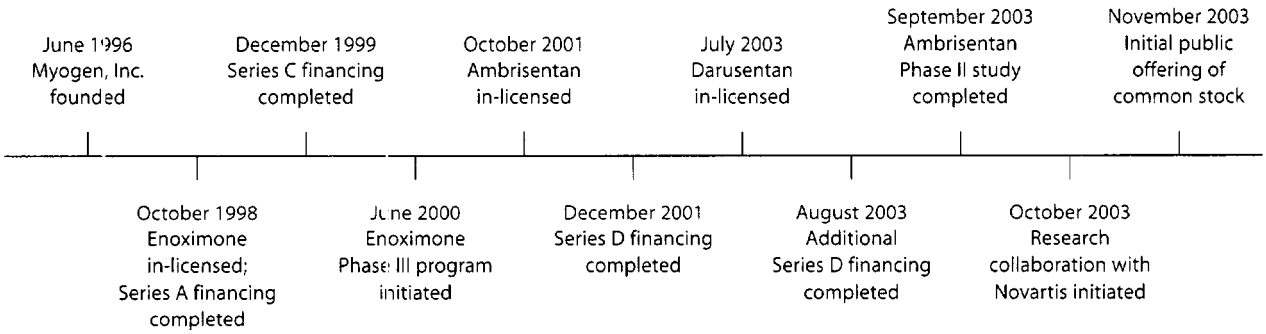
Myogen's senior management team.

J. William Freytag, Ph.D.
President and Chief Executive Officer
March 5, 2004

2004 MILESTONES

- Initiation of ARIES-1 & -2 (ambrisentan Phase III in PAH), which we announced in January;
- Completion of EMOTE (enoximone Phase III in CHF) with summary results to be reported in the first half of the year;
- Initiation of a Phase IIb trial of darusentan in resistant hypertension; and
- Completion of patient enrollment and drug treatment in ESSENTIAL I & II (enoximone Phase III in CHF)

TIMELINE:



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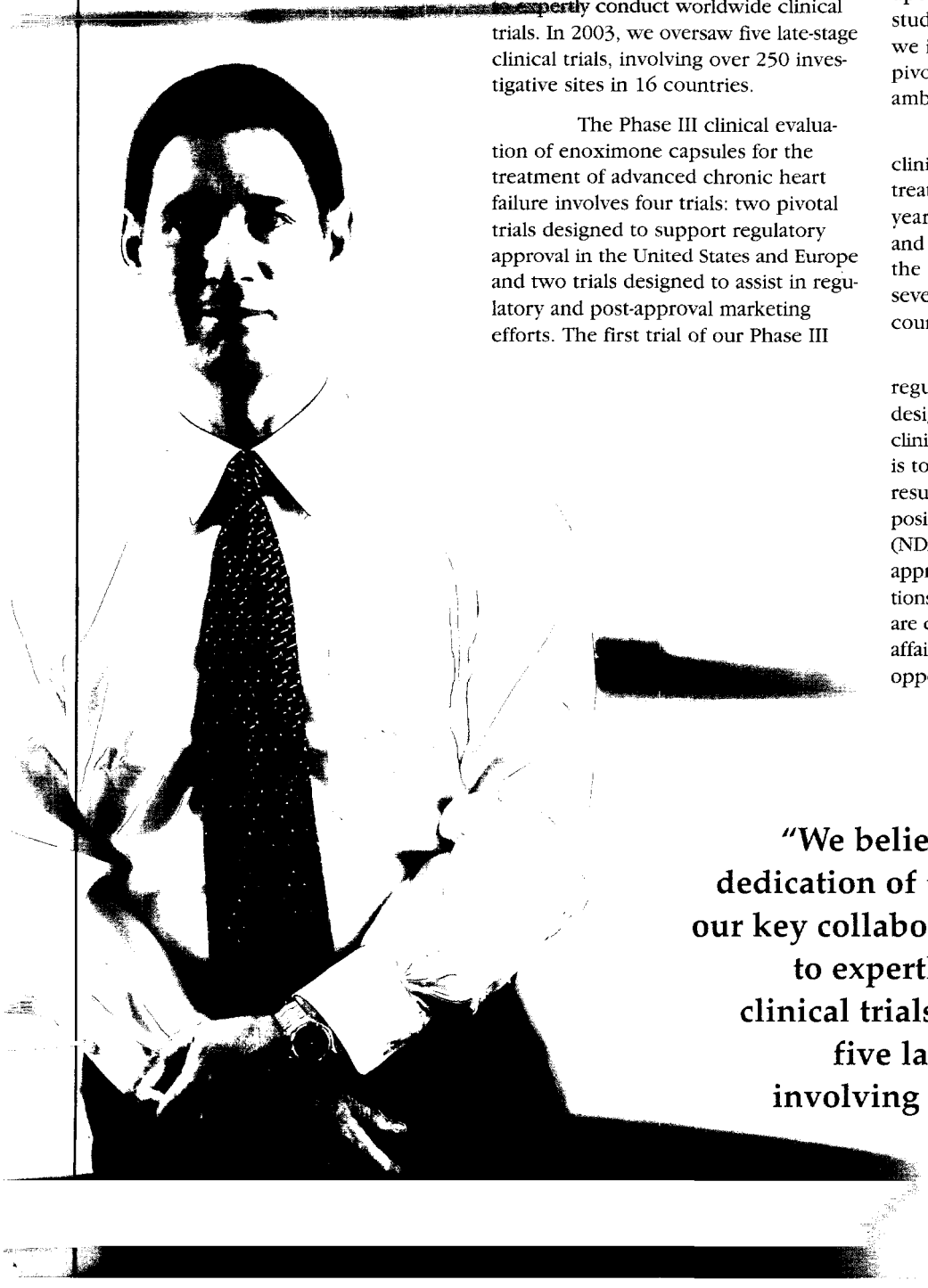
Clinical Development & Regulatory Affairs—Michael Gerber, M.D.



Myogen's clinical group is responsible for the design, conduct and analysis of clinical trials to evaluate the Company's development-stage compounds provided either through the in-licensing activity of the commercial development team or identified and developed by the research and development group. We believe the experience and dedication of the clinical group and our key collaborators enable Myogen to expertly conduct worldwide clinical trials. In 2003, we oversaw five late-stage clinical trials, involving over 250 investigative sites in 16 countries.

The Phase III clinical evaluation of enoximone capsules for the treatment of advanced chronic heart failure involves four trials: two pivotal trials designed to support regulatory approval in the United States and Europe and two trials designed to assist in regulatory and post-approval marketing efforts. The first trial of our Phase III program was initiated in June 2000. The EMOTE study was completed in February 2004. We expect patients in the pivotal trials, ESSENTIAL I & II, to complete enrollment and drug treatment this year.

The Phase II clinical evaluation of ambrisentan for the treatment of pulmonary arterial hypertension was completed in September 2003. Based upon analysis of the results of the study and interaction with the FDA, we initiated ARIES-1&-2, our two pivotal Phase III clinical trials of ambrisentan, in January 2004.

We plan to initiate the Phase IIb clinical evaluation of darusentan for the treatment of resistant hypertension this year. With the addition of new trials and the continuation of on-going trials, the clinical group will be conducting seven late-stage clinical trials during the course of 2004.

Up to now, the clinical and regulatory groups have focused on designing and conducting our various clinical trials. Our challenge for the future is to complete these studies and, if the results of our Phase III clinical trials are positive, prepare New Drug Applications (NDA) for submission to the FDA and the appropriate marketing approval applications for foreign regulatory agencies. We are currently expanding our regulatory affairs group to address these upcoming opportunities.

"We believe the experience and dedication of the clinical group and our key collaborators enable Myogen to expertly conduct worldwide clinical trials. In 2003, we oversaw five late-stage clinical trials, involving over 250 investigative sites in 16 countries."

Scientific Strategy—Michael Bristow, M.D., Ph.D.

The Myogen staff and our academic collaborators at the University of Colorado Health Science Center and the University of Texas Southwest Medical Center have made significant contributions to defining the molecular bases of cardiovascular disease. This understanding is critical to discovering and developing therapies that address the underlying mechanisms of cardiovascular disease as well as evaluating in-licensing opportunities and guiding our clinical development efforts.

We feel that our experience with enoximone emphasizes the benefits of a development strategy guided by fundamental scientific understanding. Over the past 25 years, drugs such as beta-blockers, calcium channel blockers and ACE inhibitors have helped to increase the survival times of patients who suffer from cardiovascular diseases. Despite these advances, many current therapies do not adequately address the underlying molecular mechanisms of cardiovascular disease. Cardiovascular disease remains progressive in a large portion of patients, many of who continue to deteriorate even when treated with multiple drugs simultaneously.

A prime example is chronic heart failure (CHF), a debilitating condition that occurs as the heart becomes progressively less able to pump an adequate supply of blood throughout the body. It generally occurs in patients with a long history of uncontrolled high blood pressure or in patients that have suffered a heart attack or some other heart-damaging event. It is estimated that half of all patients with CHF die within five years of diagnosis. CHF is one of the largest health problems in the developed world, with annual direct and indirect healthcare costs in the United States alone exceeding $24 billion. In the United States, approximately five million patients are afflicted with CHF, with an additional 550,000 new cases reported each year.

Based upon our evaluation of extensive clinical research and an advanced understanding of the molecular basis of chronic heart failure, we believe that enoximone capsules have the potential to both alleviate symptoms and reduce hospitalizations for patients with advanced chronic heart failure, resulting in a decrease in associated costs. This belief guided our in-licensing of enoximone from its previous sponsor and the development of our clinical program to evaluate enoximone in CHF.

"Chronic heart failure is one of the largest health problems in the developed world, with annual direct and indirect healthcare costs in the United States alone exceeding $24 billion."

Research and Development—Richard Gorczynski, Ph.D.

The goal of our target and drug discovery research is to discover and develop disease-modifying drugs for chronic heart failure and related disorders. Our discovery research involves the integration of three research programs supported by a proprietary heart tissue bank, and involves collaborations with the academic laboratories of three prominent scientists working in heart muscle disease: Dr. Eric Olson at the University of Texas Southwestern Medical Center, Dr. Michael Bristow at the University of Colorado Health Science Center and Dr. Leslie Leinwand at the University of Colorado.

The causes and effects of cardiac hypertrophy have been extensively documented, but the underlying molecular mechanisms that link the molecular signals to cell changes, or cardiac signaling pathways, remain poorly understood. Understanding pathologic cardiac signaling pathways is a central theme of Dr. Olson's laboratories and the subject of a research program that we sponsor. This work has led to the discovery of several key signaling pathways that we believe control cardiac hypertrophy and its progression to dilated cardiomyopathy. We are now screening chemical libraries with high-throughput assays based on these targets. Several lead chemical structures have been identified that block abnormal growth of heart muscle cells, or cardiomyocyte hypertrophy. Further characterization and evaluation of these compounds is underway. Our research has been supported by several Phase I and Phase II Small Business Innovation Research grants from the Federal Government.

The strength of our research program has generated interest among outside parties. In October 2003, we established a research collaboration with the Novartis Institutes for BioMedical Research, Inc. in Cambridge, Massachusetts for the discovery and development of novel drugs for the treatment of cardiovascular disease. We believe this partnership will accelerate our research in chronic heart failure while preserving Myogen's opportunity to participate in the commercialization of any products that result from our collaboration.

"Understanding pathologic cardiac signaling pathways is a central theme of Dr. Olson's laboratories and the subject of a research program that we sponsor. This work has led to the discovery of several key signaling pathways that we believe control cardiac hypertrophy and its progression to dilated cardiomyopathy."

Commercial Development—John Julian

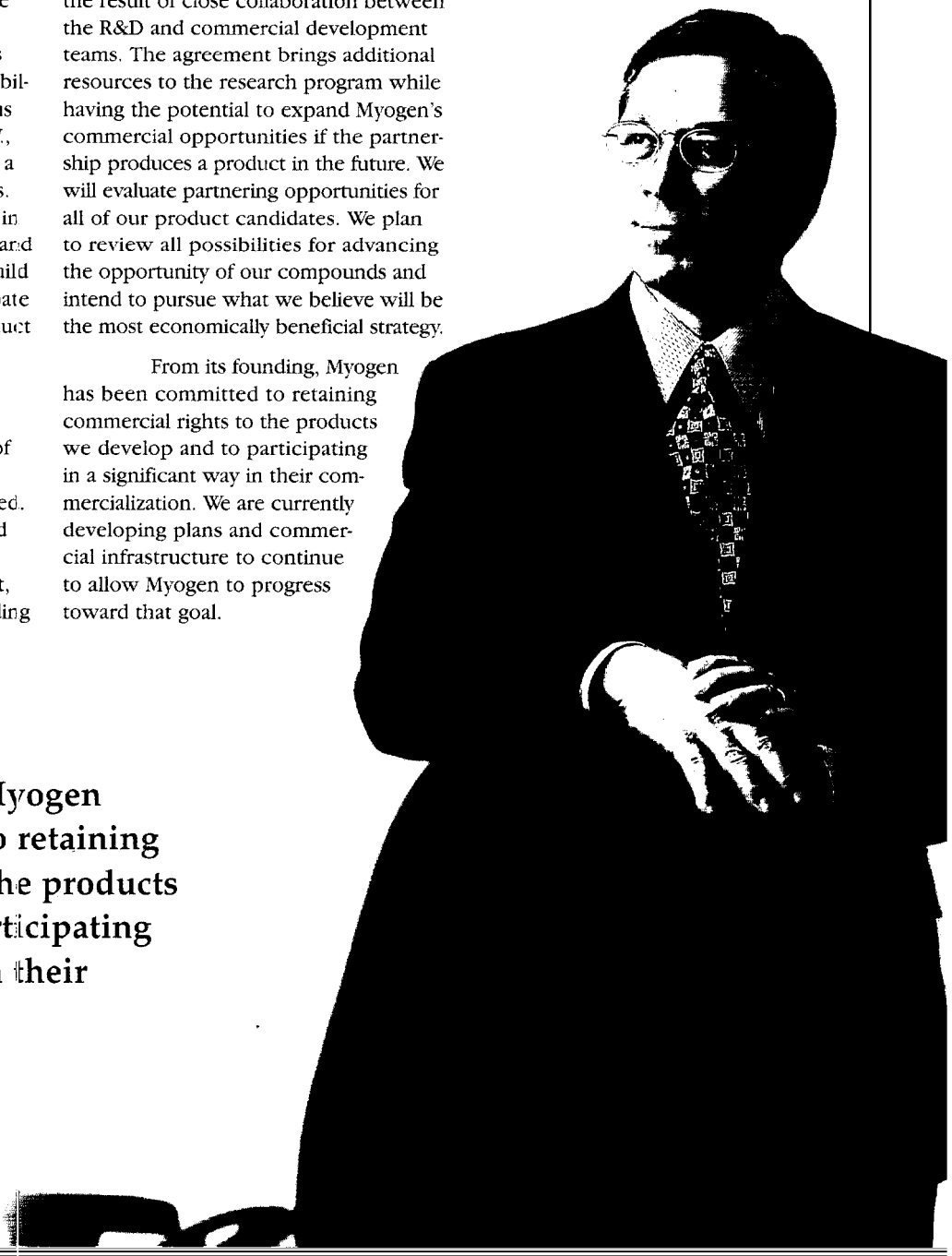
The Myogen commercial development team has four main areas of focus: existing product sales; identifying, evaluating and completing in-licensing opportunities; identifying and developing strategic collaborations with partners for the development and commercialization of our product candidates and preparing Myogen to actively participate in the commercial launches of our current product candidates should they be successful in the clinic and approved by regulatory authorities.

Myogen is somewhat unique in that we are a development stage biotechnology company that also has small, but growing, commercial capabilities. We currently sell the intravenous formulation of enoximone, Perfan I.V., in eight countries in Europe through a network of distributors and partners. Sales of Perfan I.V. were $2.8 million in 2003. We believe our European sales and marketing experience will help us build the capabilities to effectively participate in the commercialization of our product candidates, enoximone capsules, ambrisentan and darusentan.

In-licensing clinical stage compounds is a critical component of Myogen's strategy. Our three current product candidates were all in-licensed. Our ability to add value to compound development is driven by our understanding of the cardiovascular market, our fundamental scientific understanding of cardiovascular disorders and our expertise in designing and conducting cardiovascular clinical trials.

The drug development process requires that the necessary resources be available at the appropriate time to advance our product opportunities. To augment the equity financing of the Company, our team is responsible for evaluating and entering into partnering opportunities which have the ability to add to our existing resources. Our research partnership with Novartis was the result of close collaboration between the R&D and commercial development teams. The agreement brings additional resources to the research program while having the potential to expand Myogen's commercial opportunities if the partnership produces a product in the future. We will evaluate partnering opportunities for all of our product candidates. We plan to review all possibilities for advancing the opportunity of our compounds and intend to pursue what we believe will be the most economically beneficial strategy.

From its founding, Myogen has been committed to retaining commercial rights to the products we develop and to participating in a significant way in their commercialization. We are currently developing plans and commercial infrastructure to continue to allow Myogen to progress toward that goal.



"From its founding, Myogen has been committed to retaining commercial rights to the products we develop and to participating in a significant way in their commercialization."

Finance and Administration—Joseph Turner

Our group is responsible for providing the support and resources necessary to achieve Myogen's goal of becoming a fully integrated biopharmaceutical firm. This includes focusing on having: accurate, timely and transparent reporting of the Company's financial results; adequate capital available to fund the Company's operations; the appropriate staff available; and, the physical and information technology infrastructures capable of meeting the Company's needs.

In 2003, we raised $40 million in a private placement of preferred stock and approximately $80 million in our initial public offering of common stock. At the end of the year, we had $114.3 million in cash, cash equivalents and short-term investments. We believe these funds should cover the Company's operating expenses through the middle of 2005.

The fundamental vitality and strength of our Company lies in our people. Since Myogen's founding in 1996, we have grown from one employee to over 60. If our product candidates are successful in the clinic, we will need to continue to grow to prepare for regulatory submissions and commercialization of our products. Our growth will necessitate a focused human resources effort to attract and retain talented staff who thrive on the challenges integral to our industry and our Company mission.

As the Company expands, our infrastructure must be expanded to reduce the possibility of delays and work interruptions. We currently lease 28,000 square feet of office and lab space in Westminster, Colorado. This year will see a major overhaul of our IT capabilities and processes as we implement additional systems.

We also intend to continue to improve our existing, and implement additional, internal controls to ensure the Company's ability to manage the growth we anticipate as well as to comply with the many reporting and regulatory requirements that accompany being a public company. We believe we are in compliance with the provisions of the Sarbanes-Oxley legislation and will be able to comply with the additional provisions that are scheduled to take effect.

"At the end of the year, we had $114.3 million in cash, cash equivalents and short-term investments. We believe these funds should cover the companies operating expenses through the middle of 2005."

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.**

For the fiscal year ended December 31, 2003.

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

For the transition period from to

Commission file number 000-50438

Myogen, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**84-1348020**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

7575 West 103rd Avenue, Suite 102
Westminster, Colorado 80021
(303) 410-6666
(Address, including zip code, and telephone number, including area code, of principal executive offices)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock $.001 Par Value
(Title of Class)

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 (Section 229.405 of this chapter) 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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

There was no established public trading market for the Registrant's common stock as of the last business day of the Registrant's most recently completed second fiscal quarter.

As of February 23, 2004 there were 26,465,885 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this report on Form 10-K to the extent stated therein.

TABLE OF CONTENTS

PART I

Unless the context requires otherwise, references in this report to "Myogen," the "Company," "we," "us," and "our" refer to Myogen, Inc.

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements concerning our plans to continue development of our current product candidates; conduct clinical trials with respect to our product candidates; seek regulatory approvals; address certain markets; engage third-party manufacturers to supply our clinical trial and commercial requirements; hire sales and marketing personnel; and evaluate additional product candidates for subsequent clinical and commercial development. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," or "continue" or the negative of such terms and other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements not specifically described above also may be found in these and other sections of this report.

Item 1. *Business*

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapeutics for the treatment of cardiovascular disorders. We have three product candidates in late-stage clinical development: enoximone capsules for the treatment of chronic heart failure, ambrisentan for the treatment of pulmonary arterial hypertension and darusentan for the treatment of resistant hypertension. We are evaluating enoximone capsules in four Phase III clinical trials. If these trials progress as planned, we expect three of these trials, including the trials we believe will be required for regulatory approval, will be fully enrolled and patients will have completed treatment by the end of 2004. We completed a Phase II clinical trial of ambrisentan in September 2003, yielding positive results, and we initiated two pivotal Phase III clinical trials in January 2004. We intend to begin our Phase IIb clinical evaluation of darusentan in 2004. All of our product candidates are orally administered small molecules that we believe offer advantages over currently available therapies. In addition, we currently market an intravenous formulation of enoximone, Perfan I.V., for the treatment of acute decompensated heart failure in eight countries in Europe.

Through our internal research program and academic collaborations, we are developing an advanced understanding of the biological pathways of heart disease and have discovered several novel molecular targets that we believe play a key role in heart failure. We believe this understanding of the biology of cardiovascular disease combined with our clinical development expertise in cardiovascular therapeutics provide us with the capability to discover novel therapies, as well as identify, license or acquire products that address serious, debilitating cardiovascular disorders that are not adequately treated with existing therapies.

In October 2003, we entered into a research collaboration with the Novartis Institutes for BioMedical Research, Inc. ("Novartis") for the discovery and development of novel drugs for the treatment of cardiovascular disease. In exchange for a $4.0 million upfront payment, a deferred payment of an additional $1.0 million after the first year and obligations to provide research funding to us for a minimum of three years, Novartis has the exclusive right to license drug targets and compounds developed through the collaboration. Upon execution of a license, Novartis is obligated to fund all further development of the licensed product candidate, make payments to us upon the achievement of certain milestones which may total up to $17.1 million for each product candidate and pay us royalties for sales of any products that are successfully commercialized. Upon the completion of Phase II clinical trials of any product candidate Novartis has

licensed from us, we have the option to enter into a co-promotion and profit sharing agreement with them for that product candidate, subject to our reimbursement of a portion of the development expenses up to that point, our agreement to share the future development and marketing expenses and elimination of the royalty payable to us.

We were incorporated in Colorado in June 1996 and we reincorporated in Delaware in May 1998. Our website address is www.myogen.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments to those reports, are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC.

The Cardiovascular Opportunity

The term cardiovascular disease is used to describe a continuum of clinical conditions resulting primarily from three underlying chronic diseases: atherosclerosis, hypertension and diabetes. These underlying diseases cause permanent damage to the heart, blood vessels and kidneys, leading to progressively debilitating clinical conditions such as chronic heart failure, pulmonary arterial hypertension, systemic hypertension, chronic kidney disease, heart attack and stroke.

Cardiovascular disease is the leading cause of death and disability in the United States, accounting for 20% of all hospitalizations in short-stay, non-Federal hospitals and over 60% of all deaths. The American Heart Association estimated that the total direct and indirect costs of cardiovascular disease in the United States would be $300 billion in 2003, including $36 billion in drug costs and $105 billion in hospitalization and nursing home costs. Despite improved treatments and increased awareness of preventative measures, 62 million people in the United States currently suffer from cardiovascular disease.

Over the past 25 years, drugs such as beta-blockers, calcium channel blockers and angiotensin converting enzyme, or ACE, inhibitors have been used to treat various cardiovascular diseases. New classes of orally administered compounds such as endothelin receptor antagonists have been studied and recently approved for the treatment of pulmonary arterial hypertension. Intravenous hormones such as natriuretic peptide have also been introduced as a new treatment option for acute decompensated heart failure. Several of these drugs have helped to increase the survival times of patients who suffer from cardiovascular diseases. However, many current therapies do not adequately address the underlying molecular mechanisms of cardiovascular disease. Cardiovascular disease remains progressive in a large portion of patients, many of whom continue to deteriorate even when treated with multiple drugs simultaneously. We believe that recent advances in the understanding of the molecular biology of cardiovascular diseases provide an opportunity to improve on existing therapies and to discover and develop new therapeutics to ameliorate the symptoms and perhaps to slow or reverse the progression of the diseases.

Our Strategy

Our goal is to create an integrated biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics that address the fundamental mechanisms involved in cardiovascular disease, with an initial focus on chronic heart failure, pulmonary arterial hypertension and resistant hypertension. The key elements of our strategy are to:

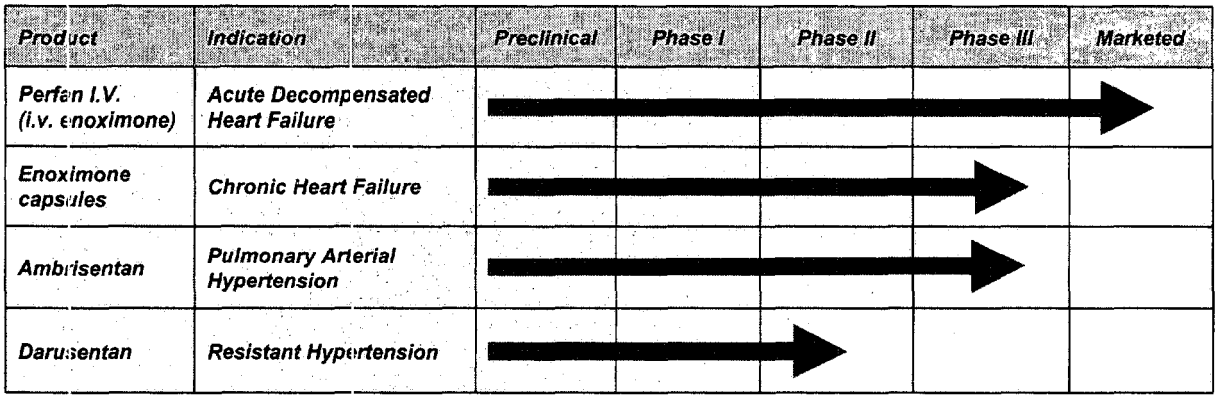
- *Complete the clinical development of our late-stage cardiovascular therapeutic product portfolio.* We are currently focused on developing and obtaining regulatory approval for three late-stage product candidates: enoximone capsules, ambrisentan and darusentan.
- *Acquire additional product candidates.* We intend to pursue attractive product acquisition opportunities. We believe our expertise in cardiovascular medicine and understanding of the biological pathways associated with cardiovascular disorders makes us an attractive partner for companies seeking to out-license product candidates.
- *Discover and develop novel therapeutics for the treatment of cardiovascular diseases.* We will continue to focus our target and drug discovery research programs and our collaborations on

discovering and developing disease-modifying therapeutics for cardiovascular disease. We entered into a research collaboration with Novartis to support these programs.

- *Develop sales and marketing capabilities.* We expect to retain significant commercial rights to all of our product candidates and plan to develop a direct sales force focused on targeted markets. We also intend to establish co-promotion arrangements with larger pharmaceutical or biotechnology firms, which would allow us to address larger markets.
- *Establish strategic collaborations.* We intend to complement our internal capabilities by selectively entering into collaborations with pharmaceutical and biotechnology companies that improve our ability to move new compounds into the clinic and new products into the marketplace.

Our Product Portfolio

Led by two of our academic founders, Dr. Michael Bristow and Dr. Eric Olson, our staff and collaborators have made significant contributions to defining the molecular bases of cardiovascular disease and improving its treatment. We believe that our expertise enables us to discover and develop therapies that address the underlying mechanisms of cardiovascular disease, evaluate and in-license product candidates and guide our clinical development efforts. We currently market one product in Europe for the treatment of acute decompensated heart failure and are developing three product candidates for three distinct cardiovascular indications.



Enoximone

Enoximone is a small organic molecule that exhibits highly selective inhibition of type-III phosphodiesterase, or PDE-III, an enzyme that is present in the heart and plays an important regulatory role in cardiac function. PDE-III inhibitors block the action of this enzyme, increasing the force of contraction of the heart, thereby increasing cardiac output. Compounds that increase the force of contraction of the heart, like enoximone, are referred to as positive inotropes. Enoximone also causes vasodilation, an increase in the diameter of blood vessels, through its effects on smooth muscle cells that surround blood vessels, which results in lower pressure against which the heart must pump. Positive inotropy and vasodilation can both be therapeutically useful in the treatment of heart failure. We are currently working to complete the clinical evaluation of enoximone capsules. If those clinical trials are successful and the required regulatory approvals are obtained, enoximone capsules would be the first PDE-III inhibitor to be commercialized in oral form for the treatment of chronic heart failure. In addition, we currently market the intravenous formulation of enoximone, Perfan I.V., which is indicated for the treatment of acute decompensated heart failure and was first approved in Europe in 1989.

Therapeutic Opportunity

Chronic heart failure, also referred to as congestive heart failure, is a debilitating condition that occurs as the heart becomes progressively less able to pump an adequate supply of blood throughout the body. Chronic

heart failure has many causes. It generally occurs in patients with a long history of uncontrolled high blood pressure or in patients that have suffered a heart attack or some other heart-damaging event. It is estimated that half of all patients with chronic heart failure die within five years of diagnosis. Chronic heart failure is one of the largest health problems in the developed world, with annual direct and indirect healthcare costs in the United States alone exceeding $24 billion. In the United States, approximately five million patients are afflicted with chronic heart failure, with an additional 550,000 new cases reported each year.

Following diagnosis, patients with chronic heart failure are typically treated with multiple oral medications, including ACE inhibitors, beta-blockers, vasodilators, diuretics and digoxin. ACE inhibitors and beta-blockers suppress the stress placed on the heart by increased levels of the hormones angiotensin and norepinephrine and have demonstrated an ability to increase patient survival time. Vasodilators and diuretics minimize the work the heart must perform by increasing the diameter of blood vessels and ridding the body of excess fluid. Digoxin is a weak positive inotrope used to increase cardiac output early in the progression of chronic heart failure.

Although medical therapy is improving, heart failure remains a major debilitating and progressive condition characterized by high mortality, frequent hospitalization and deteriorating patient quality of life. The severity of chronic heart failure is typically classified using a system established by the New York Heart Association that assesses the patient's degree of functional limitation based primarily on shortness of breath. This system is divided into four classes, I through IV, with Class IV being the most severe. Physicians use this system to track patients' disease progression and responses to therapies.

As patients enter the advanced stages of chronic heart failure, Classes III and IV, their cardiac function deteriorates, leading to an accumulation of fluid in the lungs, referred to as pulmonary congestion. Eventually, pulmonary congestion and the resulting breathlessness and fatigue reach a critical point referred to as acute decompensated heart failure. At this point the patient must be hospitalized and treated with powerful intravenous diuretics, vasodilators and positive inotropes such as dobutamine, natriuretic peptide (Natrecor), milrinone or Perfan I.V., all of which serve to increase the efficiency of the circulatory system, providing symptomatic relief. After stabilization and discharge from the hospital, patients often decompensate again within months and must be readmitted to the hospital for another round of intravenous treatment. As their disease progresses, the frequency of decompensation and hospitalization increases until patients must be maintained on continuous or intermittent treatment with these intravenous agents, which is both confining and costly.

We believe that patients with advanced chronic heart failure can benefit greatly from the chronic use of an oral inotropic agent that would provide the desired symptomatic relief to the patients and reduce the frequency of hospitalizations by delaying additional episodes of acute decompensated heart failure. An oral product with these characteristics could also wean patients with severe heart failure who are currently dependent on intravenous inotropic therapy from those agents and allow them the opportunity to leave the hospital and return to a more normal daily life. We believe that as a result of these significant clinical benefits, such an agent would decrease the overall costs associated with the treatment of heart failure. Attempts to date to develop and commercialize a product with these characteristics have been unsuccessful, primarily because of drug-related increases in adverse events, including mortality at high doses.

Based upon our evaluation of extensive clinical research and an advanced understanding of the molecular basis of chronic heart failure, we believe that enoximone capsules have the potential to both alleviate symptoms and reduce hospitalizations for patients with advanced chronic heart failure, resulting in a decrease in associated costs.

Enoximone Capsules

We are currently conducting four Phase III trials of low-dose enoximone capsules in patients with advanced chronic heart failure. If these trials progress as planned, we expect three of these trials, including the trials we believe will be required for regulatory approval, will be fully enrolled and patients will have completed treatment by the end of 2004. If our clinical program is successful, enoximone capsules will be the first oral inhibitor of PDE-III to be commercialized for the treatment of chronic heart failure.

Overview of Prior Clinical Trials

In the 1980s, Merrell Dow, now part of Aventis, conducted clinical evaluation of enoximone capsules for the treatment of chronic heart failure. Enoximone capsules were evaluated in approximately 5,000 patients with chronic heart failure in multiple Phase I and Phase II clinical trials conducted in the United States, Europe and Japan. The drug was initially tested at doses that we now consider high, 100 to 300 milligrams administered three times a day. At these high doses, patients treated with enoximone capsules demonstrated clinically significant increases in quality of life scores and maximal exercise capacity. However, in one Phase II placebo-controlled trial involving 151 patients administered enoximone capsules at doses of 100 milligrams or placebo capsules three times a day, there was a statistically significant increase in the mortality rate in the group of patients receiving enoximone capsules compared to the group receiving placebo capsules: 36% of the patients treated with enoximone capsules died during the trial versus 23% of the patients treated with placebo.

Dr. Michael Bristow, our medical founder and the principal investigator on several previous trials of enoximone capsules, made an unexpected observation during this period: enoximone capsules administered at lower doses appeared to retain efficacy without increasing mortality. Subsequently, Dr. Bristow demonstrated in a series of Phase II clinical trials that:

- enoximone capsules administered at doses of 25 and 50 milligrams three times a day increased maximal exercise capacity with no increase in mortality in patients with Class II and III chronic heart failure after 12 weeks of treatment (two trials involving 219 patients receiving placebo, 25 milligrams or 50 milligrams three times a day);
- enoximone capsules administered at doses of 25 to 75 milligrams three times a day extended the survival times of patients with Class IV chronic heart failure awaiting a heart transplant (186-patient parallel-control, open label trial, meaning that both the researcher and patient know the patient was receiving the drug); and
- enoximone capsules administered at doses of 25 and 50 milligrams three times a day enabled patients with Class IV chronic heart failure, and otherwise too weak to tolerate beta-blockers, to receive and benefit from beta-blocker therapy. These benefits included a significant reduction in the severity of their chronic heart failure symptoms and hospitalization events (30-patient, open-label trial).

In addition, Dr. Bristow conducted a series of open-label trials of enoximone capsules involving over 200 patients to gather additional clinical data. Based on this extensive clinical experience, we sought and successfully obtained a worldwide license from Aventis (formerly Hoechst Marion Roussel) to enoximone for the treatment of cardiovascular diseases and designed a clinical development program to advance enoximone capsules through the final stages of clinical development.

Overview of Current Phase III Trials

In June 2000, we initiated our Phase III program to evaluate the safety and efficacy of enoximone capsules for the long-term treatment of patients with advanced chronic heart failure. In these studies, enoximone capsules are being used in addition to standard therapies, including diuretics, ACE inhibitors and beta-blockers. Our Phase III program includes four trials designed to collectively demonstrate that enoximone capsules at doses of 25 or 50 milligrams administered three times a day are effective in reducing hospitalizations, improving symptoms of chronic heart failure, improving quality of life and reducing the need for intravenous inotropic therapy:

- EMOTE is a randomized, double-blind, placebo-controlled Phase III trial of approximately 200 patients with the most advanced stage of chronic heart failure, and who are dependent on intravenous inotrope therapy. The trial is designed to evaluate the use of enoximone capsules to wean patients off of intravenous inotrope therapy. Patients received 26 weeks of treatment. This trial is being conducted in the United States. Patient enrollment began in June 2000 and was completed in July 2003. The last patient completed treatment on February 9, 2004. We plan to analyze the data from this study in March 2004 and release results shortly thereafter. Upon completion of their participation in the trial,

patients were given the opportunity to enroll in an open-label extension, which is ongoing and may continue until enoximone capsules are commercially available or we terminate the study.

- ESSENTIAL I is a randomized, double-blind, placebo-controlled pivotal Phase III trial of approximately 900 patients with Class III and IV chronic heart failure that are being treated with beta-blockers and other therapies according to current guidelines. The trial will track the time from randomization to cardiovascular hospitalization or death for each patient as the primary endpoint. On average, patients will receive treatment for at least 12 months. This trial is being conducted in North and South America. Patient enrollment began in February 2002, and we expect to complete the treatment phase by the end of 2004.
- ESSENTIAL II is a pivotal Phase III trial identical in design and size to ESSENTIAL I. This trial is being conducted in Western and Eastern Europe. Patient enrollment began in April 2002, and we expect to complete the treatment phase by the end of 2004.
- EMPOWER is a randomized, double-blind, placebo-controlled Phase III trial of approximately 175 patients with Class III and IV chronic heart failure. Patients will be treated for 26 to 36 weeks with either (i) placebo, (ii) extended release metoprolol, a frequently prescribed beta-blocker or (iii) extended release metoprolol in combination with enoximone capsules. The primary objective of this study is to determine whether enoximone capsules can increase the tolerability to metoprolol in patients previously shown to be intolerant to beta-blocker treatment. Patient enrollment began in September 2003. EMPOWER is not required for regulatory approval, but might assist us in post-approval marketing efforts. The study is enrolling substantially slower than anticipated and we intend to re-assess the viability of the study at the end of the second quarter of 2004.

The ESSENTIAL trials will be considered completed when the accumulated cardiovascular hospitalizations or deaths for patients reaches a pre-specified number. In September 2003, we determined that the rate of occurrence to date of cardiovascular hospitalizations or deaths was lower than originally predicted. As a result, we decided to enroll an additional 400 patients, approximately 200 in each trial. If the ESSENTIAL trials progress as planned, we believe the accumulated cardiovascular hospitalizations or deaths in the trials will reach the pre-specified number by the end of 2004.

We believe that if the ESSENTIAL trials are successful, they will be adequate to support both United States regulatory approval of enoximone capsules, as well as approvals in various international markets. Although we do not believe that EMOTE and EMPOWER will be required for initial regulatory approval, we believe these studies, if completed and successful, will assist in regulatory and post-approval marketing efforts.

Perfan I.V.

Perfan I.V. is the intravenous formulation of enoximone that we market in eight European countries. Clinical studies supporting the use of Perfan I.V. were completed in the late 1980s, and the drug was first approved in Europe in 1989. Perfan I.V. is used in a hospital setting to treat patients with acute decompensated heart failure and to wean patients from cardiopulmonary bypass following open-heart surgery. We recorded sales of Perfan I.V. of $2.8 million in 2003. We believe our European sales experience helps prepare us for the potential commercial launch of future products, such as enoximone capsules, ambrisentan and darusentan.

Selective Oral Endothelin Receptor Antagonists: Ambrisentan and Darusentan

Ambrisentan and darusentan are members of a class of therapeutic agents known as endothelin receptor antagonists, or ETRAs, that can be orally administered. Endothelin is a small peptide hormone that is believed to play a critical role in the control of blood flow and cell growth. Elevated endothelin blood levels are associated with several cardiovascular disease conditions, including pulmonary arterial hypertension, chronic kidney disease, hypertension, chronic heart failure, stroke and restenosis of arteries after balloon angioplasty or stent implantation. Therefore, many scientists believe that agents that block the detrimental effects of endothelin will provide significant benefits in the treatment of these conditions. There are two classes of

endothelin receptors, ET_A and ET_B, which play significantly different roles in regulating blood vessel diameter. The binding of endothelin to ET_A receptors located on smooth muscle cells causes vasoconstriction, or narrowing of the blood vessels. However, the binding of endothelin to ET_B receptors located on the vascular endothelium causes vasodilation through the production of nitric oxide. The activity of the ET_B receptor is thought to be counter-regulatory, protecting against excessive vasoconstriction.

We believe that a significant opportunity exists for a new class of selective ETRAs that bind to the ET_A receptor in preference to the ET_B receptor. Selective ET_A antagonists are likely to block the negative effects of endothelin by preventing the harmful effects of vasoconstriction and cell proliferation, while preserving the beneficial effects of the ET_B receptor. We believe that the potential clinical benefits of selective ET_A antagonists will position these compounds as the treatment of choice for certain cardiovascular diseases.

Ambrisentan and darusentan are ETRAs that are highly selective for the ET_A receptor. The compounds demonstrate high potency, high bioavailability and half-lives that we believe may be suitable for once a day dosing. We believe the selectivity and potency of these ETRAs may offer significant advantages over non-selective ETRAs, including enhanced efficacy and a reduction in adverse side effects. We have initially chosen to evaluate ambrisentan in pulmonary arterial hypertension and darusentan in resistant hypertension.

Ambrisentan

Ambrisentan is an ET_A selective endothelin receptor antagonist being developed as an oral therapy for patients with pulmonary arterial hypertension. We completed a Phase II clinical trial of ambrisentan in September 2003 and we initiated two pivotal Phase III clinical trials for this indication in January 2004.

Therapeutic Opportunity

Pulmonary arterial hypertension is a highly debilitating disease of the lungs characterized by severe constriction of the blood vessels in the lungs leading to very high pulmonary arterial pressures. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated. Pulmonary arterial hypertension can occur with no known underlying cause, or it can occur secondary to diseases like scleroderma (an autoimmune disease of the connective tissues), cirrhosis of the liver, congenital heart defects and HIV infection. Patients with pulmonary arterial hypertension suffer from extreme shortness of breath as the heart struggles to pump against these high pressures causing such patients to ultimately die of heart failure. Pulmonary arterial hypertension afflicts approximately 40,000 patients, predominantly women, in the United States.

Mild to moderate pulmonary arterial hypertension is currently treated with calcium channel blockers, diuretics and anticoagulants. As patients advance into more severe stages of disease, moderate to severe pulmonary arterial hypertension, therapeutic options become more limited. Prior to 2001, only continuous intravenous infusion of prostacyclin (Flolan) was available as a treatment for patients with more advanced stages of pulmonary arterial hypertension. In mid-2002, Remodulin, a more stable form of prostacyclin that can be administered via continuous subcutaneous infusion, was approved by the FDA.

The most significant therapeutic advance for patients with moderate to severe pulmonary arterial hypertension took place in December 2001 with the approval of Tracleer, a twice-a-day oral formulation of bosentan, a non-selective ETRA. Tracleer was demonstrated in clinical trials to improve exercise capacity and quality of life. We believe that ambrisentan could have several additional clinical benefits over existing therapies, including:

- lower incidence of liver toxicity;
- once daily dosing based on its half-life; and
- lower incidence of adverse interactions with other drugs, including anticoagulants.

Overview of Phase II Clinical Results

In September 2003, we completed a randomized, double-blind, multi-center, dose-ranging Phase II study evaluating the effect of ambrisentan on exercise capacity of patients with moderate to severe pulmonary arterial hypertension. Exercise capacity was the primary efficacy endpoint and was measured as the change from baseline in the six-minute walk test distance after 12 weeks of treatment. The secondary endpoints were Borg Dyspnea Index, Patient Global Assessment, time to clinical worsening and World Health Organization, or WHO, Functional Class, which are tests used by physicians to assess the severity of pulmonary arterial hypertension. Right heart and pulmonary artery hemodynamics (blood pressures and blood flow in the heart and lungs) were evaluated in a subset of patients.

A total of 64 patients were randomized to one of four ambrisentan dose groups (1.0, 2.5, 5.0 or 10.0 milligrams). Doses were administered orally once a day for 12 weeks. After 12 weeks of treatment, patients were allowed to enter an optional 12-week open-label extension period of the study followed by an optional long-term open-label safety study that is currently ongoing. The results of this trial demonstrated:

- a statistically significant and clinically meaningful increase in the primary efficacy endpoint (six-minute walk test) in all four ambrisentan dose groups;
- an improvement in all secondary endpoints and pulmonary vascular hemodynamics;
- ambrisentan was generally safe and well tolerated;
- among the patients taking anticoagulant therapy, there were no apparent harmful interactions with anticoagulants requiring dose adjustments; and
- a low incidence of potential liver toxicity as assessed by liver function tests.

Abnormal elevations of liver function test (LFT) results, indicative of potential liver toxicity, have previously been reported as complications in trials of other endothelin receptor antagonists. LFT abnormalities were defined in our study as a confirmed serum aminotransferase level greater than three times the upper limit of the normal range. During the 12-week blinded treatment period of this trial, one patient was taken off ambrisentan due to an abnormally high LFT result (eight times the upper limit of the normal range). After halting treatment, the patient's serum aminotransferase level returned to a normal level without apparent adverse effects on the patient's health. During the second 12-week open-label extension period, another patient had their dose of ambrisentan reduced due to a confirmed abnormally high LFT result. Two additional patients had LFT results that fluctuated above the normal range during the open-label extension period, and on one occasion each had an initial LFT result that was marginally above the threshold of three times the upper limit of the normal range, but upon repeat testing, the results were below the threshold. Detailed results of this trial are scheduled to be presented by the principal investigator, Dr. Lewis Rubin, at the annual meeting of the American Thoracic Society on May 23, 2004.

Phase III Trials

In January 2004 we initiated two pivotal Phase III clinical trials, ARIES 1 and ARIES 2, for ambrisentan in pulmonary arterial hypertension. The ARIES trials are randomized, double-blind, placebo-controlled trials of identical design except for the doses of ambrisentan and the geographic locations of the investigative sites. The study design anticipates enrolling 186 patients (62 patients per dose group) in each trial. ARIES 1 will evaluate ambrisentan doses of 5.0 milligrams and 10.0 milligrams administered orally once per day for 12 weeks to patients in the United States and Canada. ARIES 2 will evaluate ambrisentan doses of 2.5 milligrams and 5.0 milligrams administered orally once per day for 12 weeks to patients in Europe and South America. The primary efficacy endpoint is exercise capacity, measured as the change from baseline in the six-minute walk test distance compared to placebo. Secondary endpoints include Borg Dyspnea Index, WHO Functional Class, a quality of life assessment and time to clinical worsening. Upon completion of their participation in the ARIES trials, eligible patients will be given the opportunity to enroll in an extension study.

Darusentan

Darusentan is an ET_A selective endothelin receptor antagonist being developed as an oral therapy for patients with resistant hypertension.

Therapeutic Opportunity

Hypertension affects approximately 50 million individuals in the United States and approximately one billion worldwide. Despite the availability and use of several classes of drugs (diuretics, ACE inhibitors, angiotensin receptor blockers, beta-blockers, calcium channel blockers) to treat hypertension, a very significant percentage of these patients do not achieve blood pressures within the recommended range, a condition described as "resistant hypertension." The higher the blood pressure, the greater the chance of heart attack and stroke. The relationship between blood pressure and cardiovascular events is continuous, consistent and independent of other risk factors.

The relationship between blood pressure and cardiovascular events is particularly true for patients with chronic kidney disease. Chronic kidney disease is a progressive condition that is often associated with diabetes and leads to end-stage kidney failure. Patients with end-stage kidney failure experience a high rate of mortality, primarily due to cardiovascular events such as heart attack and stroke. The National Kidney Foundation estimates that 20 million people have chronic kidney disease and an additional 20 million more are at risk of developing chronic kidney disease and that hypertension is the second leading cause of the condition in the United States, accounting for 23% of all cases. The majority of patients with chronic kidney disease suffer from hypertension and approximately 75% of all patients are being treated with anti-hypertensive agents. Unfortunately, the blood pressure of over 70% of the patients receiving anti-hypertensive therapy remains uncontrolled. We believe that there is a significant opportunity for an agent that is capable of improving control of blood pressure in this patient population, leading to the potential for enhanced patient outcomes, such as a reduction in the number of serious cardiac events.

Overview of Prior Phase II Clinical Results

In 2000, the safety and efficacy of darusentan were evaluated by Abbott Laboratories in approximately 390 patients with hypertension in a randomized, double-blind, placebo-controlled, multi-center Phase II trial. The primary endpoint in the trial was change in resting diastolic blood pressure. Changes in systolic blood pressure and pulse rate were secondary endpoints.

The results of this study demonstrated that darusentan produced statistically significant and clinically meaningful reductions in diastolic and systolic blood pressures in a dose-dependent manner. Pulse rate remained unchanged in all groups. Headache was the most commonly reported adverse event, with no relevant difference among placebo and active treatment groups. Flushing and peripheral edema were seen in a dose-dependent fashion in the active treatment groups only. There were no treatment-related abnormal elevations in liver enzymes in the study.

Overview of Planned Clinical Trial

We are finalizing the overall clinical development plan for evaluating darusentan in patients with resistant hypertension and we expect to begin a Phase IIb trial in 2004.

Other Indications

Endothelin appears to be involved in the progression of several other cardiovascular conditions, including chronic heart failure, acute renal failure, stroke and restenosis of arteries after balloon angioplasty or stent implantation. We believe that ET_A selective ETRAs, such as ambrisentan or darusentan, could have therapeutic potential in some of these indications and we are currently evaluating whether to pursue any of these additional indications.

Discovery Research

The goal of our target and drug discovery research is to discover and develop disease-modifying drugs for chronic heart failure and related disorders. Our discovery research involves the integration of three research programs supported by a proprietary heart tissue bank, and involves collaborations with the academic laboratories of three prominent scientists working in heart muscle disease: Dr. Eric Olson at the University of Texas Southwestern Medical Center (UTSWMC), Dr. Michael Bristow at the University of Colorado Health Science Center (UCHSC) and Dr. Leslie Leinwand at the University of Colorado (UC). Our internal research program, augmented by the work of our academic collaborators, has led to the identification of several novel targets for drug discovery, and we are now screening chemical libraries with high-throughput assays based on these targets. Several lead chemical structures have been identified that block abnormal growth of heart muscle cells, or cardiomyocyte hypertrophy. Further characterization and evaluation of these compounds is underway. In October 2003, we established a collaboration agreement with Novartis to advance this work.

- *Cardiac signaling pathways.* Patients with chronic heart failure develop an enlargement of the heart called cardiac hypertrophy. The causes and effects of cardiac hypertrophy have been extensively documented, but the underlying molecular mechanisms that link the molecular signals to cell changes, or cardiac signaling pathways, remain poorly understood. Understanding these signaling pathways is a central theme of Dr. Olson's laboratories at UTSWMC and the subject of a research program that we sponsor. This work has led to the discovery of several key signaling pathways that control cardiac hypertrophy.

- *Fetal gene program.* One of the characteristic changes that occur in a failing heart is a change in gene expression wherein fetal genes that were turned off shortly after birth are reactivated in the disease process. Although this response may initially be beneficial to a patient with chronic heart failure, it becomes harmful as the disease progresses. Our scientists and academic collaborators at UCHSC and UC are focused on identifying the set of fetal genes that are reactivated in chronic heart failure, understanding the consequences of their reactivation and discovering the means to control their expression. Our work has led to the discovery of what we believe to be an important gene reactivation that occurs in the failing human heart, which appears to be responsible for weakening the contraction of the heart.

- *Cardiogenomics and cardioproteomics.* We have initiated a survey of the genes (cardiogenomics) and proteins (cardioproteomics) that are expressed in normal and diseased human hearts. Knowledge of these differences might allow us to identify the complete set of genes that are involved in the disease process. Our cardiogenomics efforts have led to the identification of more than 200 genes that might be involved in the failing heart.

- *Heart tissue bank.* Through a materials transfer agreement with UCHSC, we have access to what we believe is one of the largest collections of diseased and non-diseased human heart tissue. Dr. Michael Bristow and his team have worked since 1987 in close collaboration with heart transplant centers to collect a growing quantity of high quality, well-characterized heart tissue. The heart tissue bank is a valuable resource in supporting all aspects of our target discovery program including: (i) identifying genes and proteins that are differentially expressed in human heart failure, (ii) confirming that signaling pathways discovered in animal models have relevance to human cardiovascular disease and (iii) elucidating the reactivation of fetal genes.

We believe our advanced understanding of the biology of cardiovascular disease combined with our clinical development expertise in cardiovascular therapeutics allows us to identify, license or acquire products. The Novartis collaboration presently covers nearly all of our discovery research projects. However, as we progress projects that are not funded by this partner, we intend to enter into collaborations with other pharmaceutical and biotechnology companies that allow us to build upon our expertise in cardiovascular disease. We will seek arrangements that improve our ability to move new compounds into the clinic and new products into the marketplace.

Sales and Marketing

Assuming that we receive regulatory approval for our product candidates, we plan to commercialize them by building a focused sales and marketing organization complemented by co-promotion arrangements with pharmaceutical or biotechnology partners. Our sales and marketing strategy is to:

- *Build a direct sales force.* We believe that a relatively small sales force could effectively reach the specialists and medical institutions that treat the majority of patients in indications such as advanced chronic heart failure and pulmonary arterial hypertension. We intend to build this sales force ourselves or through a contract sales organization.
- *Build a marketing organization.* We plan to build a marketing and sales management organization to develop and implement product plans and support our sales force.
- *Establish co-promotion alliances.* We intend to enter into co-promotion arrangements with larger pharmaceutical or biotechnology firms when necessary to reach larger markets than would be possible with our own sales force. For example, our Novartis collaboration grants us the option to enter into a co-promotion agreement for certain markets upon completion of Phase II clinical trials of product candidates they have licensed from us. We intend to retain the rights to ambrisentan, but we plan to explore co-promotion arrangements for enoximone. We expect to seek a co-promotion or co-development partner for darusentan.

We currently market Perfan I.V. through local distributors in Belgium, France, Germany, Ireland, Italy, Luxembourg, the Netherlands and the United Kingdom.

Licensing Agreements and Collaborations

In October 1998, we entered into a license agreement with Aventis (formerly Hoechst Marion Roussel) under which we received an exclusive worldwide license to develop and commercialize enoximone. In consideration for the license, we paid Aventis initial license fees totaling $5.5 million, and we are obligated to pay royalties based on net sales of enoximone for a period of 10 years beginning with the first commercial sale on a country-by-country basis. If we fail to commercialize enoximone capsules in certain markets, Aventis may market the product on its own in the affected countries, paying us a royalty on its sales. The agreement is of indefinite term, although Aventis may terminate the agreement if we fail to use reasonable commercial diligence to develop and commercialize enoximone capsules. In addition, either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

In October 2001, we entered into a license agreement with Abbott under which we received an exclusive worldwide license from Abbott to develop and commercialize ambrisentan. In consideration for the license, we have paid Abbott initial license fees totaling $5.8 million, have paid a milestone fee of $1.5 million upon the initiation of the ARIES trials and have accrued an additional $690,000 related to an additional feasibility and evaluation study performed on our behalf. If we successfully develop ambrisentan in pulmonary arterial hypertension, we will be required to make additional milestone payments totaling $4.5 million as well as royalties based on net sales of ambrisentan. If we fail to commercialize ambrisentan in certain markets, Abbott may market the product on its own in the affected countries, paying us a royalty on its sales. We must use reasonable diligence to develop and commercialize ambrisentan and to meet milestones in completing certain clinical work. The agreement is of indefinite term, although either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other. We would be obligated to make additional milestone payments if we develop ambrisentan in additional indications. However, in no event would we be obligated to pay more than $25.5 million in total license and milestone fees.

In June 2003, we entered into a license agreement with Abbott under which we received an exclusive worldwide license from Abbott to develop and commercialize darusentan. In consideration for the license, we paid Abbott initial license fees of $5.0 million and are obligated to make future milestone payments totaling $25.0 million if we successfully commercialize the drug for a single indication. Additional milestone payments would be due if we commercialize darusentan for additional indications. However, in no event would we be obligated to pay more than $50.0 million in total milestone and license fees. In addition, we will owe royalties

based on net sales of darusentan. If we seek a co-promotion arrangement for darusentan in any country or group of countries, Abbott has the right of first negotiation. Abbott also has the option to be our exclusive development and commercialization partner for darusentan in Japan, upon terms to be negotiated. If we do not commercialize darusentan in certain markets, Abbott may market the product on its own in the affected countries, paying us a royalty on its sales. We must use reasonable commercial diligence to develop and commercialize darusentan and to meet milestones in completing certain clinical work. The term of the agreement is indefinite, however, either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

We also hold four other license agreements relating to intellectual property and patents. In September 1998, we entered into an exclusive license agreement, with the right to sublicense, with University License Equity Holdings, Inc., (formerly University Technology Corporation), or ULEHI, an affiliate of UC, that allows us access to several different patents relating to the treatment of heart failure. This exclusive license may be subject to certain rights of the U.S. Government if any of the licensed subject matter is developed under a governmental funding agreement. We must use commercially reasonable efforts to bring one or more products to market and, in order to retain an exclusive license, must meet certain milestones, including providing forecast reports and selling a minimum amount of product. In consideration for the license, we paid ULEHI an initial fee of $5,900, and we are obligated to pay future license maintenance fees of $4,250 per annum, as well as royalties, which are based upon net sales of the licensed products. As of December 31, 2003, we accrued a $25,000 sublicense fee to ULEHI under this agreement, which was paid in February 2004. Under this license agreement, we also have the primary responsibility of applying for and maintaining any patent or intellectual property rights. ULEHI may only assume such responsibility in the event that we decide not to do so. We amended this agreement in November 2003 to modify the royalty structure and to include milestone payments for any drugs developed from the licensed technology, up to a maximum of $400,000 in the case of a drug for which an application for marketing approval is filed. This agreement may be terminated by either party upon breach of the agreement, or we may cancel the agreement upon six months notice to ULEHI.

In December 1999, we entered into a Patent and Technology License Agreement with the University of Texas System, or the University, which gives us exclusive rights, with the right to sublicense, to certain patents and technology relating to cardiac hypertrophy and heart failure. Concurrently, we entered into a Sponsored Research Agreement with the University to fund research at UTSWMC. Rights to inventions arising from the sponsored research are included within the exclusive license granted by the license agreement. This exclusive license may be subject to certain rights of the U.S. Government if any of the licensed subject matter is developed under a governmental funding agreement. In consideration for the license, we paid an initial license fee of $50,000 and are obligated to pay future annual fees of $50,000 per year beginning the first year following termination of the Sponsored Research Agreement, a percentage of sublicense revenue and royalties based upon net sales. Additionally, we are obligated to make milestone payments for any drugs developed from the licensed technology, up to a maximum of $3.2 million in the case of a drug for which a marketing application is approved. Patent prosecution and maintenance is carried out by a mutually agreed upon patent attorney, but we are obligated to reimburse the University for the associated patent costs. This license agreement will continue on a country by country basis in many cases until the last patent expires which currently is on September 26, 2022, based on patents issued to date, but could be extended. There are also provisions that allow termination of the license agreement upon breach of the license, upon our insolvency, or upon written mutual agreement between Myogen and the University. We must diligently attempt to commercialize a licensed or identified product or the University has certain rights to cancel the exclusivity of the license agreement if we fail to provide written evidence within sixty days of our commercialization attempts. Similarly, the University can completely terminate the license agreement in the future if we fail to provide written evidence of our commercialization attempts within sixty days. This license agreement is also subject to the terms of the Sponsored Research Agreement entered into concurrently with the Patent and Technology License Agreement, under which we currently pay $250,000 per annum through March 31, 2007. In 2003, we accrued a $162,500 sublicense fee to the University under this agreement which was paid in January 2004.

In January 2000, we entered into a Patent License Agreement with the University and the University of North Texas Health Science Center at Fort Worth (UNTHSC) which grants us exclusive rights, with the right to sublicense, to certain patents and technology relating to cardiac hypertrophy. This exclusive license may be subject to certain rights of the U.S. Government to the extent any of the licensed subject matter is developed under a governmental funding agreement. In consideration for the license, we are obligated to pay an annual license fee of $50,000 per year, a percentage of sublicense revenue and royalties based upon net sales. Additionally, we are obligated to make milestone payments for any drugs developed from the licensed technology, up to a maximum of $3.2 million in the case of a drug for which a marketing application is approved. Patent prosecution and maintenance is carried out by a mutually agreed upon patent attorney, but we are obligated to pay the associated patent costs. This license agreement will continue on a country by country basis in many cases until the last patent expires which currently is on October 15, 2018, based on patents issued to date, but could be extended. There are also provisions that allow termination of the license agreement upon breach of the license, upon our insolvency, or upon written mutual agreement between Myogen, the University and UNTHSC. We must actively attempt to commercialize products or the licensors have certain rights to cancel the exclusivity of the license agreement if we fail to provide written evidence of our or our sublicensees' commercialization attempts.

In January 2000, we issued 803,606 shares of Series B preferred stock in connection with the license agreements entered into in December 1999 and January 2000 with the University and UNTHSC.

In January 2002, we entered into a second Patent and Technology License Agreement, which was amended in February 2004, and related Sponsored Research Agreement with the University. The license grants us exclusive rights, with the right to sublicense, to certain patents and technology relating to cardiac hypertrophy, heart disease, and heart failure, including inventions that arise during the conduct of the sponsored research. The patent and technology license is also subject to certain rights of the U.S. Government if any of the licensed subject matter is developed under a governmental funding agreement. In consideration for this license, we paid an initial license fee totaling $35,000 and have an obligation to pay milestone payments potentially totaling $400,000, a percentage of sublicense revenue and royalties based upon a percentage of net sales. Since the expiration of the Sponsored Research Agreement, we are obligated to pay annual fees of $5,000 per year. In addition, we are obligated to reimburse the University for patent expenses. For most products, this agreement will terminate upon the expiration of the last patent to expire, which currently is on February 13, 2021 based on patents issued to date, but could be extended. There are also provisions that allow termination upon breach of the license, upon insolvency of the licensee, or upon written mutual agreement between Myogen and the University.

We continue to maintain a close working relationship with three of our academic founders: Dr. Michael Bristow, our Chief Science and Medical Officer and head of cardiology at UC, Dr. Leslie Leinwand, chairperson of molecular, cellular and developmental biology at UC and Dr. Eric Olson, chairman of molecular biology at UTSWMC. Dr. Olson serves as an active consultant, frequently visiting our laboratories and collaborating closely both in research areas and in our discussions with larger pharmaceutical firms. In the case of both laboratories, we have an option allowing us to acquire the rights to future cardiovascular discoveries. Both universities own shares of our stock.

In October 2003, we entered into a research collaboration with Novartis for the discovery and development of novel drugs for the treatment of cardiovascular disease. In exchange for signing fees to be paid to us totaling $5.0 million (a $4.0 million upfront payment and $1.0 million to be paid after the first year) and an obligation to provide research funding to us for a minimum of three years, Novartis has the exclusive right to license drug targets and compounds developed through the collaboration. Upon execution of a license for a product candidate, Novartis is obligated to fund all further development of that product candidate, make payments to us upon the achievement of certain milestones which may total up to $17.1 million for each product candidate and pay us royalties for sales if the product is successfully commercialized. The agreement provides Novartis the right to extend the collaboration for an additional period of up to two years. Thereafter, the collaboration can be extended by mutual agreement of the parties. Novartis has the right to terminate the agreement 18 months after the date of the original agreement, subject to a termination payment. The agreement can also be terminated upon breach of the license, insolvency of either party, mutual written

agreement or our sale to a competitor of Novartis. The agreement with Novartis provides that upon the completion of Phase II clinical trials of any product candidate they have licensed from us, we have an option to enter into a co-promotion and profit sharing agreement with Novartis for that product candidate in certain markets, subject to our reimbursement of development expenses incurred through the completion of the Phase II trials, our agreement to share future development and marketing costs and elimination of the royalty payable to us.

We also intend to selectively enter into collaborations with other pharmaceutical or biotechnology companies that allow us to build upon our expertise in heart disease.

Intellectual Property and Patents

The primary patents covering enoximone expired in 2000 in the United States and 2001 in most of the major markets in Europe. In the United States, the Hatch-Waxman Act of 1984 provides up to five years of market exclusivity from the date of marketing approval by the FDA for any new chemical entity. We believe that enoximone capsules will meet the Act's various criteria and therefore we expect to receive five years of marketing exclusivity in the United States, when and if enoximone capsules are approved. In Europe, similar legislative enactments provide exclusivity on the data package used by a drug sponsor to obtain registration for a product with an expired compound patent. This protection is awarded for six to 10 years, depending on the country and registration approach taken by the sponsor.

We have licensed from UC a patent with broad claims for the use of positive inotropes, including enoximone, to stabilize patients who are otherwise hemodynamically too unstable to accept beta-blocker therapy without such stabilization. The European counterpart application is currently undergoing prosecution.

We plan to commission the development of a proprietary extended-release oral form of enoximone to reduce dosing frequency to once per day. We expect that this new formulation could provide market exclusivity to the extended release formulation of enoximone capsules beyond the expiration of legislative protections for immediate release enoximone capsules.

The primary patents covering ambrisentan and darusentan expire in 2015 in the United States and most markets in Europe.

We have exclusive licenses to over 25 patent applications covering technology for the diagnosis and treatment of heart failure. Under our licenses, and associated sponsored research agreements, we have been granted a right of first refusal to certain future discoveries in the field of heart disease from UC and UTSWMC. We have either assumed responsibility for the prosecution of the patent applications or have significant input thereon.

Competition

The pharmaceutical industry is highly competitive. We face significant competition from pharmaceutical companies and biotechnology companies that are researching and selling products designed to treat cardiovascular disease. Many of these companies have significantly greater financial, manufacturing, marketing and product development resources than we do. Large pharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research capabilities than we do. Several pharmaceutical and biotechnology companies have established themselves in the field of cardiovascular disease. In addition, many universities and private and public research institutes are active in cardiovascular research, some in direct competition with us. We also must compete with these organizations to recruit scientists and clinical development personnel. Significant competitors working on treatments for chronic heart failure, pulmonary arterial hypertension and/or resistant hypertension are Actelion Ltd., Encysive Pharmaceuticals, Inc., GlaxoSmithKline plc, Orion Pharma, Speedel Group, United Therapeutics Corp., Vasogen Inc., and most other major pharmaceutical companies.

A number of companies, including Encysive Pharmaceuticals, Inc., have ET_A receptor selective antagonist compounds in later stage clinical development in indications competitive with ambrisentan.

Encysive's sitaxsentan is in clinical trials for the treatment of pulmonary arterial hypertension and could be approved for marketing before ambrisentan. Several companies have non-selective endothelin antagonists in development and on the market. In particular, Actelion Ltd. markets Tracleer (bosentan), a non-selective endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. In addition, Pfizer Inc is conducting trials to expand the label for sildenafil to include the treatment of pulmonary arterial hypertension.

Manufacturing

The production of enoximone, ambrisentan, and darusentan employ small molecule organic chemistry procedures standard for the pharmaceutical industry. We plan to continue to outsource manufacturing responsibilities for these and any additional future products. This manufacturing strategy allows us to direct our financial and managerial resources to the development and commercialization of products rather than the establishment of a manufacturing infrastructure.

Governmental Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- pre-clinical laboratory and animal tests;
- submission of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators; and
- FDA approval of a new drug application, or NDA, or NDA supplement.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any new approvals for our products will be granted on a timely basis, if at all.

Before the first clinical trial can begin, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial. In such a case, the study cannot be initiated until the IND sponsor and the FDA resolve any outstanding concerns. Our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development but there is no waiting period after the IND is open. An independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I:* The drug is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- *Phase II:* Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some

cases, a sponsor may decide to run what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II trial that could, if positive, serve as a pivotal trial in the approval of a drug.

- *Phase III:* When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical study sites.

Clinical trials are designed and conducted in a variety of ways. A "placebo-controlled" trial is one in which the trial tests the results of a group of patients, referred to as an "arm" of the trial, receiving the drug being tested against those of an arm that receives a placebo, which is a substance that the researchers know is not therapeutic in a medical or chemical sense. In a "double-blind" study, neither the researcher nor the patient knows into which arm of the trial the patient has been placed, or whether the patient is receiving the drug or the placebo. "Randomized" means that upon enrollment patients are placed into one arm or the other at random by computer. "Parallel control" trials generally involve studying a patient population that is not exposed to the study medication (i.e., is either on placebo or standard treatment protocols). In such studies experimental subjects and control subjects are assigned to groups upon admission to the study and remain in those groups for the duration of the study. An "open label" study is one where the researcher and the patient know that the patient is receiving the drug. A trial is said to be "pivotal" if it is designed to meet statistical criteria with respect to pre-determined "endpoints," or clinical objectives, that the sponsor believes, based usually on its interactions with the relevant regulatory authority, will be sufficient for regulatory approval. In most cases, two "pivotal" clinical trials are necessary for approval.

Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase IV studies may be made a condition to be satisfied after a drug receives approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA, or as part of an NDA supplement, for approval of a new indication if the product candidate is already approved for another indication. The FDA may deny approval of an NDA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA or NDA supplement does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug product is intended to treat a chronic disease, as is the case with the product candidates we are developing, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for new indications for our product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in

restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for enoximone or ambrisentan would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing Practices, or cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers in order to ensure that the product meets applicable specifications. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new diseases for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

RISK FACTORS

Our business faces significant risks. These risks include those described below and may include additional risks of which we are not currently aware or which we currently do not believe are material. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition or results of operations could be materially adversely affected. These risks should be read in conjunction with the other information set forth in this report.

Risks Related to Our Business

We are at an early stage of development as a company and we do not have, and may never have, any products that generate significant revenues.

We are at an early stage of development as a biopharmaceutical company, and we do not have any commercial products that generate significant revenues. Our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenues. Our efforts may not lead to commercially successful drugs, for a number of reasons, including:

- our product candidates may not prove to be safe and effective in clinical trials;
- we may not be able to obtain regulatory approvals for our product candidates or approvals may be narrower than we seek;
- we may not have adequate financial or other resources to complete the development and commercialization of our product candidates; or
- any products that are approved may not be accepted in the marketplace.

Other than sales of Perfan I.V. in Europe, which are only minor, we do not expect to be able to market any of our product candidates for a number of years. If we are unable to develop, receive approval for, or successfully commercialize any of our product candidates, we will be unable to generate significant revenues. If our development programs are delayed, we may have to raise additional capital or reduce or cease our operations.

We have a history of operating losses and we may never become profitable.

We have experienced significant operating losses since our inception in 1996. At December 31, 2003, we had an accumulated deficit of $118.5 million. For the year ended December 31, 2003 we had an operating loss of $43.0 million and for the years ended December 31, 2002 and 2001, we had operating losses of $28.8 million and $17.8 million, respectively. Revenues from the commercial sales of our only approved product, Perfan I.V., were $2.8 million and $2.3 million for the years ended December 31, 2003 and 2002, respectively, and we will not achieve profitability from the sales of this product alone. We also do not expect that research and development revenue, which was $1.0 million in 2003, will become sufficient for us to achieve profitability. We have funded our operations principally from the sale of our equity securities. We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials and research and development efforts. To become profitable, we, either alone or with our collaborators, must successfully develop, manufacture and market our product candidates, or continue to identify, develop, acquire, manufacture and market other new product candidates. We may never have any significant revenues or become profitable.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates or continue our research and development programs.

Our operations have consumed substantial amounts of cash since inception. To date, our sources of cash have been primarily limited to the sale of our equity securities. We expect to continue to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our product candidates, manufacturing clinical supplies and expanding our discovery research programs. In 2003, our

operations consumed approximately $2.6 million of cash per month, compared to $2.2 million of cash per month in 2002. This rate of cash consumption was reduced by research and development funding by an average of $0.5 million per month. We expect that our monthly cash used by operations will continue to increase for the next several years. We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our drug development or discovery research programs. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

We may experience delays in our clinical trials that could adversely affect our financial position and our commercial prospects.

With the exception of EMOTE, we do not know when our current clinical trials will be completed, if at all. We also cannot accurately predict when other planned clinical trials will begin or be completed. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Other companies are conducting clinical trials and have announced plans for future trials that are seeking or likely to seek patients with the same diseases as those we are studying. Competition for patients in cardiovascular disease trials is particularly intense because of the limited number of leading cardiologists and the geographic concentration of major clinical centers. Our Phase III ARIES trials for ambrisentan include placebo control groups, which may decrease the pace of enrollment compared to our Phase II trial. As a result of all of these factors, our trials may take longer to enroll patients than we anticipate. Delays in patient enrollment in the trials may increase our costs and slow down our product development and approval process. In addition, two of our current clinical trials for enoximone capsules are designed to continue until a pre-specified number of events have occurred to the patients enrolled. Trials such as these are subject to delays stemming from patient withdrawal and from lower than expected event rates, in addition to the risk of slower than anticipated patient enrollment. These trials may also incur increased costs if enrollment is increased in order to achieve the desired number of events. Our product development costs will also increase if we need to perform more or larger clinical trials than planned. Any delays in completing our clinical trials will delay our ability to generate revenue from product sales, and we may have insufficient capital resources to support our operations. Even if we do have sufficient capital resources, our ability to become profitable will be delayed.

Adverse events in our clinical trials may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Our product candidates may produce serious adverse events. These adverse events could interrupt, delay or halt clinical trials of our product candidates and could result in the Food and Drug Administration, or FDA, or other regulatory authorities denying approval of our product candidates for any or all targeted indications. An independent data safety monitoring board, the FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. We cannot assure you that any of our product candidates will be safe for human use.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in-licensed the product candidates.

We are developing product candidates, including enoximone capsules, ambrisentan and darusentan, that we have in-licensed from other pharmaceutical companies. Many of the pre-clinical studies and some of the

clinical studies on these product candidates were conducted by other companies before we in-licensed the product candidates. In some cases, the studies were conducted when regulatory requirements were different from today. We would incur unanticipated costs and experience delays if we were required to repeat some or all of those studies. Even if the previous studies are acceptable to regulatory authorities, we may have to spend additional time analyzing and presenting the results of the studies. Problems with the previous studies could cause our regulatory applications to be delayed or rejected. For example, as a result of changing regulatory standards, we may be required to repeat certain animal toxicology studies for enoximone prior to the submission of our application for marketing approval. If we must repeat these studies, we would experience an increase in our expenditures and the final regulatory approval of enoximone could be jeopardized or delayed.

If our product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and we will be unable to market them.

Other than Perfan I.V., which is approved for use in several European countries, our current product candidates, enoximone capsules, ambrisentan and darusentan, are in clinical development and have not received regulatory approval from the FDA or any foreign regulatory authority.

The regulatory approval process typically is extremely expensive, takes many years and the timing of any approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell such products and therefore may never be profitable.

As part of the regulatory approval process, we must conduct pre-clinical studies and clinical trials for each product candidate to demonstrate safety and efficacy. The number of pre-clinical studies and clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results and regulations applicable to any particular product candidate.

The results of pre-clinical studies and initial clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. We cannot assure you that the data collected from the pre-clinical studies and clinical trials of our product candidates will be sufficient to support FDA or other regulatory approval. In addition, the continuation of a particular study after review by an independent data safety monitoring board does not necessarily indicate that our product candidate will achieve the clinical endpoint.

The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- a product candidate may not be safe or effective;
- the manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work.

Any delay in, or failure to receive or maintain, approval for any of our products could prevent us from ever generating meaningful revenues or achieving profitability.

Even if our products meet safety and efficacy endpoints in clinical trials, regulatory authorities may not approve them, or we may face post-approval problems that require withdrawal of our products from the market.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our interpretations of data from pre-clinical studies and clinical trials. Regulatory agencies also may approve a product candidate for fewer indications than requested or may grant approval subject to the performance of post-marketing studies for a product candidate. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Even if we receive regulatory approvals, our product candidates may later exhibit adverse effects that limit or prevent their widespread use or that force us to withdraw those product candidates from the market. In addition, a marketed product continues to be subject to strict regulation after approval. Any unforeseen problems with an approved product or any violation of regulations could result in restrictions on the product, including its withdrawal from the market. Any delay in, or failure to receive or maintain regulatory approval for, any of our products could prevent us from ever generating meaningful revenues or achieving profitability.

There can be no assurance that enoximone capsules do not increase mortality.

Clinical trials with type-III phosphodiesterase, or PDE-III, inhibitors, including enoximone capsules, have shown that at certain doses these compounds can increase the risk of mortality in specific patient populations. In studies of enoximone capsules administered at doses of 100 to 300 milligrams three times a day, some patients experienced abnormal rhythms in the beating of the heart. In one Phase II placebo-controlled trial involving 151 patients administered placebo capsules or enoximone capsules at 100 milligrams three times a day, there was a statistically significant increase in the mortality rate in the group of patients receiving enoximone capsules compared to the group of patients receiving placebo capsules: 36% of the patients treated with enoximone capsules died during the evaluation period versus 23% of the patients treated with placebo. We are testing enoximone capsules administered at doses of 25 and 50 milligrams three times a day. We cannot assure you that a similar mortality effect will not occur at these lower doses in our clinical trials or in commercial usage after approval. If we are unable to clearly demonstrate that mortality is not increased by enoximone capsules at these lower doses, we are not likely to receive regulatory approval to market enoximone capsules.

Endothelin receptor antagonists, including ambrisentan and darusentan, have demonstrated toxicity in animals.

Prior to regulatory approval for a product candidate, we are required to conduct studies of our product candidates on animals to determine if they have the potential to have toxic effects. The toxicology tests for ambrisentan and darusentan indicated that they both cause birth defects in rabbits. Other toxicology tests indicated that ambrisentan and darusentan caused damage to the testes causing infertility in rodents and that ambrisentan had the potential to cause damage to the testes in dogs. We assume that similar toxicities could occur in humans. As a result, the FDA will only consider approving ambrisentan and darusentan for the treatment of severe diseases such as pulmonary arterial hypertension or resistant hypertension and will prohibit their use in women who may become pregnant.

Market acceptance of our product candidates is uncertain.

We cannot assure you that physicians will prescribe or patients will use enoximone capsules, ambrisentan or darusentan, if they are approved. Physicians will prescribe our products only if they determine, based on experience, clinical data, side effect profiles and other factors, that they are preferable to other products then in use or beneficial in combination with other products. Recommendations and endorsements by influential physicians will be essential for market acceptance of our products, and we may not be able to obtain these recommendations and endorsements. Because of prior reports of increased mortality caused by high dose enoximone capsules in earlier clinical trials, physicians may be unwilling to use enoximone capsules in treating their patients. Physicians may not be willing to use ambrisentan and darusentan because of demonstrated adverse side effects such as damage to testes in some animal species. Additionally, market acceptance of endothelin receptor antagonists will be limited because they are known to cause birth defects in animals and are believed to do the same in humans.

Enoximone capsules for the treatment of chronic heart failure and ambrisentan for the treatment of pulmonary arterial hypertension both address highly competitive markets and the availability of other drugs and devices for the same indications may slow or reduce market acceptance of our products. Drugs such as beta blockers, angiotensin converting enzyme inhibitors and diuretics have been on the market for many years, and physicians have experience with prescribing these products for the treatment of chronic heart failure. Tracleer, a non-selective endothelin receptor antagonist, is a drug that has been approved for pulmonary

arterial hypertension, the same indication we intend for ambrisentan, and has been available since December 2001. Adoption of ambrisentan may be slow if physicians continue to prescribe Tracleer. In addition, sitaxsentan, an ET_A selective endothelin receptor antagonist like ambrisentan, is in clinical trials for the treatment of pulmonary arterial hypertension. Sitaxsentan is at a more advanced stage of development than ambrisentan and could be on the market before ambrisentan. If sitaxsentan is approved and achieves market acceptance prior to ambrisentan, the adoption of ambrisentan may be slowed or reduced.

Many other factors influence the adoption of new pharmaceuticals, including marketing and distribution restrictions, adverse publicity, product pricing and reimbursement by third-party payors. Even if our product candidates achieve market acceptance, the market may not be large enough to result in significant revenues. The failure of our product candidates to achieve market acceptance would prevent us from ever generating meaningful product revenues.

If we become subject to product liability claims, the damages may exceed our insurance.

It is impossible to predict from the results of animal studies the potential adverse effects that a product candidate may have in humans. We face the risk that the use of our product candidates in human clinical trials will result in adverse effects. If we complete clinical testing for our product candidates and receive regulatory approval to market our products, we will mark our products with warnings that identify the known potential adverse effects and the patients who should not receive our product. We cannot assure that physicians and patients will comply with these warnings. In addition, unexpected adverse effects may occur even with use of our products that have received approval for commercial sale.

In pre-clinical testing, ambrisentan and darusentan caused birth defects in animals. Based on these results and similar results with other endothelin receptor antagonists, we have concluded that ambrisentan and darusentan could cause birth defects in humans. Neither ambrisentan nor darusentan should be taken by women who are pregnant, or are capable of getting pregnant and not practicing adequate forms of birth control; however, there can be no assurance that ambrisentan or darusentan will not be taken by these women. Additionally, there can be no assurance that a patient will not exceed the recommended dose of our products and suffer adverse consequences. If a child is born with a birth defect or a patient suffers harm from exceeding the approved dose on our products, we may be subject to product liability claims that exceed any insurance coverage that may be in effect at the time.

We have obtained liability insurance of $10 million for Perfan I.V. and our product candidates in clinical trials. We cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we currently hold, or that we or our collaborators may obtain, may not be adequate to protect us from any liabilities. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. We may be unable to obtain additional coverage or afford such coverage. We may not have sufficient resources to pay for any liabilities resulting from a claim beyond the limit of our insurance coverage. If we cannot protect against potential liability claims, we or our collaborators may find it difficult or impossible to commercialize our products. We may not be able to renew or increase our insurance on reasonable terms, if at all.

If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our products effectively.

We have limited experience in sales, marketing and distribution. To directly market and distribute any products, we must build a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product

revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

Since we will rely on third-party manufacturers, we may be unable to control the availability or cost of producing our products.

There can be no assurance that our products, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. Although there are several potential manufacturers capable of manufacturing our products, we intend to select and rely initially on one third-party to manufacture each of our approved products. Establishing a replacement source for any of our products could require at least 12 months and significant additional expense. We will need to expand relationships with manufacturers we have used in the past or establish new relationships with different third-party manufacturers for our products. We may not be able to contract for manufacturing capabilities on acceptable terms, if at all. Furthermore, third-party manufacturers may encounter manufacturing or quality control problems or may be unable to obtain or maintain the necessary governmental licenses and approvals to manufacture our products. Any such failure could delay or prevent us from receiving regulatory approvals and marketing our products. Our dependence on third parties may reduce our profit margins and delay or limit our ability to develop and commercialize our products on a timely and competitive basis.

Our third-party manufacturers and their manufacturing facilities and processes are subject to regulatory approval, which may delay or disrupt our development and commercialization efforts.

Third-party manufacturers of our products or product candidates must ensure that all of the processes, methods and equipment are compliant with the current Good Manufacturing Practices, or cGMP, and conduct extensive audits of vendors, contract laboratories and suppliers. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. Compliance by third-party manufacturers with cGMP requires record keeping and quality control to assure that the product meets applicable specifications and other requirements. Manufacturing facilities are subject to inspection by regulatory agencies at any time. If an inspection by regulatory authorities indicates that there are deficiencies, third-party manufacturers could be required to take remedial actions, stop production or close the facility, which would disrupt the manufacturing processes and limit the supplies of our products or product candidates. If they fail to comply with these requirements, we also may be required to curtail the clinical trials of our product candidates, and may not be permitted to sell our products or may be limited in the jurisdictions in which we are permitted to sell them.

Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we are unable to directly control the timing, conduct and expense of our clinical trials.

We rely primarily on third parties to conduct our clinical trials, including the EMOTE, ESSENTIAL and ARIES trials, as well as the planned clinical trials for darusentan. As a result, we have had and will continue to have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

If we do not find development and commercialization collaborators for our product candidates, we may have to reduce or delay our rate of product development and commercialization and increase our expenditures.

Our existing collaborations have been with academic scientists and institutions for basic scientific research and we recently entered into a research collaboration with Novartis relating to targets and compounds identified in our discovery research program. To date, we have not entered into any collaboration agreements for the development or commercialization of our existing product candidates. We plan to enter into relationships with selected pharmaceutical or biotechnology companies to help develop and commercialize our product candidates. We may not be able to negotiate collaborations with these other companies for the development or commercialization of our product candidates on acceptable terms. If we are not able to establish such collaborative arrangements, we may have to reduce or delay further development of some of our programs, increase our planned expenditures and undertake development and commercialization activities at our own expense.

If we enter into development or commercialization collaborations with pharmaceutical or biotechnology companies, including a license agreement or a co-promotion and profit sharing agreement with Novartis, these relationships will also be subject to a number of risks, including:

- collaborators may not pursue further development and commercialization of compounds resulting from collaborations or may elect not to renew research and development programs;
- collaborators may delay clinical trials, underfund a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require the development of a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of these products; and
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant legal proceedings.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and review.

Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, we or our third-party manufacturers will be required to adhere to regulations setting forth current good manufacturing practices. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. Furthermore, we or our third-party manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign authorities before obtaining marketing approval and will be subject to periodic inspection by these regulatory authorities. Such inspections may result in compliance issues that could prevent or delay marketing approval, or require the expenditure of financial or other resources to address. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Our success depends on retention of our President and Chief Executive Officer, Chief Science and Medical Officer and other key personnel.

We are highly dependent on our President, Chief Executive Officer and Chairman, J. William Freytag, Ph.D., Chief Science and Medical Officer, Michael R. Bristow, M.D., Ph.D. and other members of our management team. We are named as the beneficiary on term life insurance policies covering Drs. Freytag and Bristow in the amount of $2.0 million each. We also depend on academic collaborators for each of our research and development programs. The loss of any of our key employees or academic collaborators could

delay our discovery research program and the development and commercialization of our product candidates or result in termination of them in their entirety. Drs. Freytag and Bristow, as well as others on our executive management team, have severance agreements with us, but the agreements provide for "at-will" employment with no specified term. Our future success also will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unsuccessful in our recruitment and retention efforts, our business will be harmed.

We also rely on consultants, collaborators and advisors to assist us in formulating and conducting our research. All of our consultants, collaborators and advisors are employed by other employers or are self-employed and may have commitments to or consulting contracts with other entities that may limit their ability to contribute to our company.

If our discovery research program is not successful, we may be unable to develop additional product candidates.

We have devoted and expect to continue to devote significant resources to our discovery research program. For the years ended December 31, 2003, 2002 and 2001, we spent $3.3 million, $3.5 million and $2.4 million, respectively, on our discovery research program. We are obligated under sponsored research agreements to make annual payments of $350,000 to the University of Texas Southwestern Medical Center. However, this program may not succeed in identifying additional therapeutic targets, product candidates or products. If we do not develop new products, and if our existing product candidates do not receive regulatory approval or achieve commercial success, we would have no other way to achieve any meaningful revenue. Moreover, if we do not develop new products, our revenues from any of our product candidates that are approved will eventually decline as they face competition when any applicable patents, or periods of market exclusivity expire. The collaboration agreement we entered into with Novartis in October 2003 provides Novartis with an exclusive option to all of our discoveries for a three year period. Novartis may choose to terminate or not renew the agreement with us, possibly delaying our development programs and increasing our operating loss.

Our operations may be impaired unless we can successfully manage our growth.

We expect to continue to expand our research and development, product development, sales and marketing and administrative operations. Our number of employees and operational spending have nearly quadrupled since fiscal year 2000. This expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. To manage further growth, we will be required to improve existing, and implement additional, operational and financial systems, procedures and controls and hire, train and manage additional employees. We cannot assure that (i) our current and planned personnel, systems, procedures and controls will be adequate to support our anticipated growth, (ii) management will be able to hire, train, retain, motivate and manage required personnel or (iii) management will be able to successfully identify, manage and exploit existing and potential market opportunities. Our failure to manage growth effectively could limit our ability to achieve our research and development and commercialization goals.

If we engage in any acquisition, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

Since our inception, we have acquired three product candidates through in-licensing. One of our strategies for business expansion is the acquisition of additional products and product candidates. We may attempt to acquire these product candidates, or other potentially beneficial technologies, through in-licensing or the acquisition of businesses, services or products that we believe are a strategic fit with our business. Although we currently have no commitments or agreements with respect to any acquisitions, if we undertake an acquisition, the process of integrating the acquired business, technology, service or product may result in

unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits of any acquisition for a variety of reasons, such as an acquired product candidate proving to not be safe or effective in later clinical trials. We may fund any future acquisition by issuing equity or debt securities, which could dilute your ownership percentage. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed.

Our attempts to increase future sales of Perfan I.V. may be unsuccessful.

Our current revenue is derived solely from European sales of Perfan I.V. and we recorded $2.8 million in sales of this product in 2003. The revenue we receive on sales of Perfan I.V. currently exceeds our costs associated with having it manufactured and sold. The sales of Perfan I.V. fund our European sales efforts and help offset some of the costs we incur to develop our product candidates. We believe that our sales and marketing efforts in Europe will, at most, lead to only modest increases in Perfan I.V. sales, and sales may decline over time due to the expiration of patent protection for Perfan I.V. and competition from other drugs sold for the same indication as Perfan I.V., some of which sell for significantly lower prices. If we do not maintain or increase our sales of Perfan I.V. in Europe, our operating losses will increase. We could also be forced to discontinue our European sales program, depriving us of potential commercialization and sales experience and contacts which may be important for the successful commercial launch of any of our product candidates that receive regulatory approval. We are evaluating the costs and potential benefits of developing and commercializing Perfan I.V. in the United States. However, if we undertake this program, we may not be able to achieve sufficient sales to justify the time, capital and resources expended.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company with 57 employees, 24% of whom have joined us in the last 12 months. We also have significantly fewer employees than many other companies that have the same or fewer product candidates in late stage clinical development and we rely heavily on third parties to conduct many important functions. Further, as a publicly traded company we are subject to significant regulations, some of which have either only recently been adopted or are currently proposals subject to change. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, we cannot assure that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Our operations involve hazardous materials, and compliance with environmental laws and regulations is expensive.

Our research and development activities involve the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, radioactive materials including tritium and phosphorus-32 and biological materials including human tissue samples that have the potential to transmit diseases. Our operations also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling and disposal of these materials. We generally contract with third parties for the disposal of such substances and store certain low level radioactive waste at our facility until the materials are no longer considered radioactive. While we believe that we comply with current regulatory requirements, we cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with

civil penalties or criminal fines and in complying with environmental laws and regulations. Although we carry a $2.0 million pollution and remediation insurance policy, we cannot assure that this would be sufficient to cover our potential liability if we experienced a loss.

Currency fluctuations may negatively affect our financial condition.

We sell Perfan I.V. in Europe and also expect to commercialize other products outside the United States and, as a result, our business is affected by fluctuations in foreign exchange rates between the U.S. dollar and foreign currencies. Our reporting currency is the U.S. dollar and, as a result, financial positions are translated into U.S. dollars at the applicable foreign exchange rates. Our revenues are denominated in foreign currencies while the majority of our expenses are denominated in U.S. dollars. As exchange rates fluctuate, such fluctuations may adversely affect our results of operations, financial position and cash flows. In addition, we conduct clinical trials in many countries, exposing us to cost increases if the U.S. dollar declines in value compared to other currencies.

Risks Related to Our Industry

Our competitors may develop and market drugs that are less expensive, more effective or safer than our product candidates.

The pharmaceutical market is highly competitive. Many pharmaceutical and biotechnology companies have developed or are developing products that will compete with products we are developing. Several significant competitors are working on, or already have approval for, drugs for the same indications as enoximone capsules, ambrisentan and darusentan. It is possible that our competitors will develop and market products that are less expensive, more effective or safer than our future products or that will render our products obsolete. Some of these products are in late-stage clinical trials. It is also possible that our competitors will commercialize competing products before any of our product candidates are approved and marketed. Actelion Ltd. received FDA approval in December 2001 for Tracleer, a non-selective endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. United Therapeutics Corp. received FDA approval in May 2002 for Remodulin for the treatment of pulmonary arterial hypertension. GlaxoSmithKline plc markets Flolan for pulmonary arterial hypertension. Encysive Pharmaceuticals, Inc. is developing sitaxsentan, an ET_A selective endothelin receptor antagonist which has demonstrated efficacy in a Phase IIb/III study and may be approved for pulmonary arterial hypertension earlier than ambrisentan. A number of other companies, including Abbott Laboratories, have ET_A selective endothelin receptor antagonists in late-stage clinical development and could compete with ambrisentan and darusentan. We expect that competition from pharmaceutical and biotechnology companies, universities and public and private research institutions will increase. Many of these competitors have substantially greater financial, technical, research and other resources than we do. We may not have the financial resources, technical and research expertise or marketing, distribution or support capabilities to compete successfully.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

- government and health administration authorities;
- private health insurers;
- managed care programs; and
- other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting

both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, their market acceptance may be reduced.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is the discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at a lower price. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003 the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our products, adversely affecting our profitability. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

Changes in or interpretations of accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for business and market practices of biopharmaceutical companies, including policies regarding expensing stock options, are subject to further review, interpretation and guidance from relevant accounting authorities, including the Securities and Exchange Commission, or SEC. For example, we currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. Although the standards have not been finalized and the timing of a final statement has not been established, the FASB has announced their support for recording expense for the fair value of stock options granted. If we were to change our accounting policy to record expense for the fair value of stock options granted and retroactively restate all prior periods presented, then our operating expenses could increase. We rely heavily on stock options to compensate existing employees and attract new employees. If we are required to expense stock options, we may then choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. If we did not reduce our reliance on stock options, our reported losses would increase. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

Risks Related to Our Intellectual Property

Since we will not obtain additional patent protection for enoximone capsules, we expect to rely solely on the Hatch-Waxman Act and similar foreign statutes to obtain market exclusivity.

The primary composition of matter patents covering enoximone have expired. We therefore have no direct means to prevent third parties from making, selling, using or importing enoximone in the United States, Europe or Japan. Instead, we expect to rely upon the United States Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, and applicable foreign legislation, to achieve market exclusivity for enoximone capsules. For new drug applications, or NDAs, for new chemical entities not previously approved, the Hatch-Waxman Act provides for marketing exclusivity to the first

applicant to gain approval for a particular drug by prohibiting acceptance or approval of an abbreviated new drug application, or ANDA, from a generic competitor for up to five years after approval of the original NDA. This exclusivity only applies to submissions of an ANDA and would not prevent a third party from conducting pivotal clinical trials and thereafter filing a complete regulatory submission for enoximone. Our competitors will be free during any period of statutory exclusivity to develop the data necessary either to file an ANDA at the end of the exclusivity period or to conduct studies in support of a complete NDA filing during the period of market exclusivity. Japanese law may provide us with marketing exclusivity in that country for a period up to six years following Japanese marketing approval. Although statutory market exclusivity in Europe, the United States and Japan may apply even when the composition of matter patent has already expired, it is possible that enoximone will not qualify for such exclusivity, or alternatively, the terms of the Hatch-Waxman Act, or similar foreign statutes, could be amended to our disadvantage. If we do not qualify for marketing exclusivity for enoximone capsules, the competition we face would increase, reducing our potential revenues.

We may not be able to extend market exclusivity for enoximone capsules by developing an extended release formulation.

Our current strategy includes attempting to obtain an additional period of market exclusivity for enoximone capsules by developing an extended release formulation before the marketing exclusivity period for enoximone capsules ends. We have not yet identified a specific extended release formulation. If we pursue this development strategy, we expect to file for and obtain patents covering the specific formulation developed, as well as its use for the treatment of various diseases. If we successfully develop an extended release formulation of enoximone capsules and successfully conduct clinical trials to demonstrate its safety and efficacy, a separate three years of marketing exclusivity could be obtained. This would not, however, prevent a competitor from filing an ANDA for the immediate release formulation after expiration of the five-year exclusivity period. There can be no assurance that such an extended release formulation will be successfully developed in a timely manner, that adequate patent protection can be obtained or that any such formulation would provide a commercial advantage. In addition, many third parties have patents covering many of the technologies and manufacturing processes needed to develop and make extended release formulations. There can be no assurance that we can obtain rights to such patents on attractive financial terms, if at all.

We rely on compounds and technology licensed from third parties and termination of any of those licenses would result in the loss of significant rights.

We have exclusive, worldwide licenses to enoximone for the treatment of cardiovascular disease, ambrisentan for all indications, and darusentan for all indications other than cancer. We also have the worldwide exclusive rights to certain patents and patent applications licensed from the University of Colorado and the University of Texas Southwestern Medical Center and rights to license future technology and patent applications arising out of research sponsored at those institutions related to heart failure. Key financial and other terms for future technology would still need to be negotiated with the research institutions, and it may not be possible to obtain any such license on terms that are satisfactory to us.

Our licenses generally may be terminated by the licensor if we fail to perform our obligations under the license, including obligations to develop and commercialize the compounds and technologies under license. The license agreements also generally require us to meet specified milestones or show commercially reasonable diligence in the development and commercialization of the compounds or technology under the license. If our agreements are terminated, we would lose the rights to the product candidates, reducing our potential revenues.

If we are unable to protect our proprietary technology, we may not be able to compete effectively.

Our success depends in part on our ability to obtain and enforce patent protection for our products, both in the United States and other countries, to prevent our competitors from developing, manufacturing and marketing products based on our technology. The scope and extent of patent protection for our product candidates is uncertain and frequently involves complex legal and factual questions. We cannot predict the breadth of claims that will be allowed and issued in patents related to biotechnology or pharmaceutical

applications. Once such patents have issued, we cannot predict how the claims will be construed or enforced. In addition, statutory differences between countries may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States.

Furthermore, the patents that we have licensed with respect to enoximone, ambrisentan and darusentan are owned by third parties. These third parties, with our advice and input, are responsible for and control the prosecution and enforcement of these patents. A failure by these third parties to adequately prosecute and enforce these patents could result in a decline in the value of the patents and have a material adverse effect on our business. Since we collaborate with third parties on some of our technology, there is also the risk that disputes may arise as to the rights to technology or drugs developed in collaboration with other parties.

The coverage claimed in a patent application can be significantly narrowed before a patent is issued, both in the United States and other countries. We do not know whether any of our pending or future patent applications will result in the issuance of patents. To the extent patents have been issued or will be issued, we do not know whether these patents will be subject to further proceedings that may limit their scope, provide significant proprietary protection or competitive advantage, or cause them to be circumvented or invalidated. Furthermore, patents already issued to us, or patents that may issue on our pending applications, may become subject to dispute, including interference, reissue or reexamination proceedings in the United States, or opposition proceedings in foreign countries. Any of these proceedings could result in the limitation or loss of rights.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. While we believe that we have protected our trade secrets, some of our current or former employees, consultants, scientific advisors or collaborators may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop equivalent knowledge, methods and know-how or gain access to our proprietary information through some other means.

We may be accused of infringing on the proprietary rights of third parties, which could impair our ability to successfully commercialize our product candidates.

Our success depends in part on operating without infringing the proprietary rights of third parties. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a patent holder believes that one of our product candidates infringes on its patent, it may sue us even if we have received patent protection for our technology. If another party claims we are infringing its technology, we could face a number of issues, including the following:

- defending a lawsuit, which is very expensive and time consuming;
- defending against an interference proceeding in the United States Patent and Trademark Office, which also can be very expensive and time consuming;
- an adverse decision in a lawsuit or in an interference proceeding resulting in the loss of some or all of our rights to our intellectual property;
- paying a large sum for damages if we are found to be infringing;
- being prohibited from making, using, selling or offering for sale our product candidates or our products, if any, until we obtain a license from the patent holder. Such a license may not be granted to us on satisfactory terms, if at all, and even if we are granted a license, we may have to pay substantial royalties or grant cross-licenses to our patents; and
- redesigning the manufacturing methods or the use claims of our product candidates so that they do not infringe on the other party's patent in the event that we are unable to obtain a license, which, even if possible, could require substantial additional capital, could necessitate additional regulatory approval, and could delay commercialization.

Risks Related to Our Stock

The market price of our common stock may be highly volatile.

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. Since initial trading of our stock began in October 2003 through February 23, 2004, our average daily trading volume has been 139,560 shares. Substantially all of the 5.75 million shares sold in our initial public offering, which includes the underwriters' over-allotment shares, are freely tradable without restrictions or further registration under the Securities Act of 1933. Of our remaining shares outstanding, approximately 20.7 million shares will be eligible for sale in the public market beginning on April 27, 2004 upon the expiration of the lock-up agreements with the underwriters. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results of our clinical trials;
- actual or anticipated regulatory approvals of our products or of competing products;
- changes in laws or regulations applicable to our products;
- changes in the expected or actual timing of our development programs;
- actual or anticipated variations in quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- new products or services introduced or announced by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the loss of a collaborator, including Novartis;
- developments concerning our collaborations;
- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

In addition, the stock market in general, the Nasdaq National Market and the market for technology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of biotechnology and life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources.

Item 2. *Properties*

We currently lease approximately 28,200 square feet of office and laboratory space in Westminster, Colorado. The lease expires on February 28, 2007, although we can elect to terminate the lease two years early, subject to an early termination payment. We have an option to extend the lease until 2014. We believe that there is adequate space for lease in our area to support our future growth requirements.

Item 3. *Legal Proceedings*

We are not currently a party to any legal proceedings.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of security holders, through solicitation of proxies or otherwise, during the fourth quarter of 2003.

PART II

Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters*

Market Information and Holders

Our common stock is traded on the Nasdaq National Market under the symbol "MYOG." Trading of our common stock commenced on October 30, 2003, following completion of our initial public offering. The following table sets forth, for the periods indicated, the high and low closing sales prices for our common stock as reported by the Nasdaq National Market:

Year Ended December 31, 2003	High	Low
Fourth Quarter (from October 30, 2003)	$16.90	$11.70

On February 23, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $15.53 per share. On February 23, 2004, we had approximately 112 holders of record of our common stock.

Dividends

We have never paid any cash dividends on our capital stock and do not intend to pay any such dividends in the foreseeable future. Our term loan prohibits payment of any dividends on our common stock.

Equity Compensation Plan Information

The following table shows certain information concerning our common stock to be issued in connection with our equity compensation plans as of December 31, 2003:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)(2)	2,729,392	$2.34	851,868
Equity compensation plans not approved by security holders	0	$0.00	0
Total	2,729,392	$2.34	851,868

(1) As of December 31, 2003, 3,581,260 shares were reserved for issuance under our 2003 Equity Incentive Plan. On January 1 of each year during the term of our 2003 Equity Incentive Plan, beginning on January 1, 2004 through and including January 1, 2013, the number of shares in the reserve automatically will be increased by the lesser of 5% percent of our then-outstanding shares on a fully-diluted basis, or 2,500,000 shares of common stock. Our Board of Directors approved a reduction of the share increase to our 2003 Equity Incentive Plan effective January 1, 2004 to 750,000 shares.

(2) As of December 31, 2003, 100,000 shares were reserved for issuance under our 2003 Employee Stock Purchase Plan. On January 1 of each year during the term of our 2003 Employee Stock Purchase Plan, beginning on January 1, 2004 through and including January 1, 2013, the number of shares in the reserve automatically will be increased by the lesser of 1.25% percent of our then-outstanding shares on a fully-diluted basis, or 500,000 shares of common stock. On January 1, 2004, the share reserve of our 2003 Employee Stock Purchase Plan was increased by 150,000 shares.

Recent Sales of Unregistered Securities

During the first two fiscal quarters of 2003, we issued and sold 4,374 shares of our common stock that were not registered under the Securities Act of 1933, as amended (the "Securities Act"), to our employees and consultants for cash consideration with an aggregate exercise price of $5,467.50. During the same period, we granted options to purchase 156,630 shares of common stock at an exercise price of $1.25 per share.

During the fourth fiscal quarter of 2003, we issued and sold 48,457 shares of our common stock that were not registered under the Securities Act, to our employees and consultants for cash consideration with an aggregate exercise price of $56,349.65. During the same period, we granted options to purchase 24,000 shares of common stock at exercise prices ranging from $6.88 per share to $16.00 per share.

No underwriters were involved in the foregoing stock or option issuances. The issuance of these securities was exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act as transactions by an issuer under compensatory benefit plans and contracts relating to compensation within the parameters required by Rule 701.

Use of Proceeds from Sales of Registered Securities

On November 4, 2003, we closed the sale of 5,000,000 shares of our common stock in our initial public offering (the "Offering"), and on November 7, 2003, we closed the sale of an additional 750,000 shares of our common stock pursuant to the exercise by the underwriters of an over-allotment option. The Registration Statement on Form S-1 (Reg. No. 333-108301) (the "Registration Statement") we filed to register our common stock in the Offering was declared effective by the Securities and Exchange Commission on October 29, 2003. The Offering commenced as of October 29, 2003 and did not terminate before any securities were sold. The offering has been completed and all shares were sold at an initial price per share of $14.00. The aggregate purchase price of the Offering amount registered was $80,500,000.

The managing underwriters for the initial public offering were Credit Suisse First Boston LLC, J.P. Morgan Securities Inc., CIBC World Markets Corp. and Lazard Freres & Co. LLC. We incurred expenses in connection with the Offering of $7.2 million, which consisted of direct payments of: (i) $1.4 million in legal, accounting and printing fees; (ii) $5.6 million in underwriters' discounts, fees and commissions; and (iii) $0.2 million in miscellaneous expenses. No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

After deducting expenses of the offering, we received net offering proceeds of approximately $73.3 million. As of December 31, 2003, the entire net proceeds from the offering were invested in short-term financial instruments.

None of the net proceeds were directly or indirectly paid to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

Item 6. *Selected Consolidated Financial Data*

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in this report. The consolidated statement of operations data for the years ended December 31, 2003, 2002 and 2001 and the cumulative period from June 10, 1996 (date of Inception) through December 31, 2003, and the consolidated balance sheet data as of December 31, 2003 and 2002, are derived from, and qualified by reference to, our audited consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2000 and 1999 and the consolidated balance sheet data as of December 31, 2001, 2000 and 1999, are derived from our audited consolidated financial statements that do not appear in this report. The historical results are not necessarily indicative of the operating results to be expected in the future.

	Years Ended December 31,					Cumulative Period from June 10, 1996, (Date of Inception) Through December 31, 2003
	2003	2002	2001	2000	1999	
	(In thousands, except share and per share data)					
Consolidated Statement of Operations Data:						
Revenues:						
Product sales	$ 2,846	$ 2,343	$ 1,808	$ 427	$ —	$ 7,424
Research and development contracts	1,010	—	—	—	—	1,010
	3,856	2,343	1,808	427	—	8,434
Costs and expenses:						
Cost of product sold	885	877	756	167	—	2,687
Research and development(1)	37,365	24,950	15,288	7,672	2,247	88,720
Selling, general and administrative(1)	4,387	4,650	3,497	2,830	1,277	17,838
Stock-based compensation	4,192	681	38	14	—	4,925
	46,829	31,158	19,579	10,683	3,524	114,170
Loss from operations	(42,973)	(28,815)	(17,771)	(10,256)	(3,524)	(105,736)
Interest income (expense), net	(136)	786	659	836	203	2,400
Loss before income taxes	(43,109)	(28,029)	(17,111)	(9,420)	(3,321)	(103,336)
Income taxes	39	18	3	—	—	61
Net loss	(43,148)	(28,048)	(17,114)	(9,420)	(3,321)	(103,397)
Accretion of mandatorily redeemable convertible preferred stock	(13,187)	(14,684)	(607)	(3,696)	(326)	(32,500)
Dividend related to beneficial conversion feature of preferred stock(2)	(39,935)	—	—	—	—	(39,935)
Net loss attributable to common stockholders	$ (96,270)	$ (42,731)	$(17,721)	$(13,116)	$ (3,647)	$(175,832)
Basic and diluted net loss per common share	$ (17.79)	$ (42.59)	$ (19.80)	$ (14.95)	$ (4.17)	
Weighted-average shares used in computing basic and diluted net loss per share(3)	5,411,891	1,003,426	894,865	877,400	874,449	

	As of December 31,				
	2003	2002	2001	2000	1999
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 114,252	$ 33,798	$ 56,504	$ 9,781	$18,307
Working capital	107,630	31,751	55,814	9,646	18,105
Total assets	121,273	38,144	58,541	11,716	18,717
Long-term obligations	5,064	3,740	33	108	—
Mandatorily redeemable convertible preferred stock(2)	—	106,566	91,917	29,073	24,272
Common stock	26	1	1	1	1
Deficit accumulated during the development stage	(118,477)	(75,329)	(35,408)	(17,784)	(5,883)
Total stockholders' equity/(deficit)	103,922	(76,829)	(35,569)	(17,934)	(5,957)

(1) For the years ended December 31, 2003 and 2002, research and development and selling, general and administrative expenses exclude stock-based compensation of $2,373 and $1,819, and $431 and $250, respectively. For the cumulative period from June 10, 1996 (Inception) to December 31, 2003, research and development and selling, general and administrative expenses exclude stock-based compensation of $2,856 and $2,070, respectively.

(2) In August 2003, we raised $39.9 million through the sale of additional shares of Series D mandatorily redeemable convertible preferred stock. In November 2003, we issued approximately 19.4 million shares of common stock upon the conversion of all of the outstanding shares of Series A, C and D mandatorily redeemable convertible preferred stock at the completion of our initial public offering. We recorded a non-cash beneficial conversion charge of $39.9 million in 2003, which is calculated as the difference between the Series D preferred stock offering price and the estimated fair value of the Series D preferred stock, limited to the amount of the proceeds from the sale of the Series D preferred stock.

(3) The weighted average shares used in computing basic and diluted net loss per share is calculated based on the weighted-average number of common shares outstanding during the year and excludes all dilutive potential common stock, including options, mandatorily redeemable convertible preferred stock, convertible preferred stock, common stock subject to repurchase and warrants. In November 2003, we sold 5.75 million shares of common stock for net proceeds of $73.3 million in our initial public offering. Concurrently, we issued approximately 19.6 million shares of common stock upon the conversion of all of the outstanding shares of Series A, B, C and D preferred stock. Accordingly, this resulted in the increase in the weighted average common shares outstanding for the year ended December 31, 2003.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapeutics for the treatment of cardiovascular disorders. We believe that our advanced understanding of the biology of cardiovascular disease combined with our clinical development expertise in cardiovascular therapeutics provide us with the capability to discover novel therapies, as well as identify, license or acquire products that address serious, debilitating cardiovascular disorders that are not adequately treated with existing therapies.

We have three product candidates in late-stage clinical development: enoximone capsules for the treatment of chronic heart failure, ambrisentan for the treatment of pulmonary arterial hypertension and darusentan for the treatment of resistant hypertension. We are evaluating enoximone capsules in four Phase III trials. If these trials progress as planned, we expect three of these trials, including the trials we believe will be required for regulatory approval, will be fully enrolled and patients will have completed

treatment by the end of 2004. We completed a Phase II clinical trial of ambrisentan in September 2003 and we initiated pivotal Phase III trials of this product candidate in January 2004. We intend to begin Phase IIb clinical evaluation of darusentan in 2004. All of our product candidates are orally administered small molecules that we believe offer advantages over currently available therapies. In addition, we currently market an intravenous formulation of enoximone, Perfan I.V., for the treatment of acute decompensated heart failure in eight countries in Europe.

Through our internal research program and academic collaborations, we are developing an advanced understanding of the biological pathways of heart disease and have discovered several novel molecular targets that we believe play a key role in heart failure.

We are in the development stage and since inception have devoted substantially all of our efforts to the discovery, in-licensing and development of drugs to treat cardiovascular disease. We have incurred losses each year since our inception and had an accumulated deficit of $118.5 million as of December 31, 2003. We incurred operating losses of $43.0 million, $28.8 million and $17.8 million for the years 2003, 2002 and 2001, respectively. Our research and development expenses have historically been much higher than our revenues.

Our current revenue is derived from sales of Perfan I.V. in eight European countries and research and development contract revenues from our agreement with Novartis signed in October 2003. Prior to our licensing the worldwide rights to enoximone in 1998, Perfan I.V. was marketed in Europe by Aventis. In 1999, we formed our wholly-owned German subsidiary, Myogen GmbH, to manage our sales and marketing activities in Europe. From 2000 through 2002, we entered into agreements with distributors to distribute Perfan I.V. in Belgium, France, Germany, Ireland, Italy, Luxembourg, the Netherlands and the United Kingdom. We recorded our first sales of Perfan I.V. in 2000. Even if our sales and marketing efforts lead to modest increases in Perfan I.V. sales in future periods, we do not expect that such increases will result in a material reduction in our overall net loss. Our cost of product sold reflects the cost of Perfan I.V., which we purchase exclusively from contract manufacturers, and the cost of royalties payable to Aventis.

Our primary business activities have been focused on the development of enoximone capsules, ambrisentan and darusentan. From inception to December 31, 2003, we have incurred expenses of approximately $50.9 million, $18.8 million and $5.1 million for the development of enoximone capsules, ambrisentan and darusentan, respectively. These expenses represent both clinical development costs and the costs associated with non-clinical support activities such as toxicological testing, manufacturing process development and regulatory consulting services. We also report the costs of product licenses in this category, including our milestone obligations associated with the licensing of enoximone, ambrisentan and darusentan.

While some of our research and development expenses are the result of the internal costs related directly to our employees, a majority of the expenses are charged to us by external service providers, including clinical research organizations and contract manufacturers. The cost of our clinical trial programs is the most significant portion of our development expenses, with the number of patients enrolled in a trial and the attendant level of contract research organization and clinical site activity being the principal cost determinants. We expect that expenses in the research and development category will increase for the foreseeable future as we add personnel and expand our clinical trial activities. The amount of the increase is difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, the rate of patient enrollment and the detailed design of future trials. In addition, the results from our trials, as well as the results of trials of similar drugs under development by others, will influence the number, size and duration of planned and unplanned trials.

We have a discovery research effort, which is conducted on our premises by our scientists, through collaborative agreements with academic laboratories and in conjunction with Novartis. In October 2003, we entered into a research collaboration with the Novartis Institutes for BioMedical Research, Inc. ("Novartis") for the discovery and development of novel drugs for the treatment of cardiovascular disease. In exchange for license payments and a commitment to fund our research, Novartis has the exclusive right to license drug targets and compounds developed through the collaboration. Upon execution of a license, Novartis is obligated to fund all further development of the licensed product candidate, make payments to us upon the achievement of certain milestones and pay us royalties for sales of any products that are successfully commercialized. Upon

the completion of Phase II clinical trials of any product candidate Novartis has licensed from us, we have the option to enter into a co-promotion and profit sharing agreement with them for that product candidate, subject to our reimbursement of a portion of the development expenses up to that point, our agreement to share the future development and marketing expenses and elimination of the royalty payable to us.

Our selling, general and administrative expense category consists of our sales, marketing, business development, finance, accounting and general administration costs. These costs are primarily comprised of expenses related directly to our staff, as well as external costs associated with service providers such as lawyers, accountants and insurers. We anticipate that selling, general and administrative expenses will increase for the foreseeable future as we expand our operating activities and as a result of costs associated with becoming a publicly traded company.

Our on-going clinical programs studying enoximone capsules, ambrisentan and darusentan will be lengthy and expensive. Even if these trials show our product candidates to be safe and effective in treating their target indications, we do not expect to be able to record commercial sales of any of our product candidates for several years. As a result, we expect to incur significant and growing losses for the foreseeable future. Although the size and timing of our future operating losses is subject to significant uncertainty, we expect them to continue to increase over the next several years as we continue to fund our development programs and prepare for potential commercial launch of our product candidates. Our primary source of working capital has been equity financings.

The pace and outcome of our clinical development programs and the progress of our discovery program in discovering new product candidates are difficult to predict. If we enter into additional third party collaborations or acquire new product candidates, it may be difficult or impossible for us to predict the timing or amounts of any related licensing payments or expenses. As a result, we anticipate that our quarterly results will fluctuate for the foreseeable future. In view of this variability and of our limited operating history, we believe that period-to-period comparisons of our operating results are not meaningful and you should not rely on them as indicative of our future performance.

Results of Operations

Years Ended December 31, 2003, 2002 and 2001

Revenues

	Years Ended December 31,		
	2003	2002	2001
	(In thousands)		
Revenues:			
Product sales	$2,846	$2,343	$1,808
Research and development contracts	1,010	—	—
	$3,856	$2,343	$1,808

Product Sales

Product sales were derived from sales of Perfan I.V. in Europe. Approximately $470,000 of the increase in 2003 as compared to 2002 was due to a favorable change in the euro exchange rate. The remainder was due to an increase in sales volume, partially offset by a decrease in the average selling price. The increase in 2002 as compared to 2001 was primarily due to the initiation of sales in Italy ($191,000 increase) and a full year of sales in France ($144,000 increase) and the United Kingdom ($142,000 increase). We expect that Perfan I.V. sales will remain modest in coming years.

Research and development contracts revenue

Research and development contracts revenues for the year ended December 31, 2003 were related to the research agreement with Novartis executed in October 2003; therefore, there was no corresponding revenue in

the prior periods. The research and development revenue consists of license revenue totaling $385,000 and research support funding of $625,000. The license revenue is related to the non-refundable upfront payment from Novartis, which is recognized ratably over the longer of the three-year contractual term or estimated life of the relationship. The research support funding is related to the fully burdened cost of the researchers working on the further development of specific potential drug targets and is recognized in the period in which the services are performed.

Costs and Expenses

	Years Ended December 31,		
	2003	2002	2001
		(In thousands)	
Costs and expenses:			
Cost of product sold	$ 885	$ 877	$ 756
Research and development (excluding stock-based compensation)	37,365	24,950	15,287
Selling, general and administrative (excluding stock-based compensation expense)	4,387	4,650	3,497
Stock-based compensation	4,192	681	38
	$46,829	$31,158	$19,578

Cost of Product Sold

The cost of product sold for Perfan I.V. increased slightly in 2003 as compared to 2002 due to currency fluctuations partially offset by a reduction in material costs associated with a change in contract manufacturing. The increase in 2002 as compared to 2001 was due to increased product sales volume, partially offset by reduced costs due to a change in contract manufacturers. Due to these factors, the cost of Perfan I.V. sold as a percentage of product sales was 31.1%, 37.5% and 41.8% for the years ended December 31, 2003, 2002 and 2001, respectively.

Research and Development

Research and development expenses, excluding stock-based compensation expenses are summarized as follows:

	Years Ended December 31,		
	2003	2002	2001
		(In thousands)	
Development			
Enoximone capsules	$19,718	$14,588	$ 6,864
Ambrisentan	7,962	4,368	1,017
Darusentan	149	—	—
Total development	27,829	18,956	7,881
License fees			
Enoximone	—	1,500	1,500
Ambrisentan	1,000	1,000	3,500
Darusentan	5,000	—	—
Other	188	—	—
Total license fees	6,188	2,500	5,000
Discovery research	3,348	3,494	2,406
Total research and development	$37,365	$24,950	$15,287

The increase in development costs for enoximone capsules in 2003 as compared to 2002 was primarily due to the following:

- $3.9 million increase in clinical investigator site payments and external contract costs associated with clinical monitoring and program management efforts, as a result of higher patient enrollment and ongoing patient progress in the ESSENTIAL trials;
- $941,000 increase in the costs associated with work on developing the commercial manufacturing process for enoximone;
- $511,000 increase in the internal costs associated with the management of the enoximone trials, primarily due to an increase in our staff; and
- $255,000 increase in costs associated with producing clinical trial materials for the ESSENTIAL trial.

These increases are partially offset by a $715,000 decrease in costs associated with the continuing EMOTE trial, reflecting reduced costs, as this study nears completion.

The increase in development costs for enoximone capsules in 2002 as compared to 2001 was primarily due to the initiation and progress of patient enrollment in our ESSENTIAL trials early in the year.

The increase in development costs for ambrisentan in 2003 as compared to 2002 was primarily related to:

- $1.9 million increase in expenses related to non-clinical toxicology studies;
- $1.4 million increase in expenses due to the cost of activities in preparation for initiating our two Phase III ARIES trials;
- $819,000 increase in expenses due to the initiation of the extension study for our Phase II PAH trial; and
- $337,000 increase in internal expenses associated with the management of the ambrisentan trials.

These increases were partially offset by a $957,000 decrease in costs from those incurred in 2002, which were related to the exploration of a potential additional indication of ambrisentan that we did not pursue.

The increase in ambrisentan development expenses in 2002 as compared to 2001 was primarily due to:

- $1.8 million for the Phase II pulmonary arterial hypertension clinical trial which began enrollment in October 2002;
- $928,000 associated with exploring a potential additional indication for ambrisentan which we elected not to pursue; and
- $170,000 attributable to the manufacturing, regulatory and analytical efforts required to continue to develop ambrisentan.

In 2003, the license fees were attributable to the $5.0 million in-licensing payment for darusentan and the final $1.0 million cost reimbursement payment for ambrisentan. The 2002 and 2001 license fees were principally for enoximone and ambrisentan, with enoximone accounting for $1.5 million in each of these years.

Although total discovery research expenses were relatively consistent from 2002 to 2003, in 2003 we recorded an increase in internal spending of $568,000 to expand our high through-put screening efforts. This was offset by a decrease of $310,000 in our support of research programs at academic laboratories and a decrease of $234,000 in reported costs due to increased SBIR funding, which was treated as an offset to expense. The increase in 2002 primarily reflects an increase in our research and development activity and related staffing.

Selling, General and Administrative

The $263,000 decrease in selling, general and administrative expense in 2003 as compared to 2002 primarily relates to a decrease of $230,000 in consulting costs and a $200,000 decrease in relocation and travel

costs offset by a $150,000 increase in insurance costs related to becoming a public company. The principal components of the increase in 2002 as compared to 2001 were $358,000 for a financing which was not completed, $216,000 primarily for external consultants associated with our business development activities, $206,000 for increases in staffing and supporting costs in our European sales subsidiary and general growth in our administrative activities.

Stock-Based Compensation

Stock-based compensation expenses were $4.2 million, $681,000 and $38,000 for the years ended December 31, 2003, 2002 and 2001, respectively. The increase in each period was due to an increase in the number of options granted to employees and consultants and an increase in the fair value of our common stock. The stock-based compensation expense for each period was allocated between selling, general and administrative and research and development as follows:

	Year Ended December 31,		
	2003	2002	2001
	In thousands		
Research and development	$2,373	$431	$38
Selling, general and administrative	1,819	250	—
	$4,192	$681	$38

Interest Income, Net

Interest income net of interest expense was ($136,000), $786,000 and $659,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Interest income was $585,000, $926,000 and $727,000 for the years ended December 31, 2003, 2002 and 2001, respectively. The decrease in interest income in 2003 relates to the decreased cash balance for the first three quarters of 2003 and the overall decline in interest rates. The increase in interest income in 2002 reflects the increased invested cash balances from the sale of our Series D preferred stock in the second half of 2001. Interest expense was $721,000, $140,000 and $68,000 for the years ended December 31, 2003, 2002 and 2001, respectively. In 2003, the increase in interest expense is primarily due to a full year of interest payments on the $5 million term loan entered into in December 2002. In 2002, the increase in interest expense was the result of interest due on a milestone payment for the ambrisentan license agreement.

Accretion of Mandatorily Redeemable Convertible Preferred Stock

Accretion of mandatorily redeemable convertible preferred stock was $13.2 million, $14.7 million and $607,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Accretion of the mandatorily redeemable convertible preferred stock for the years ended December 31, 2003 and 2002 represented the accretion associated with the Series A, Series C and Series D mandatorily redeemable convertible preferred stock. The $1.5 million decrease in 2003 is due to the conversion of all mandatorily redeemable convertible preferred stock upon completion of our initial public offering in November 2003, offset by an increase associated with the issuance of an additional $39.9 million of Series D mandatorily redeemable convertible preferred stock in August 2003. In connection with the issuance of Series D mandatorily redeemable convertible preferred stock in 2001, the Company amended and restated its Certificate of Incorporation, which included a revision to the redemption provisions for the Series A and Series C mandatorily redeemable convertible preferred stock then outstanding. The change in the redemption provisions resulted in a reduced redemption value at the time of the revision and consequently reduced the accretion of mandatorily redeemable convertible preferred stock in 2001.

Liquidity and Capital Resources

From our inception on June 10, 1996 to December 31, 2003, we funded our operations primarily with $200.7 million (net of issuance costs) from private equity financings and our initial public offering,

$5.3 million from term loans, $7.4 million from sales of Perfan I.V., $4.0 million related to a research and development contract and $2.4 million from net interest income earned on cash equivalents and short-term investments. Cash, cash equivalents and short-term investments amounted to $114.3 million at December 31, 2003. Certain instruments, although possessing a contractual maturity greater than ten years, are classified as short-term investments due to their ready marketability. On August 27, 2003, we raised net proceeds of $39.9 million through the sale of additional shares of our Series D preferred stock. On November 7, 2003, we completed our initial public offering which raised net proceeds of $73.3 million. These additional funds have been invested in instruments with maturities of 12 months or less. Our cash outflows in the next 12 months are expected to consist primarily of external expenses related to our research and development programs, as well as payroll costs. We believe our cash is sufficient to meet these needs. Our cash outflows beyond one year are also expected to consist primarily of external expenses related to our research and development programs, as well as payroll costs. We believe that the proceeds of the initial public offering, together with the proceeds of the Novartis collaboration and potential additional collaborations and future equity offerings, will allow us to fund our future working capital and capital expenditures for the foreseeable future.

Our cash, cash equivalents and short-term investments are held in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, municipal bonds, mortgage-backed securities, commercial paper and money market accounts. Our Board of Directors has approved our written investment policy, which limits our investment instruments to those mentioned above. We review compliance with this policy on a monthly basis.

At December 31, 2003, we had approximately $1.3 million in net fixed assets. We expect to purchase additional equipment and to invest in leasehold improvements in 2004, and we expect our spending on fixed assets to grow in future years.

Operating activities resulted in net cash outflows of $31.7 million, $26.5 million and $16.4 million for the years ended December 31, 2003, 2002 and 2001 respectively. The cumulative net cash outflow from operating activities from our inception to December 31, 2003 was $88.3 million. The use of cash in all periods was primarily a result of our losses from operations associated with our research and development activities.

Investing activities resulted in a net cash outflow of $43.1 million, a net cash inflow of $7.0 million and a net cash outflow of $30.8 million for the years ended December 31, 2003, 2002 and 2001 respectively. The net cash outflow for the year ended December 31, 2003 resulted primarily from $114.8 million in purchases of short-term investments offset by $71.7 million in proceeds related to the maturity of short-term investments. The net cash inflow for the year ended December 31, 2002 primarily from $66.5 million in purchases of short-term investments offset by $74.8 million in proceeds from the maturity of short-term investments. The net cash outflow for the year ended December 31, 2001 resulted primarily from $41.6 million in the purchase of short-term investments offset by $11.0 million in proceeds from the maturity of short-term investments. Cumulative investing activities from inception to December 31, 2003 resulted in net cash outflows of $72.1 million, with $2.1 million in net capital asset expenditures and $323.3 million in purchases of short-term investments offset by $253.4 million in proceeds from the maturity of short-term investments.

Financing activities resulted in net cash inflows of $112.2 million, $5.0 million and $63.3 million, for the years ended December 31, 2003, 2002 and 2001, respectively. Financing activities for 2003 primarily consisted of the sale of additional shares of our Series D preferred stock with net proceeds of $39.9 million and our initial public offering which raised net proceeds of $73.3 million, offset by approximately $1.1 million of payments on our term loan. Financing activities for the year 2002 consisted primarily of borrowing under our term loan. Financing activities for the year 2001 consisted of the issuance of our Series D preferred stock for $63.3 million, net of issuance costs. Cumulative financing activities from our inception to December 31, 2003 resulted in net cash inflows of $204.6 million, primarily related to the issuance of our Series A, C and D preferred stock, the sale of shares of our common stock in our initial public offering and borrowings under our term loans.

We anticipate that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations for at least the next 12 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves

risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our clinical trials, those aspects of our drug discovery program not funded by Novartis or other aspects of our operations.

Obligations and Commitments

The following summarizes our significant contractual obligations, which are comprised of our notes payable, capital and operating lease obligations as of December 31, 2003, and the effect these significant contractual obligations are expected to have on our liquidity and cash flows in future periods:

		Payments Due by Period			
Contractual Obligations	Total	Less Than One Year	One to Three Years	Four to Five Years	After Five Years
			In thousands		
Notes payable(1)	$3,909	$1,777	$2,132	$—	$—
Capital lease obligations(2)	189	54	104	31	—
Operating leases(3)	1,127	343	724	60	—
Total contractual obligations	$5,225	$2,174	$2,960	$91	$—

(1) Amounts are equal to the annual maturities of our long-term debt outstanding as of December 31, 2003.

(2) Amounts represent principal payments due under various capital lease obligations as of December 31, 2003. These arrangements expire in various years through 2008.

(3) These commitments are associated with contracts that expire in various years through 2007. Payments due reflect fixed rent expense.

Total lease expense for the years ended December 31, 2003, 2002 and 2001 was $416,000, $394,000 and $257,000, respectively. We have future payment commitments for operating leases of approximately $1.1 million, principally for our office and laboratory space. In addition, many of our contracts with clinical research organizations, contract manufacturers, academic research agreements and others contain termination provisions that would require us to make final payments if we were to terminate prematurely. The size of these payments depends upon the timing and circumstances of the termination and therefore the extent of the future commitments cannot be meaningfully quantified.

Net Operating Loss Carryforwards

At December 31, 2003, we had $82.3 million of net operating loss carryforwards and approximately $1.4 million in research and development credits available to offset future regular and alternative taxable income. These net operating loss carryforwards expire beginning in 2011 through 2019. The Internal Revenue Code places certain limitations on the annual amount of net operating loss carryforwards that can be utilized if certain changes in our ownership occur.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial consolidated statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions 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. Our critical accounting policies that require the use of estimates and informed management judgments include:

- revenue recognition;
- accounting for research and development expenses;
- estimating the value of our equity instruments for use in deferred stock-based compensation calculations; and
- accounting for income taxes.

Revenue Recognition.

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition in Financial Statements" (SAB 104). We consider this methodology to be the most appropriate for our business model and current revenue streams.

Product Sales. Sales are recognized when the following four revenue recognition criteria are met: (i) persuasive evidence of an arrangement exists; (ii) product is shipped from the distributor to the customer; (iii) the selling price is fixed or determinable; and (iv) collection is reasonably assured. Once the product is shipped to the customer, the Company does not allow product returns.

Research and development contracts. We may enter into collaborative agreements with pharmaceutical companies where the other party generally receives exclusive marketing and distribution rights for certain products for set time periods and set geographic areas. The rights associated with this research and development is assigned or can be assigned to the collaborator or through a license at the collaborator's option. The terms of the collaborative agreements can include nonrefundable licensing fees, funding of research and development efforts, payments based on achievement of certain milestones, and royalties on product sales.

Non-refundable license fees received are recorded as deferred revenue once received or irrevocably committed, and are recognized ratably over the longer of the development period to which they relate or contractual term. Where there are two or more distinct phases embedded into one contract (such as product development and subsequent commercialization or manufacturing), the contracts may be considered multiple element arrangements. When it can be demonstrated that each of these phases are at fair value, they are treated as separate earnings processes with upfront fees being recognized over only the initial product development phase. The relevant time period for the product development phase is based on management estimates and could vary depending upon the outcome of clinical trials and the regulatory approval process. As a result, management continually reviews the appropriate time period.

Milestones, based on designated achievement points that are considered at risk and substantive at the inception of the collaborative contract, are recognized as earned when the earnings process is complete and the corresponding payment is reasonably assured. We evaluate whether milestones are at risk and substantive based on the contingent nature of the milestone, specifically reviewing factors such as the technological and commercial risk that needs to be overcome and the level of investment required. Milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Revenues from research funding are recognized when the services are performed and is typically based on the fully burdened cost of a researcher working on a collaboration. Revenue is recognized ratably over the period as services are performed, with the balance reflected as deferred revenue until earned.

Accounting for research and development expenses. Our research and development expense category is primarily composed of costs associated with product development for enoximone capsules, ambrisentan and darusentan. These expenses represent both clinical development costs and the costs associated with non-clinical support activities such as toxicological testing, manufacturing process development and regulatory consulting services. Clinical development costs represent internal costs for personnel, external costs incurred at clinical sites and contractual payments to third party clinical research organizations to perform certain clinical trials. We also report the costs of product licenses in this category, including our ongoing milestone obligations associated with the licensing of ambrisentan and darusentan. Our product candidates do not currently have regulatory approval; accordingly, we expense the license and milestone fees when we incur the liability. We have a discovery research effort, which is conducted in part on our premises by our scientists and in part through collaborative agreements.

While some of our research and development expenses are the result of the internal costs related directly to our employees, a majority of the expenses are charged to us by external service providers, including clinical research organizations and contract manufacturers, and by our academic collaborators. We accrue research and development expenses for activity occurring during the fiscal period prior to receiving invoices from clinical sites and third party clinical research organizations. We accrue external costs for clinical studies based on the progress of the clinical trials, including patient enrollment, progress by the enrolled patients through the trial, and contractual costs with clinical research organizations and clinical sites. We record internal costs primarily related to personnel in clinical development and external costs related to non-clinical studies and basic research when incurred. Amounts received from other parties to fund our research and development efforts where the reimbursing party does not obtain any rights to the research or drug candidates are recognized as a reduction to research and development expense as the costs are incurred. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period.

We expect that expenses in the research and development category will increase for the foreseeable future as we add personnel, expand our clinical trial activities and increase our discovery research capabilities. The amount of the increase is difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, progress in our discovery research program, the rate of patient enrollment and the detailed design of future trials. In addition, the results from each of our trials, as well as the results of trials of similar drugs under development by others, will influence the number, size and duration of both planned and unplanned trials.

Valuation of equity instruments. We record compensation expense related to options issued to consultants and options issued to, or common stock sold to, employees at less than the fair value. As a result, we have recorded deferred stock-based compensation expense that represents, in the case of employees, the difference between the option exercise price and the fair value of our common stock. In the case of consultants, deferred stock-based compensation represents the fair value of the options granted, computed using the Black-Scholes option-pricing model. These expenses are based on the fair value of the options and common stock. Because there has been no public market for our common stock until recently, we have estimated the fair value of these equity instruments using various valuation methods. Subsequent to the commencement of our initial public offering on October 30, 2003, we estimate the fair value of these equity instruments using the value for our common stock that the public market establishes. Deferred stock-based compensation for employees is recognized over the remaining vesting period of the related option. Deferred stock-based compensation related to consultants is recognized over the vesting period of the related option and the amount recognized is subject to change based on changes in the fair value of our common stock. We recognize stock-based compensation using an accelerated method as described in Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans, an Interpretation of APB Opinions No. 15 and 25* (FIN 28).

Accounting for income taxes. We must make significant management judgments when determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. At December 31, 2003, we recorded a full valuation allowance of $39.5 million against our net deferred tax asset balance, due to uncertainties related to our deferred tax assets as a result of

our history of operating losses. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods we may need to change the valuation allowance, which could materially impact our financial position and results of operations.

Recent Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities* (FIN 46). FIN 46 addresses consolidation by business enterprises of variable interest entities, which have certain characteristics. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies, in the first fiscal year beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 has not had, nor do we believe it will have, a material impact on our current or prospective consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, certain financial instruments that embody obligations for the issuer are required to be classified as liabilities. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise will be effective at the beginning of the first interim period beginning after June 15, 2003. We do not expect the provisions of this statement to have a significant impact on our current or prospective consolidated financial statements.

In November 2003, the EITF reached a consensus on Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* The FASB ratified this consensus in November 2003. EITF Issue No. 03-1 requires certain quantitative and qualitative disclosures for marketable debt and equity securities classified as available-for-sale or held-to-maturity that are impaired at the balance sheet date but for which an other-than-temporary impairment has not been recognized. The adoption of EITF Issue No. 03-1 did not have a material impact on our financial condition or results of operations. As of December 31, 2003, we had no material unrealized losses on our marketable debt or equity securities.

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, *Revenue Recognition,* ("SAB 104") which supercedes SAB 101, *Revenue Recognition in Financial Statements.* SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements and to rescind the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* ("FAQ") issued with SAB 101. Selected portions of the FAQ have been incorporated into SAB 104. The adoption of SAB 104 did not have a material impact on our revenue recognition policies.

Item 7A. ***Quantitative and Qualitative Disclosures on Market Risk***

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, trade accounts receivable, accounts payable and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. The maximum allowable duration of a single issue is 18 months with an average duration of the issues in the portfolio of nine months.

As of December 31, 2003, we had an investment portfolio of short-term investments in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, municipal bonds, mortgage-backed securities, commercial paper and money market accounts of

$69.9 million excluding those classified as cash and cash equivalents. Our short-term investments consist primarily of bank notes, various government obligations and asset-backed securities. These securities are classified as available-for-sale and are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of stockholders' equity/(deficit). Unrealized losses are charged against income when a decline in fair market value is determined to be other than temporary. The specific identification method is used to determine the cost of securities sold.

The investment portfolio is subject to interest rate risk and will fall in value in the event market interest rates increase. Due to the short duration of our investment portfolio, we believe an immediate 10% change in interest rates would not be material to our financial condition or results of operations.

The euro is the functional currency for Myogen GmbH. We translate asset and liability accounts to the U.S. dollar based on the exchange rate as of the balance sheet date, while the income statement and cash flow statement amounts are translated to the U.S. dollar at the average exchange rate for the period. Exchange gains and losses resulting from such translation are included as a separate component of stockholders' equity/(deficit). Transaction gains and losses are recognized in income during the period in which they occur and are included in selling, general and administrative expenses. In addition, we conduct clinical trials in many countries, exposing us to cost increases if the U.S. dollar declines in value compared to other currencies.

Item 8. ***Financial Statements and Supplementary Data***

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. ***Changes in and Disagreements with Accountants on Accounting Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), as of the end of the period covered by this report. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in our periodic reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and can therefore only provide reasonable, not absolute, assurance that the design will succeed in achieving its stated goals.

In addition, we reviewed our internal controls, and there have been no changes in our internal controls over financial reporting during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this Item concerning the Company's directors is incorporated by reference to the information set forth in the sections entitled "Proposal 1 — Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of the Company's fiscal year ended December 31, 2003 (the "Proxy Statement"). The information required by this

Item concerning the executive officers of the Company is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Executive Officers and Key Employees."

Item 11. ***Executive Compensation***

The information required by this Item regarding executive compensation is incorporated by reference to the information set forth in the sections of the Proxy Statement entitled "Compensation of Executive Officers," "Compensation of Directors," "Employment, Severance and Change of Control Agreements," and "Compensation Committee Interlocks and Insider Participation."

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management."

Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Certain Transactions."

Item 14. ***Principal Accountant Fees and Services***

The information required by this Item regarding principal accountant fees and services and audit committee pre-approval policy is incorporated by reference to the information set forth in the sections of the Proxy Statement entitled "Independent Auditors' Fees" and "Pre-Approval Policies and Procedures."

PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a) The following documents are being filed as part of this report:

(1) *Consolidated Financial Statements.* The following consolidated financial statements of Myogen, Inc. are filed as part of this report.

(2) *Financial Statement Schedules.* All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

(b) *Reports on Form 8-K:*

1. On December 4, 2003, the Company filed a current report on Form 8-K entitled "Myogen Reports Third Quarter 2003 Results."

(c) *Exhibits:*

Exhibit Number	Description
3.1*	Restated Certificate of Incorporation.
3.2*	Amended and Restated Bylaws.
4.1*	Specimen Stock Certificate.
10.1*(1)	2003 Equity Incentive Plan of the Company, Form of Grant Notice and Form of Stock Option Agreement.
10.2*(1)	2003 Employee Stock Purchase Plan of the Company.
10.3*	Series A Preferred Stock Purchase Agreement, dated May 21, 1998 between Myogen and the parties named therein.
10.4*	Series B Preferred Stock Purchase Agreement, dated March 16, 2000 between Myogen and the parties named therein.
10.5*	Series C Preferred Stock Purchase Agreement, dated November 23, 1999, as amended on December 8, 1999, between Myogen and the parties named therein.
10.6*	Series D Preferred Stock Purchase Agreement, dated August 21, 2001, as amended on November 2, 2001 and December 27, 2001, between Myogen and the parties named therein.
10.7*	Series D Preferred Stock Purchase Agreement, dated August 27, 2003, between Myogen and the parties named therein.
10.8*	Third Amended and Restated Investor Rights Agreement, dated August 21, 2001, as amended on August 27, 2003, between Myogen and certain of our stockholders.
10.9*	Third Amended and Restated Stockholders Agreement, dated August 21, 2001, as amended on December 27, 2001, between Myogen and certain of our stockholders.
10.10*(1)	Form of Employment Agreement entered into between Myogen and certain of its executives, including reference schedule.
10.11*	Form of Indemnification Agreement entered into by each of Myogen's Executive Officers and Directors.
10.12*	Lease Agreement between the Company and Church Ranch Business Center, LLC, dated January 1, 2002.
10.13*	Warrant to purchase shares of Series C preferred stock issued to Silicon Valley Bank, dated January 26, 2000.
10.14*	Venture Loan and Security Agreement by and among GATX Ventures, Inc., Silicon Valley Bank and the Company, dated December 6, 2002.
10.15*	Warrant to purchase shares of Series D preferred stock issued to GATX Ventures, Inc., dated December 6, 2002.
10.16*	Warrant to purchase shares of Series D preferred stock issued to Silicon Valley Bank, dated December 6, 2002.
10.17*=	License Agreement between Hoechst Marion Roussel, Inc. and the Company, dated October 1, 1998, as amended November 23, 1999 and June 2, 2003.
10.18*=	License Agreement between Abbott Deutschland Holding GmbH and the Company, dated October 8, 2001.
10.19*=	Intellectual Property License Agreement between the University Technology Corporation and the Company, dated September 1, 1998, as amended January 26, 2001 and November 12, 2002.

Exhibit Number	Description
10.20*=	Materials Transfer Agreement between the Regents of the University of Colorado and the Company, dated September 4, 1998, as amended January 4, 2001.
10.21*=	Patent and Technology License Agreement between the Board of Regents of The University Of Texas System and the Company, dated December 1, 1999, as amended July 7, 2000 and December 20, 2001.
10.22*=	Exclusive Patent And Technology License Agreement between the Board of Regents of The University of Texas System and the Company, dated January 1, 2002.
10.23*=	License Agreement between Abbott Laboratories and the Company, dated June 30, 2003.
10.24*=	Collaboration and Option Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company, dated October 8, 2003.
10.25*=	Form of License, Development and Commercialization Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company.
10.26*=	Materials Transfer Agreement between the Regents of the University of Colorado and the Company, dated September 12, 2003.
10.27	Indemnification Agreement between Kirk K. Calhoun and the Company, dated as of January 16, 2004.
10.28	First Amendment to Lease Agreement between Sevo Miller, Inc., as receiver on behalf of Church Ranch Business Center, LLC, and the Company, dated December 2, 2003.
10.29†	Third Amendment to Intellectual Property License Agreement between University License Equity Holdings, Inc. and the Company, dated November 24, 2003.
10.30†	Amendment No. 3 to Patent and Technology License Agreement between the Board of Regents of the University of Texas System and the Company, dated November 6, 2003.
10.31†	Amendment No. 1 to Patent and Technology License Agreement between the Board of Regents of the University of Texas System and the Company, dated as of February 10, 2004.
10.32†	Patent License Agreement between the University of Texas System, the University of North Texas Health Science Center at Fort Worth and the Company, dated January 13, 2000.
21.1*	List of Subsidiaries.
23.1	Consent of PricewaterhouseCoopers LLP.
24.1	Powers of Attorney. Reference is made to page 52.
31.1	Certification of principal executive officer required by Rule 13a-14(a).
31.2	Certification of principal financial officer required by Rule 13a-14(a).
32.1	Section 1350 Certification.

* Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-108301) and amendments thereto, declared effective October 29, 2003.

(1) Indicates Management Contract or Compensatory Plan or Arrangement.

= We have been granted confidential treatment with respect to the omitted portions of this agreement.

† We have applied for confidential treatment with respect to portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

Date: March 1, 2004

MYOGEN, INC.

By: /s/ J. WILLIAM FREYTAG
J. William Freytag
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints J. William Freytag and Joseph L. Turner, and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 1, 2004, and in the capacities indicated:

Name	Title	Date
/s/ J. WILLIAM FREYTAG J. William Freytag	President, Chief Executive Officer and Chairman *(Principal Executive Officer)*	March 1, 2004
/s/ JOSEPH L. TURNER Joseph L. Turner	Senior Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 1, 2004
/s/ MICHAEL R. BRISTOW Michael R. Bristow	Chief Science and Medical Officer and Director	March 1, 2004
/s/ KIRK K. CALHOUN Kirk K. Calhoun	Director	March 1, 2004
/s/ JERRY T. JACKSON Jerry T. Jackson	Director	March 1, 2004

Name	Title	Date
/s/ DANIEL J. MITCHELL Daniel J. Mitchell	Director	March 1, 2004
/s/ ARNOLD L. ORONSKY Arnold L. Oronsky	Director	March 1, 2004
/s/ ANDREW N. SCHIFF Andrew N. Schiff	Director	March 1, 2004
/s/ SIGRID VAN BLADEL Sigrid Van Bladel	Director	March 1, 2004

MYOGEN, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT AUDITORS

To the Stockholders and Board of Directors
of Myogen, Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Myogen, Inc. and its subsidiary (a development stage enterprise) at December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 and, cumulatively, for the period from June 10, 1996 (date of inception) to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. These consolidated financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

Denver, Colorado
March 1, 2004

MYOGEN, INC.
(A Development Stage Enterprise)

CONSOLIDATED BALANCE SHEETS

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,337,721	$ 6,993,146
Short-term investments	69,914,627	26,804,619
Accrued interest receivable	607,393	178,202
Trade accounts receivable	1,274,861	741,852
Research and development contract amounts due within one year	1,625,000	500,000
Inventories	724,282	860,200
Other current assets	1,434,174	340,151
Total current assets	119,918,058	36,418,170
Property and equipment, net	1,304,028	1,691,931
Other assets	51,238	33,590
Total assets	$ 121,273,324	$ 38,143,691
LIABILITIES, MANDATORILY REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable	$ 7,594,935	$ 2,748,647
Accrued liabilities	1,350,114	938,102
Current portion of deferred revenue	1,666,667	—
Current portion of capital lease obligations	37,015	25,968
Current portion of notes payable, net of discount	1,639,246	954,004
Total current liabilities	12,287,977	4,666,721
Deferred revenue, net of current portion	2,948,029	—
Capital lease obligations, net of current portion	121,617	106,870
Notes payable, net of current portion and discount	1,993,906	3,633,152
Commitments and contingencies (see Note 8 and Note 13)		
Mandatorily redeemable convertible preferred stock	—	106,565,591
Stockholders' equity/ (deficit):		
Series B convertible preferred stock, $0.001 par value, no shares authorized and outstanding as of December 31, 2003; 810,000 shares authorized and 803,606 shares issued and outstanding as of December 31, 2002; aggregate liquidation preference of $1,104,958 as of December 31, 2002	—	804
Preferred Stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2003, no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 and 17,375,000 shares authorized and 26,457,927 and 1,024,361 shares issued and outstanding as of December 31, 2003 and 2002	26,458	1,025
Additional paid-in capital	229,080,380	—
Deferred stock-based compensation	(6,730,195)	(1,726,692)
Other comprehensive income	22,185	225,420
Deficit accumulated during the development stage	(118,477,033)	(75,329,200)
Total stockholders' equity/(deficit)	103,921,795	(76,828,643)
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders' equity/(deficit)	$ 121,273,324	$ 38,143,691

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

MYOGEN, INC.
(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

	2003	2002	2001	Cumulative Period From June 10, 1996 (Inception) to December 31, 2003
Revenues:				
Product sales	$ 2,845,713	$ 2,342,899	$ 1,807,984	$ 7,423,714
Research and development contracts	1,010,305	—	—	1,010,305
	3,856,018	2,342,899	1,807,984	8,434,019
Costs and expenses:				
Cost of product sold	885,145	877,434	756,304	2,686,686
Research and development (excluding stock-based compensation expense of $2,372,888, $430,838, $37,996 and $2,855,709, respectively)	37,364,578	24,949,510	15,287,311	88,719,670
Selling, general and administrative (excluding stock-based compensation expense of $1,819,368, $250,405, $0 and $2,069,773, respectively)	4,386,635	4,649,830	3,497,016	17,838,749
Stock-based compensation	4,192,256	681,243	37,996	4,925,482
	46,828,614	31,158,017	19,578,627	114,170,587
Loss from operations	(42,972,596)	(28,815,118)	(17,770,643)	(105,736,568)
Interest (expense) income, net	(135,891)	785,843	659,291	2,399,995
Loss before income taxes	(43,108,487)	(28,029,275)	(17,111,352)	(103,336,573)
Income taxes	39,346	18,304	3,147	60,797
Net loss	(43,147,833)	(28,047,579)	(17,114,499)	(103,397,370)
Accretion of mandatorily redeemable convertible preferred stock	(13,187,174)	(14,683,739)	(606,604)	(32,499,556)
Deemed dividend related to beneficial conversion feature of preferred stock	(39,935,388)	—	—	(39,935,388)
Net loss attributable to common stockholders	$(96,270,395)	$(42,731,318)	$(17,721,103)	$(175,832,314)
Basic and diluted net loss per common share	$ (17.79)	$ (42.59)	$ (19.80)	
Weighted average common shares outstanding	5,411,891	1,003,426	894,865	

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

MYOGEN, INC.
(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY/(DEFICIT)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Net loss	—	$ —	—	$ —	$ —	$ —	$ —	$ —	$ (71,348)	$ (71,348)
Balance at December 31, 1996	—	—	—	—	—	—	—	—	(71,348)	(71,348)
Comprehensive income:										
Net loss	—	—	—	—	—	—	—	—	(285,383)	(285,383)
Total comprehensive income	—	—	—	—	—	—	—	—	(285,383)	(285,383)
Balance at December 31, 1997	—	—	—	—	—	—	—	—	(356,731)	(356,731)
Issuance of common stock for cash and notes receivable	—	—	680,000	680	15,071	—	(7,850)	—	—	7,901
Issuance of common stock in exchange for license agreements	—	—	46,542	47	23,224	—	—	—	—	23,271
Issuance of common stock for notes receivable	—	—	147,907	148	73,364	—	(73,512)	—	—	—
Comprehensive income:										
Net loss	—	—	—	—	—	—	—	—	(1,990,914)	(1,990,914)
Total comprehensive income	—	—	—	—	—	—	—	—	(1,990,914)	(1,990,914)
Balance at December 31, 1998	—	—	874,449	875	111,659	—	(81,362)	—	(2,347,645)	(2,316,473)
Payments on notes receivable from stockholders	—	—	—	—	—	—	5,671	—	—	5,671
Receipt of funds for par value of restricted stock	—	—	—	—	739	—	—	—	—	739
Other	—	—	—	—	(303)	—	303	—	—	—
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	—	(112,095)	—	—	—	(215,787)	(327,882)

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Comprehensive income:										
Net loss	—	—	—	—	—		—	—	(3,319,539)	(3,319,539)
Total comprehensive income									(3,319,539)	(3,319,539)
Balance at December 31, 1999	—	—	874,449	875	—	—	(75,388)	—	(5,882,971)	(5,957,484)
Issuance of Series B convertible preferred stock	803,606	804	—	—	1,104,154	—	—	—	—	1,104,958
Warrants issued in conjunction with note payable	—	—	—	—	10,815	—	—	—	—	10,815
Issuance of common stock in August 2000 at $0.50 per share upon the exercise of options	—	—	4,354	4	2,173	—	—	—	—	2,177
Issuance of common stock in November 2000 at $0.50 per share upon the exercise of options	—	—	10,542	11	5,260	—	—	—	—	5,271
Issuance of common stock in December 2000 at $1.15 per share upon the exercise of options	—	—	3,000	3	3,447	—	—	—	—	3,450
Issuance of common stock upon the exercise of warrants	—	—	350	—	175	—	—	—	—	175
Deferred stock-based compensation related to options granted to consultants	—	—	—	—	89,576	(89,576)	—	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	—	13,987	—	—	—	13,987
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	—	(1,215,600)	—	—	—	(2,480,557)	(3,696,157)

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Comprehensive income:										
Foreign currency translation adjustment	—	—	—	—	—	—	—	(1,334)	—	(1,334)
Net loss	—	—	—	—	—	—	—	—	(9,420,275)	(9,420,275)
Total comprehensive income								(1,334)	(9,420,275)	(9,421,609)
Balance at December 31, 2000	803,606	804	892,695	893	—	(75,589)	(75,388)	(1,334)	(17,783,803)	(17,934,417)
Issuance of common stock in May 2001 at $0.86 per share upon the exercise of options	—	—	250	—	288	—	—	—	—	288
Issuance of common stock in July 2001 at $1.18 per share upon the exercise of options	—	—	255	—	301	—	—	—	—	301
Issuance of common stock in August 2001 at $0.59 per share upon the exercise of options	—	—	375	—	223	—	—	—	—	223
Issuance of common stock in December 2001 at $1.20 per share upon the exercise of options	—	—	16,628	17	13,800	—	—	—	—	13,817
Deferred stock-based compensation related to options granted to consultants	—	—	—	—	82,346	(82,346)	—	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	—	37,996	—	—	—	37,996
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	—	(96,958)	—	—	—	(509,646)	(606,604)
Comprehensive income:										
Foreign currency translation adjustment	—	—	—	—	—	—	—	(2,554)	—	(2,554)

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Unrealized gain on investments available for sale	—	—	—	—	—	—	—	36,520	—	36,520
Net loss	—	—	—	—	—	—	—	—	(17,114,499)	(17,114,499)
Total comprehensive income								33,966	(17,114,499)	(17,080,533)
Balance at December 31, 2001	803,606	804	910,203	910	—	(119,939)	(75,388)	32,632	(35,407,948)	(35,568,929)
Issuance of common stock in January 2002 at $0.50 per share upon the exercise of options	—	—	6,000	6	2,994	—	—	—	—	3,000
Issuance of common stock in February 2002 at $1.18 per share upon the exercise of options			52,083	52	61,542	—	—	—	—	61,594
Issuance of common stock in March 2002 at $1.25 per share upon the exercise of options	—	—	833	1	1,040	—	—	—	—	1,041
Issuance of common stock in April 2002 at $1.17 per share upon the exercise of options	—	—	11,616	12	13,576	—	—	—	—	13,588
Issuance of common stock in May 2002 at $1.25 per share upon the exercise of options	—	—	1,250	1	1,561	—	—	—	—	1,562
Issuance of common stock in June 2002 at $1.25 per share upon the exercise of options	—	—	2,083	2	2,602	—	—	—	—	2,604
Issuance of common stock in October 2002 at $2.08 per share upon the exercise of options	—	—	1,892	2	3,936	—	—	—	—	3,938

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Issuance of common stock in December 2002 at $1.25 per share upon the exercise of options ...	—	—	3,751	4	4,685	—	—	—	—	4,689
Issuance of common stock upon the exercise of warrants ..	—	—	34,650	35	17,290	—	—	—	—	17,325
Deferred stock-based compensation related to options granted to employees and consultants.....	—	—	—	—	2,287,996	(2,287,996)	—	—	—	—
Amortization of deferred stock-based compensation.....	—	—	—	—	—	681,243	—	—	—	681,243
Warrants issued in conjunction with note payable.....	—	—	—	—	412,844	—	—	—	—	412,844
Repayment of notes receivable.....	—	—	—	—	—	—	75,388	—	—	75,388
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	—	(2,810,066)	—	—	—	(11,873,673)	(14,683,739)
Comprehensive income:										
Foreign currency translation adjustment.....	—	—	—	—	—	—	—	137,455	—	137,455
Change in unrealized gain on investments available for sale	—	—	—	—	—	—	—	55,333	—	55,333
Net loss	—	—	—	—	—	—	—	—	(28,047,579)	(28,047,579)
Total comprehensive income								192,788	(28,047,579)	(27,854,791)
Balance at December 31, 2002	803,606	804	1,024,361	1,025	—	(1,726,692)	—	225,420	(75,329,200)	(76,828,643)
Issuance of common stock in January 2003 at $1.25 per share upon exercise of options	—	—	4,375	4	5,464	—	—	—	—	5,468

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Issuance of common stock in July 2003 at $1.05 per share upon exercise of options ...	—	—	11,333	11	11,934	—	—	—	—	11,945
Issuance of common stock in August 2003 at $1.25 per share upon exercise of options	—	—	600	1	749	—	—	—	—	750
Issuance of common stock in September 2003 at $0.63 per share upon exercise of options	—	—	14,625	15	9,267	—	—	—	—	9,282
Issuance of common stock in October 2003 at $1.16 per share upon exercise of options	—	—	48,447	48	55,608	—	—	—	—	55,656
Issuance of common stock for cash-initial public offering in November 2003, net of offering costs of $7,174,830	—	—	5,750,000	5,750	73,319,420	—	—	—	—	73,325,170
Deferred stock-based compensation related to options granted to employees and consultants.....	—	—	—	—	9,195,759	(9,195,759)	—	—	—	—
Amortization of deferred stock-based compensation.....	—	—	—	—	—	4,192,256	—	—	—	4,192,256
Accretion of mandatorily redeemable convertible preferred stock	—	—	—	—	(13,187,174)	—	—	—	—	(13,187,174)
Discount associated with Series D mandatorily redeemable convertible preferred stock in August 2003 at $6.875 per share	—	—	—	—	39,935,388	—	—	—	—	39,935,388

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount						
Beneficial conversion feature of Series D mandatorily redeemable convertible preferred stock in August 2003 at $6.875 per share	—	—	—	—	(39,935,388)	—	—	—	—	(39,935,388)
Conversion of Series A mandatorily redeemable convertible preferred stock	—	—	1,206,998	1,207	7,997,573	—	—	—	—	7,998,780
Conversion of Series B convertible preferred stock	(803,606)	(804)	160,713	161	643	—	—	—	—	—
Conversion of Series C mandatorily redeemable convertible preferred stock	—	—	2,618,175	2,618	23,884,293	—	—	—	—	23,886,911
Conversion of Series D mandatorily redeemable convertible preferred stock	—	—	15,618,300	15,618	127,786,844	—	—	—	—	127,802,462
Comprehensive income:										
Foreign currency translation adjustment	—	—	—	—	—	—	—	(105,874)	—	(105,874)
Change in unrealized gain on investments available for sale	—	—	—	—	—	—	—	(97,361)	—	(97,361)
Net loss	—	—	—	—	—	—	—	—	(43,147,833)	(43,147,833)
Total comprehensive income								(203,235)	(43,147,833)	(43,351,068)
Balance at December 31, 2003	—	$ —	26,457,927	$26,458	$229,080,380	$(6,730,195)	$ —	$ 22,185	$(118,477,033)	$103,921,795

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

MYOGEN, INC.
(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,			Cumulative Period From June 10, 1996 (Inception) to December 31,
	2003	2002	2001	2003
Cash Flows From Operating Activities:				
Net loss	$(43,147,833)	$(28,047,579)	$(17,114,499)	$(103,397,370)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	413,522	302,994	138,495	1,012,235
Amortization of deferred stock-based compensation	4,192,256	681,243	37,996	4,925,482
Amortization of debt discount	137,615	4,022	3,713	148,430
Amortization of investment (discount)/premium	75,701	191,211	(28,062)	238,850
Stock exchanged for license	—	—	—	1,163,229
Loss on disposal of property and equipment	11,671	22,638	—	34,309
Changes in operating assets and liabilities:				
Trade accounts receivable	154,936	(280,657)	(317,617)	(490,463)
Research and development contract amounts	(625,000)	—	—	(625,000)
Inventories	135,918	6,787	12,273	(724,282)
Prepaid expenses, accrued interest and other assets	(1,295,551)	(750,468)	272,209	(2,303,739)
Accounts payable	4,222,118	840,154	507,926	6,986,013
Deferred revenue	3,614,696	—	—	3,614,696
Accrued liabilities	403,791	570,201	77,749	1,109,906
Net cash used in operating activities	(31,706,160)	(26,459,454)	(16,409,817)	(88,307,704)
Cash Flows From Investing Activities:				
Acquisitions of property and equipment	(275,640)	(1,316,986)	(208,107)	(2,436,556)
Proceeds from sale of property and equipment	318,201	14,272	—	332,473
Purchases of short-term investments	(114,804,787)	(66,472,688)	(41,566,494)	(323,343,411)
Proceeds from maturities of short-term investments	71,653,555	74,750,969	11,000,000	253,374,600
Net cash provided by (used in) investing activities	(43,108,671)	6,975,567	(30,774,601)	(72,072,894)
Cash Flows From Financing Activities:				
Proceeds from related party note	—	75,388	—	370,275
Repayments of related party note	—	—	—	(289,887)
Proceeds from notes payable	—	5,000,000	—	5,250,000
Payments on notes payable	(1,091,619)	(132,716)	(78,679)	(1,341,619)
Proceeds from issuance of mandatorily redeemable convertible preferred stock, net of issuance costs	39,935,388	(35,110)	63,342,365	127,151,604
Proceeds from issuance of common stock, net of issuance costs	73,408,271	109,341	14,629	73,551,213
Payments on capital leases	(31,293)	(25,599)	—	(56,892)
Net cash provided by financing activities	112,220,747	4,991,304	63,278,315	204,634,694
Effect of exchange rates on cash	(61,341)	142,444	(2,554)	83,625
Net increase (decrease) in cash and cash equivalents	37,344,575	(14,350,139)	16,091,343	44,337,721
Cash and cash equivalents, beginning of period	6,993,146	21,343,285	5,251,942	—
Cash and cash equivalents, end of period	$ 44,337,721	$ 6,993,146	$ 21,343,285	$ 44,337,721
Supplemental Disclosure of Non-Cash Financing Activities:				
Interest paid	$ 583,409	$ 14,089	$ 39,555	$ 648,791
Acquisition of property and equipment under capital leases	53,532	158,437	—	211,969
Common stock issued in exchange for notes receivable	—	—	—	81,362
Convertible preferred stock issued in exchange for license	—	—	—	1,163,229
Mandatorily redeemable convertible preferred stock issued in lieu of cash commission on issuance of Series D mandatorily redeemable convertible preferred stock	—	—	928,961	928,961
Conversion of Series B convertible preferred stock for common stock upon initial public offering	804	—	—	804
Conversion of mandatorily redeemable preferred stock for common stock upon initial public offering	159,688,153	—	—	159,688,153
Deferred research and development contract revenue due within one year	1,000,000	—	—	1,000,000

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Formation and Business of the Company

Myogen, Inc. and its subsidiary (the "Company") are in the development stage and are engaged in the discovery, development and sale of therapeutic drugs for the treatment of cardiovascular conditions. Myogen, Inc. was incorporated in the State of Colorado on June 10, 1996 ("Inception") and on May 15, 1998 reincorporated in the State of Delaware. The Company currently markets one product in Europe for the treatment of acute decompensated heart failure, and it has three product candidates in late-stage clinical development for three cardiovascular indications. In addition, the Company's research program is focused on creating disease-modifying drugs for chronic heart failure and other cardiovascular diseases.

In 1998, the Company obtained a license to enoximone for the treatment and prevention of certain forms of heart disease in humans. In 1999, the Company established Myogen GmbH, a wholly owned subsidiary located in Germany, through which the intravenous formulation of enoximone, Perfan I.V., is sold in eight countries in Europe. The Company has granted certain European distributors exclusive rights to distribute Perfan I.V. in Belgium, France, Germany, Ireland, Italy, Luxembourg, the Netherlands and the United Kingdom. In June 2000, the Company began Phase III clinical evaluation of the oral formulation of enoximone, enoximone capsules, with the initiation of EMOTE. In 2002, the Company initiated two additional enoximone capsule Phase III trials, and initiated a fourth such trial in the third quarter of 2003.

In September 2001, the Company in-licensed ambrisentan, a compound that it may develop for the treatment of various indications. In 2002, the Company initiated a Phase II clinical trial of ambrisentan for pulmonary arterial hypertension. This trial was completed in 2003.

In June 2003, the Company in-licensed darusentan, a compound that it intends to develop initially for resistant hypertension.

Prior to commercial sales of a drug, the Company must complete the clinical trials and receive the necessary regulatory approvals. Should the Company be unable to obtain such approvals, there could be a material adverse effect on its financial position, results of operations and cash flows.

In November 2003, the Company completed an initial public offering of 5,750,000 shares of its common stock. The Company received net proceeds of $73.3 million, net of $7.2 million in expenses and underwriters' discount relating to the issuance and distribution of securities.

2. Liquidity

The Company has incurred significant losses and negative cash flows from operations in every fiscal period since Inception. For the years ended December 31, 2003, 2002 and 2001, the Company incurred losses from operations of $42,972,596, $28,815,118 and $17,770,643, respectively, and negative cash flows from operations of $31,706,160, $26,459,454 and $16,409,817, respectively. As of December 31, 2003, the Company had a deficit accumulated during the development stage of $118,477,033. Management anticipates that operating losses and negative cash flows from operations will continue for at least the next several years.

To date, the Company has satisfied its cash commitments primarily through public and private placements of equity securities. From Inception to December 31, 2003, the Company raised $200,702,817 of net cash proceeds from the sale of equity securities.

Management believes that the cash on hand will be sufficient to continue operations for at least the next 12 months. Failure to generate sufficient revenues or raise additional capital could have a material adverse effect on the Company's ability to achieve its intended business objectives. Management plans on raising additional financing to meet future working capital and capital expenditure needs. There can be no assurance that such additional financing will be available or, if available, that such financing can be obtained on terms satisfactory to the Company.

3. Summary of Significant Accounting Policies

Basis of Presentation

The Company has generated limited revenue to date and its activities have consisted primarily of developing products, licensing products, raising capital and recruiting personnel. Accordingly, the Company is considered to be in the development stage as of December 31, 2003 as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises.*

On October 24, 2003, the Company effected a one-for-five reverse stock split. All references in the consolidated financial statements to common shares, common share prices and per common share amounts have been adjusted retroactively for all periods presented to reflect this stock split. The Company's preferred shares, preferred share prices and per preferred share amounts have not been adjusted for this stock split. However, as a result of the stock split, the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock conversion ratios were adjusted from one-to-one to five-to-one. On November 4, 2003, all shares of the Series A, B, C and D preferred stock converted into common stock, at a rate of one share of common stock for each five shares of preferred stock.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Myogen, Inc. and its wholly owned subsidiary, Myogen GmbH. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 amount of expenses during the reporting period. Actual results could differ from these estimates.

Risks and Uncertainties

The Company's operations are subject to certain risks and uncertainties, including those associated with the history of operating losses and risk of continued losses, early stage of development, dependence on the outcome of clinical trials and dependence on regulatory approval to sell products.

Cash and Cash Equivalents

The Company considers all investments that, when purchased, have a remaining maturity of 90 days or less, to be cash equivalents. All cash equivalents are carried at cost, which approximates fair value.

Short-term Investments

Short-term investments are investments purchased with maturities of longer than 90 days, but less than one year, held at a financial institution. Short-term investments are accounted for in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and accordingly, those classified as held-to-maturity are carried at cost plus accrued interest and total $0 and $313,695 at December 31, 2003 and 2002, respectively. In addition, those classified as available-for-sale are carried at fair value and total $69,914,627 and $26,490,924 at December 31, 2003 and 2002, respectively. Gains or losses on the sale of investments classified as available-for-sale are recognized on the specific identification method.

Unrealized gains or losses are treated as a separate component of stockholders' deficit until the security is sold or until a decline in fair market value is determined to be other than temporary. As of December 31, 2003 and 2002, the amortized cost basis, aggregate fair value and gross unrealized holding gains and losses by major security type of investment classified as available-for-sale and held-to-maturity are as follows:

Security Type	Amortized Cost Basis	Aggregate Fair Value	Unrealized Holding Gains	Unrealized Holding Losses
December 31, 2003				
Government securities	$32,509,476	$32,519,386	$ 9,910	$ —
Corporate debt securities	24,056,490	24,040,418	—	(16,072)
Commercial paper	9,093,506	9,093,736	230	—
Asset-backed securities	4,260,663	4,261,087	424	—
Total short-term investments	$69,920,135	$69,914,627	$10,564	$(16,072)
December 31, 2002				
Commercial paper	$20,453,682	$20,527,304	$73,622	$ —
Corporate debt securities	6,259,084	6,277,315	18,231	—
Total short-term investments	$26,712,766	$26,804,619	$91,853	$ —

Certain instruments, although possessing a contractual maturity greater than ten years, are classified as short-term investments due to their ready marketability. At December 31, 2003, the amortized cost basis and aggregate fair value of these short-term investments was $19,100,000 and $19,099,721, respectively.

Fair Value of Financial Instruments

The Company's financial instruments include cash, cash equivalents, short-term investments, accounts receivable, accounts payable, accrued liabilities and notes payable. The carrying amounts of the Company's financial instruments approximate fair value due to their short maturities, except for the notes payable where the fair value is $3,160,567, based on the 9.8% current borrowing rate, as compared to the carrying amount of $3,633,152 as of December 31, 2003.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on the first-in, first-out basis.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements and assets under capital leases are amortized over the shorter of the life of the lease or the estimated useful life of the assets. Repairs and maintenance costs are expensed as incurred.

Long-Lived Assets and Impairments

The Company periodically evaluates the recoverability of its long-lived assets in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS 144") and, accordingly, reduces the carrying value whenever events or changes in business conditions indicate the carrying amount of the assets may not be fully recoverable. SFAS 144 requires recognition of impairment of

long-lived assets in the event the net book value of such assets exceeds the fair value less costs to sell such assets.

Revenue Recognition

Myogen recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition in Financial Statements" (SAB 104). The Company considers this methodology to be the most appropriate for its business model and current revenue streams.

Product Sales

Sales are recognized when the following four revenue recognition criteria are met: (i) persuasive evidence of an arrangement exists; (ii) product is shipped from the distributor to the customer; (iii) the selling price is fixed or determinable; and (iv) collection is reasonably assured. Once the product is shipped to the customer, the Company does not allow product returns.

Research and development contracts

Myogen may enter into collaborative agreements with pharmaceutical companies where the other party receives exclusive marketing and distribution rights for certain products for set time periods and set geographic areas. The rights associated with this research and development are assigned or can be assigned to the collaborator through a license at the collaborator's option. The terms of the collaborative agreements can include nonrefundable funding of research and development efforts, licensing fees, payments based on achievement of certain milestones, and royalties on product sales.

Non-refundable license fees received are recorded as deferred revenue once received or irrevocably committed, and are recognized ratably over the longer of the development period to which they relate or contractual term. Where there are two or more distinct phases embedded into one contract (such as product development and subsequent commercialization or manufacturing), the contracts may be considered multiple element arrangements. When it can be demonstrated that each of these phases are at fair value, they are treated as separate earnings processes with upfront fees being recognized over only the initial product development phase. The relevant time period for the product development phase is based on management estimates and could vary depending upon the outcome of clinical trials and the regulatory approval process. As a result, management continually reviews the appropriate time period.

Milestones, based on designated achievement points that are considered at risk and substantive at the inception of the collaborative contract, are recognized as earned when the earnings process is complete and the corresponding payment is reasonably assured. The Company evaluates whether milestones are at risk and substantive based on the contingent nature of the milestone, specifically reviewing factors such as the technological and commercial risk that needs to be overcome and the level of investment required. Milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Revenues from research funding are recognized when the services are performed in order to match revenues to expenses incurred and are typically based on the fully burdened cost of a researcher working on a

collaboration. Revenue is recognized ratably over the period as services are performed, with the balance reflected as deferred revenue until earned.

Research and Development

The Company's research and development expense is primarily composed of costs associated with discovery research and product development. The latter expense represents both clinical trial costs and the costs associated with non-clinical support activities such as toxicological testing, manufacturing process development and regulatory affairs. The Company's research and development expenses include internal employee costs and research and development expenses associated with external service providers, including clinical research organizations and contract manufacturers, and by the Company's academic collaborators. The Company also reports the cost of product licenses in this category, including its milestone obligations. Research and development expenditures are charged to operations as incurred. Amounts received from other parties to fund our research and development efforts where the reimbursing party does not obtain any rights to the research or drug candidates are recognized as a reduction to research and development expense as the costs are incurred.

Net Loss Per Common Share

Net loss per common share is calculated in accordance with SFAS No. 128, *Earnings Per Share* ("SFAS 128") and SEC Staff Accounting Bulletin No. 98 ("SAB 98"). Under the provisions of SFAS 128 and SAB 98, basic net loss per common share is computed by dividing the net loss available for common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common stock, including options, mandatorily redeemable convertible preferred stock, convertible preferred stock, common stock subject to repurchase and warrants. Diluted net loss per common share for all periods presented is the same as basic net loss per share because the potential common shares were anti-dilutive. Anti-dilutive common shares not included in net loss attributable to common stockholders are summarized, on a weighted average basis, as follows:

	December 31,		
	2003	2002	2001
Common stock subject to repurchase	—	15,738	47,215
Common stock options	2,263,623	1,179,768	50,185
Warrants	33,544	11,820	36,468
Convertible preferred stock	132,980	160,721	160,721
Mandatorily redeemable convertible preferred stock	12,293,728	13,625,321	6,721,025
Total	14,723,875	14,993,368	7,015,614

Stock-Based Compensation and Unaudited Pro Forma Net Loss per Common Share

The Company measures compensation expense to employees using the intrinsic value method as prescribed by Accounting Principles Board Opinion ("APB") No. 25, *Accounting For Stock Issued to Employees* ("APB 25"), and provides pro forma disclosures of net loss as if the fair value based method was applied as prescribed by SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"). Accordingly, as allowable under SFAS 123, the Company does not recognize compensation expense for options granted to employees when the exercise price equals or exceeds the fair value of common stock as of the grant date. Stock-based awards to consultants are accounted for under the provisions of SFAS 123 and

Emerging Issues Task Force ("EITF") Issue 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

Had employee compensation cost for the Company's stock-based compensation plan been determined based on the fair value at the grant dates for awards using the Black-Scholes model prescribed by SFAS 123, the Company's pro forma net loss and pro forma net loss per share would be as follows:

	Years Ended December 31,		
	2003	2002	2001
Net loss attributable to common stockholders, as reported	$(96,270,395)	$(42,731,318)	$(17,721,103)
Deduct: total stock-based employee compensation expense determined under fair value based method	(3,508,779)	(476,234)	(87,584)
Add: total stock-based employee compensation expense recognized under the intrinsic rate based method	3,412,815	392,119	—
Pro forma net loss	$(96,366,359)	$(42,815,433)	$(17,808,687)
Pro forma basic and diluted net loss per share	$ (17.81)	$ (42.67)	$ (19.90)
Basic and diluted net loss per share, as reported	$ (17.79)	$ (42.59)	$ (19.80)

For options granted prior to the commencement of public trading of the Company's common stock, the fair value was determined at the date of grant using the Black-Scholes model with the following weighted average assumptions: no dividend yield, risk-free interest rates ranging from 2.3% to 6.8%, volatility factor of 0% and an expected life of five years. Risk-free interest rates were determined using government securities with original maturities similar to the respective expected option life at date of grant. The estimated fair value for these options was calculated using the minimum value method and may not be indicative of the future pro forma effects of option grants on reported net income (loss) for future years since this model does not take into consideration volatility and the commencement of public trading in the Company's common stock on October 30, 2003. The Black-Scholes model was utilized to calculate the value of the options issued after October 30, 2003, using the following assumptions: no dividend yield, risk-free interest rates ranging from 3.0% to 3.1%, volatility factor of 100% and an expected life of five years.

Income Taxes

Income taxes are accounted for under the asset and liability method whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be ultimately realized.

Foreign Currency Translation

The euro is the functional currency for the Company's foreign subsidiary. The Company translates asset and liability accounts to the U.S. dollar based on the exchange rate as of the balance sheet date, while income statement and cash flow statement amounts are translated to the U.S. dollar at the average exchange rate for the period. Exchange gains or losses resulting from such translation are included as a separate component of stockholders' deficit. Transaction gains and losses are recognized in income during the period in which they occur. During the years ended December 31, 2003, 2002 and 2001, the Company recognized net transaction

gains of $431,637, $122,179 and $6,928, respectively, which are included in selling, general and administrative expense.

Concentration of Risk

The Company's cash, cash equivalents and short-term investments as of December 31, 2003 and 2002 are maintained in three financial institutions in amounts that typically exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant credit risk in this area. It is the Company's practice to place its cash equivalents and short-term investments in high quality securities in accordance with a written policy approved by the Company's Board of Directors.

All product sales recorded as of December 31, 2003, 2002 and 2001 relate to product sales to independent distributors in Europe of Perfan I.V., the intravenous form of enoximone. As of December 31, 2003, customer concentrations in excess of 10% of trade accounts receivable and product sales were as follows:

	Trade Accounts Receivable		Product Sales		
Customer	2003	2002	2003	2002	2001
A	26.3%	32.7%	28.0%	27.8%	38.4%
B	5.5	11.0	25.3	29.5	33.2
C	19.9	14.9	19.0	21.9	20.5
D	9.3	12.2	12.0	11.4	6.8
E	37.9	25.0	14.2	8.1	—
Total	98.9%	95.8%	98.5%	98.7%	98.9%

The Company relies on single-source manufacturers for each of its product candidates. Establishing a replacement source for any of its product candidates could require at least 12 months and significant additional expense.

All of our research and development contract revenues and amounts due are from a single collaborator in 2003.

Recent Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities* ("FIN 46"). FIN 46 addresses consolidation by business enterprises of variable interest entities that have certain characteristics. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies, in the first fiscal year beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 has not had, nor does the Company believe it will have, a material impact on its current or prospective financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS 150"). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, certain financial instruments that embody obligations for the issuer are required to be classified as liabilities. SFAS 150 shall be effective for financial instruments entered into or modified after May 31, 2003, and otherwise shall be effective at the beginning of the first interim period beginning after June 15, 2003. The FASB issued FASB Staff Position ("FSP") 150-3 on November 7, 2003 to defer the effective date for applying the provisions of SFAS No. 150

for certain mandatorily redeemable non-controlling interests. The Company does not expect the provisions of this statement to have a significant impact on its current or prospective financial statements.

In November 2003, the EITF reached a consensus on Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* The FASB ratified this consensus in November 2003. EITF Issue No. 03-1 requires certain quantitative and qualitative disclosures for marketable debt and equity securities classified as available-for-sale or held-to-maturity that are impaired at the balance sheet date but for which an other-than-temporary impairment has not been recognized. The adoption of EITF Issue No. 03-1 did not have a material impact on the Company's financial condition or results of operations. As of December 31, 2003, the Company had no material unrealized losses on its marketable debt or equity securities.

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, *Revenue Recognition,* ("SAB 104") which supercedes SAB 101, *Revenue Recognition in Financial Statements.* SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements and to rescind the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* ("FAQ") issued with SAB 101. Selected portions of the FAQ have been incorporated into SAB 104. The adoption of SAB 104 did not have a material impact on the Company's revenue recognition policies.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current year presentation.

4. Inventories

Inventories are summarized as follows:

	December 31,	
	2003	2002
Finished products	$207,262	$266,068
Raw materials	517,020	594,132
	$724,282	$860,200

5. Property and Equipment

Property and equipment are summarized as follows:

	December 31,	
	2003	2002
Laboratory equipment and other	$1,111,136	$1,353,601
Furniture and fixtures	300,180	249,988
Computer equipment and software	423,199	380,214
Leasehold improvements	235,365	218,365
Manufacturing equipment	48,000	—
Capital projects in progress	60,213	2,324
	2,178,093	2,204,492
Less accumulated depreciation	(874,065)	(512,561)
	$1,304,028	$1,691,931

Property and equipment recorded under capital leases totaled $211,969 and $158,437 as of December 31, 2003 and 2002, respectively, and is included in computer equipment and software. In addition, amortization expense related to assets under capital lease was $46,716, $19,337, and $0 for the years ended December 31, 2003, 2002, and 2001 respectively and $66,053 for the period from Inception to December 31, 2003; the Company had no significant assets under capital lease during 2001.

6. Accounts Payable and Accrued Liabilities

Accounts payable are comprised of the following:

	December 31, 2003	December 31, 2002
Trade	$ 679,827	$ 265,614
Research and development activities	6,510,549	2,419,673
Related parties (Note 14)	404,559	63,360
	$7,594,935	$2,748,647

Accrued liabilities are comprised of the following:

	December 31, 2003	December 31, 2002
Accrued payroll	$ 388,641	$197,962
Accrued taxes	119,537	99,025
Accrued royalties	55,050	48,778
Advances for reimbursable research and development expenses	644,940	500,000
Other	141,946	92,337
	$1,350,114	$938,102

7. Borrowings

In December 2002, the Company entered into a term loan with certain financial institutions and borrowed $5,000,000 with a 36-month repayment term, subject to customary covenants. The loan accrues interest at 9.82% per annum. The first three monthly repayments were comprised of interest only; the remaining thirty-three payments are comprised of both principal and interest. Concurrent with this loan agreement, warrants were granted to the financial institutions (Note 10). Substantially all the assets of the Company are pledged as collateral for the loan.

On January 26, 2000, the Company entered into a term loan with a bank (the "Bank"). Subject to the terms of the agreement, on June 30, 2000, the Company borrowed $250,000 with a 36-month repayment term. The loan accumulated interest at the annual rate associated with the U.S. Treasury note yield to maturity on a 36-month note, as of the funding date, plus a loan margin of 300 basis points. Concurrent with this loan agreement, a warrant to purchase 9,090 shares of the Company's Series C Preferred Stock at an exercise price of $1.375 was granted to the Bank (Note 10). In December 2002, the loan was repaid in full.

Maturities of the notes payable as of December 31, 2003 are as follows:

2004	$ 1,776,861
2005	1,959,420
2006	172,100
Thereafter	—
Principal portion of future notes payable obligations	3,908,381
Less unamortized discount	(275,229)
Less current portion of notes payable	(1,639,246)
Notes payable, net of current portion and discount	$ 1,993,906

8. Commitments and Contingencies

The Company leases office and research and development facilities under agreements that expire in 2005 and 2007. In December 2003, the lease was amended to add an additional 6,200 square feet of laboratory space to be occupied April 1, 2004. Total rent expense in 2003, 2002 and 2001 was $416,128, $393,908 and $257,028, respectively.

During 2002, the Company entered into several capital leases in order to finance certain equipment acquisitions. As of December 31, 2003, the aggregate future minimum lease obligations for capital leases and non-cancelable operating leases with initial or remaining terms in excess of one year are as follows for each of the years ending December 31:

	Capital Leases	Operating Leases
2004	$ 54,303	$ 342,981
2005	54,303	362,729
2006	49,274	361,272
2007	21,146	60,212
2008	10,228	—
Total future minimum lease payments	189,254	$1,127,194
Less amount representing interest	(30,622)	
Present value of future minimum lease payments	158,632	
Less current portion	(37,015)	
Capital lease obligations, less current portion	$121,617	

From time to time, the Company becomes involved in legal proceedings arising in the ordinary course of business. The Company was not involved in any material legal proceedings as of December 31, 2003.

In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. These include indemnities of clinical investigators, consultants and contract research organizations involved in the development of the Company's clinical stage products, indemnities of distributors of its marketed product, indemnities to its lenders and indemnities to directors and officers of the Company to the maximum extent permitted under the laws of the State of Delaware. The duration of these indemnities, commitments and guarantees varies, and in certain cases, is indefinite. The majority of these indemnities, commitments and guarantees do not provide for any limitation of the maximum potential future payments the Company could be obligated to

make. The Company has not recorded any liability for these indemnities, commitments and guarantees in the accompanying consolidated balance sheets. However, the Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable and in accordance with SFAS No. 5, *Accounting for Contingencies.* No such losses have been recorded to date.

9. Preferred Stock

Undesignated Preferred Stock

As of December 31, 2003 the Company had 5,000,000 authorized but unissued shares of undesignated preferred stock.

Mandatorily Redeemable Convertible Preferred Stock

Mandatorily redeemable convertible preferred stock is summarized as follows:

	December 31,	
	2003	2002
Series A Preferred Stock, at redemption value, $0.001 par value, 0 and 6,035,000 shares authorized; 0 and 6,035,000 shares issued and outstanding as of December 31, 2003 and 2002; aggregate liquidation preference of $6,035,000 as of December 31, 2002	$ —	$ 7,246,186
Series C Preferred Stock, at redemption value, $0.001 par value, 0 and 13,100,000 shares authorized; 0 and 13,090,910 shares issued and outstanding as of December 31, 2003 and 2002; aggregate liquidation preference of $18,000,000 as of December 31, 2002	—	21,644,880
Series D Preferred Stock, at redemption value, $0.001 par value, 0 and 49,425,000 shares authorized; 0 and 49,000,696 shares issued and outstanding as of December 31, 2003 and 2002; aggregate liquidation preference of $67,375,957 as of December 31, 2002	—	77,674,525
Total mandatorily redeemable convertible preferred stock	$ —	$106,565,591

Series A

During 1998, the Company issued 6,000,000 shares of Series A Preferred Stock at $1.00 per share in a private placement to accredited investors for proceeds of $5,967,394, net of $32,606 in issuance costs. In addition, the Company issued 35,000 shares of Series A Preferred Stock in exchange for services and accounted for these shares based upon the estimated value of the shares at the issuance date.

Upon the initial closing of our initial public offering on November 4, 2003, these 6,035,000 shares of Series A Preferred Stock were automatically converted into 1,206,998 shares of common stock.

Series C

During 1999, the Company issued 13,090,910 shares of Series C Preferred Stock at $1.375 per share in a private placement to accredited investors for proceeds of $17,941,567, net of $58,434 in issuance costs.

Upon the initial closing of our initial public offering on November 4, 2003, these 13,090,910 shares of Series C Preferred Stock were automatically converted into 2,618,175 shares of common stock.

Series D

During 2001, the Company issued 49,000,696 shares of Series D Preferred Stock at $1.375 per share in a private placement to accredited investors for proceeds of $63,307,255, net of $4,068,702 in issuance costs.

On August 27, 2003, the Company issued 29,090,908 shares of Series D Preferred Stock at $1.375 per share and received proceeds of $39,935,388, net of issuance costs of $64,611. In the third quarter of 2003, the Company recorded a beneficial conversion charge, which was calculated as the difference between the offering price and the fair value of the underlying common stock, and limited to the amount of proceeds allocated to the Series D Preferred Stock in accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios.* The Company extended the date for when the Company may be required to redeem the Senior Preferred Stock from August 21, 2007 to August 26, 2009.

Upon the initial closing of our initial public offering on November 4, 2003, these 78,091,604 shares of Series D Preferred Stock were automatically converted into 15,618,300 shares of common stock.

Prior to the conversion of such shares of preferred stock upon the effectiveness of the initial public offering, the holders of the Senior Preferred Stock (which comprises the Series A, C and D preferred stock) had the following rights and preferences:

Voting Rights

The holders of the Senior Preferred Stock, voting equally with the shares of common stock, were entitled to vote upon any matter submitted to the stockholders; however, for as long as at least 1,500,000 shares of Senior Preferred Stock remained outstanding, the holders of at least 65% of the outstanding Senior Preferred Stock, voting together as a single class on an as-converted to common stock basis, were necessary for effecting or validating certain transactions or events, including changes to the capital structure of the Company. In addition, certain transactions or events required a majority vote of each class of Senior Preferred Stock.

Dividends

The holders of Senior Preferred Stock were entitled to receive non-cumulative cash dividends at a rate of 8% of the respective original issue price per annum, prior and in preference to any dividend on Series B Preferred Stock and common stock. Dividends were payable only when, as and if declared by the Board of Directors. No dividends were declared prior to conversion.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, the holders of Senior Preferred Stock were entitled to receive in exchange for and in redemption of each share of Senior Preferred Stock, prior and in preference to Series B Preferred Stock and common stock, an amount equal to the applicable original issue price for such shares, plus all declared and unpaid dividends on such shares. After payment of the full liquidation preference to the Senior Preferred Stock, any remaining assets were to be distributed ratably to the holders of all preferred stock, on an as-converted to common stock basis, and common stock until the holders of all preferred stock have received an aggregate amount per share equal to three times the applicable original issue price; thereafter, the holders of common stock, after conversion, were to receive all of the remaining assets in proportion to their applicable share.

Conversion

The Senior Preferred Stock was convertible, at the option of the holder, at any time after the date of issuance, into fully-paid non-assessable shares of common stock as determined by dividing the respective original issue price by the conversion price in effect on the date of the certificate surrendered for conversion. The conversion price was the respective original issue price as adjusted for certain dilutive issuances, splits, reorganizations, combinations and other factors. Upon the effective date of the common stock split, the conversion ratio was five preferred shares for each common share.

Automatic conversion was to occur immediately upon the earlier of (i) the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, at a per share price of at least 1.5 times the original issue price, as adjusted, of Series D Preferred Stock and cash proceeds to the Company of at least $25,000,000 or (ii) upon the date of affirmative consent from at least 65% of the outstanding shares of all preferred stock, voting together as a single class. These shares automatically converted on November 4, 2003, the date of the initial closing of our initial public offering.

Redemption

The holders of at least 65% of the then outstanding shares of Senior Preferred Stock, voting together as a single class, were entitled to require the Company to redeem the Senior Preferred Stock in three equal annual installments beginning on August 26, 2009, provided the Company received a written notice of such election at least 60 days prior to such date. The Company was obligated to redeem the Senior Preferred Stock for an amount per share equal to the applicable conversion price, plus interest calculated at 15% per annum beginning from the Series D Preferred Stock original issue date (August 21, 2001) on each outstanding share of Senior Preferred Stock based on the applicable conversion price, plus any declared and unpaid dividends on the Senior Preferred Stock. In August 2001, the Company amended and restated its Certificate of Incorporation in conjunction with the initial issuance of its Series D preferred stock. Prior to August 2001, holders of at least 65% of the then outstanding shares of Senior Preferred Stock could require the Company to redeem the Senior Preferred Stock beginning in November 2005 for an amount per share equal to the applicable conversion price, plus interest calculated at 15% per annum beginning from the original issue date of the Series C Preferred Stock (November 1999).

The holders of the Senior Preferred Stock were subject to automatic redemption in the event of any consolidation or merger of the Company, or sale of all or substantially all of the Company's assets in which the stockholders of the Company immediately prior to the transaction hold less than fifty percent of the outstanding securities of the surviving entity.

The redemption values of the Senior Preferred Stock outstanding as of December 31, 2001 and 2002 were derived by accreting 15% interest from August 21, 2001 on such stock, plus the accretion of the respective issuance costs. As of December 31, 2002, the redemption values of Series A Preferred Stock, Series C Preferred Stock and Series D Preferred Stock were $7,246,186, $21,644,880 and $77,674,525, respectively.

Convertible Preferred Stock

Series B

During 2000, the Company issued 803,606 shares of Series B Preferred Stock and warrants to purchase 35,000 shares of common stock (see Note 10) to the University of Texas System and affiliated individuals, at a deemed value of $1.375 per share, in a private placement for a license with a total assigned value of $1,104,958.

Upon the initial closing of the Company's initial public offering on November 4, 2003, these 803,606 shares of Series B Preferred Stock were automatically converted into 160,713 shares of common stock.

The holders of the Series B Preferred Stock had the following rights and preferences:

Voting Rights

The holders of the Series B Preferred Stock, voting equally with the shares of common stock, were entitled to vote upon any matter submitted to the stockholders. Certain transactions or events required the majority vote of the Series B Preferred Stock.

Dividends

The holders of the Series B Preferred Stock were entitled to receive non-cumulative cash dividends at a rate of 8% of the original issue price per annum, prior and in preference to any dividend on common stock. No dividend was to have been paid on the Series B Preferred Stock unless an applicable dividend shall have been paid on the Senior Preferred Stock. Dividends were payable only when, as and if declared by the Board of Directors. No dividends were declared prior to the conversion.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, after payment of the full liquidation preference to the Senior Preferred Stock, any remaining assets were to be distributed ratably to the holders of all preferred stock, on an as-converted to common stock basis, and common stock until the holders of all preferred stock had received an aggregate amount per share equal to three times the applicable original issue price; thereafter, the holders of common stock, after conversion, were to receive all of the remaining assets in proportion to their applicable share.

Conversion

The Series B Preferred Stock was convertible, at the option of the holder, at any time after the date of issuance, into fully-paid non-assessable shares of common stock as determined by dividing the original issue price by the conversion price in effect on the date of the certificate surrendered for conversion. The conversion price was the original issue price as adjusted for certain dilutive issuances, splits, reorganizations, combinations, and certain other factors. Upon the effective date of the common stock split, the conversion ratio was five preferred shares for each common share.

Automatic conversion was to occur immediately upon the earlier of (i) the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, at a per share price of at least 1.5 times the original issue price, as adjusted, of Series D Preferred Stock and cash proceeds to the Company of at least $25,000,000 or (ii) upon the date of affirmative consent from at least 65% of the outstanding shares of all preferred stock, voting together as a single class. These shares automatically converted on November 4, 2003, the date of the initial closing of our initial public offering.

Redemption

The holders of the Series B Preferred Stock were subject to automatic redemption in the event of any consolidation or merger of the Company, or sale of all or substantially all of the Company's assets in which the stockholders of the Company immediately prior to the transaction hold less than fifty percent of the outstanding securities of the surviving entity.

On October 24, 2003, the Company effected a one-for-five reverse stock split. All references in the consolidated financial statements to common shares, common share prices and per common share amounts have been adjusted retroactively for all periods presented to reflect this stock split. The Company's actual preferred shares, preferred share prices and per preferred share amounts have not been adjusted for this stock split. However, as a result of the stock split, the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock conversion ratios have been adjusted from one-to-one to five-to-one.

10. Stockholders' Equity/(Deficit)

Common Stock

In 1998, the Company issued 147,907 shares of restricted common stock to two officers of the Company in exchange for $73,512 in notes receivable (the "Notes"). The shares of restricted stock were subject to vesting and, in 2002, all shares became fully vested and the Notes were collected in full.

On August 27, 2003, the Company increased the authorized number of shares of common stock from 17,375,000 shares to 24,221,913 shares.

On October 24, 2003, the Company effected a one-for-five reverse stock split. All references in the consolidated financial statements to common shares, common share prices and per common share amounts have been adjusted retroactively for all periods presented to reflect this stock split. The Company's actual preferred shares, preferred share prices and per preferred share amounts have not been adjusted for this stock split. However, as a result of the stock split, the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock conversion ratios have been adjusted from one-to-one to five-to-one.

On November 4, 2003, the Company completed an initial public offering of 5,000,000 shares of its common stock. On November 7, 2003, the public offering underwriters' completed the exercise of their over-allotment option for an additional 750,000 shares. Concurrent with the closing of the initial public offering, all of the 98,021,120 shares of convertible preferred stock outstanding automatically converted into common stock at a five-to-one ratio, resulting in the issuance of 19,604,186 shares of common stock and the Company increased the authorized number of shares of common stock to 100,000,000 shares and decreased the authorized number of undesignated preferred shares to 5,000,000 shares. The Company received net proceeds of $73,325,170 from its initial public offering, net of $7,174,830 in expenses and underwriters' discount relating to the issuance and distribution of the securities.

Warrants

In December 2002, the Company issued warrants to purchase 327,273 shares of Series D Preferred Stock with an exercise price of $1.375 per share to certain financial institutions in connection with a term loan. Upon the conversion of the Preferred Stock into common stock in November 2003, these warrants became exercisable for 65,453 shares of common stock with an exercise price of $6.875 per share. The Company allocated the proceeds between the warrants and the term loan in accordance with the provisions of APB No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* ("APB 14"). Upon date of grant, the warrants were ascribed a relative fair value of $412,844 using the Black-Scholes option-pricing model with the following assumptions: dividend yield of 0%; estimated volatility of 100%; risk-free interest rate of 2.8% and a contractual life of ten years. This amount was recorded as a debt discount and is amortized over the three-year term of the loan. The life of the warrants is equal to ten years from the date of grant. As of December 31, 2003, the warrants remained outstanding.

In 2000, the Company issued warrants to purchase 35,000 shares of common stock to certain stockholders in connection with the issuance shares of Series B Preferred Stock. As of December 31, 2002, all such warrants were exercised.

In 2000, the Company issued a warrant to purchase 9,090 shares of Series C Preferred Stock with an exercise price of $1.375 per share to a financial institution in connection with a term loan. Upon the conversion of the Preferred Stock into common stock in November 2003, this warrant became exercisable for 1,818 shares of common stock with an exercise price of $6.875 per share. The Company allocated the proceeds between the warrant and the term loan in accordance with the provisions of APB 14. Upon date of grant, the warrant was ascribed a relative fair value of $10,815 using the Black-Scholes option-pricing model with the following assumptions: dividend yield of 0%; estimated volatility of 100%; risk-free interest rate of 6.6% and a contractual life of ten years. As of December 31, 2003, the warrant remained outstanding.

The Company has reserved 67,271 shares of common stock to meet its warrant obligations.

11. Stock Options and Employee Benefits

In July 1998, the Board of Directors approved the Company's 1998 Equity Incentive Plan, under which the Company may grant options, stock bonuses, stock appreciation rights and rights to purchase stock to officers, employees, consultants and directors. In September 2003, the Board of Directors approved the amendment and restatement of the 1998 Equity Incentive Plan as the 2003 Equity Incentive Plan (as amended and restated, the "Plan"), which became effective upon the initial closing of the initial public offering on November 4, 2003. The options are intended to qualify as "incentive stock options" under Section 422 of the Internal Revenue Code, unless specifically designated as non-qualifying stock options or unless exceeding the applicable statutory limit.

At December 31, 2003, the Company had reserved an aggregate of 3,581,260 shares of common stock for issuance under the Plan and 851,868 options were available for grant. Options granted may be exercised for a period of not more than ten years from the date of grant or any shorter period as determined by the Board of Directors. Options vest as determined by the Board of Directors, generally over a four-year period, subject to acceleration upon the occurrence of certain events. The option price of any incentive stock option shall equal or exceed the fair value per share on the date of grant as determined by the Company's Board of Directors prior to the initial public offering or market closing price after the initial public offering, or 110% of the fair value per share in the case of a 10% or greater stockholder.

Activity of the Plan is summarized in the following table:

	Incentive and Non-Qualifying Stock Options			
	Number of Shares	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
Outstanding at December 31, 1997	—	$ —	—	—
Granted (at market)	61,500	$ 0.50		
Exercised	—	$ —		
Canceled	(3,000)	$ 0.50		
Outstanding at December 31, 1998	58,500	$ 0.50	—	—
Granted (at market)	29,500	$ 0.81		
Exercised	—	$ —		
Canceled	(600)	$ 0.50		
Outstanding at December 31, 1999	87,400	$ 0.61	14,325	$0.50
Granted (at market)	240,300	$ 1.15		
Exercised	(17,896)	$ 0.60		
Canceled	(1,000)	$ 1.15		
Outstanding at December 31, 2000	308,804	$ 1.03	25,568	$0.68
Granted (at market)	1,123,800	$ 1.25		
Granted (above market)	38,240	$ 2.50		
Exercised	(17,508)	$ 0.85		
Canceled	(10,962)	$ 1.15		
Outstanding at December 31, 2001	1,442,374	$ 1.25	146,226	$1.13
Granted (below market)	474,280	$ 1.25		
Granted (at market)	180,724	$ 1.25		
Exercised	(79,508)	$ 1.20		
Canceled	(84,829)	$ 1.25		
Outstanding at December 31, 2002	1,933,041	$ 1.25	459,109	$1.22
Granted (below market)	850,427	$ 4.35		
Granted (at market)	26,500	$13.61		
Exercised	(79,380)	$ 1.06		
Canceled	(1,196)	$ 1.24		
Outstanding at December 31, 2003	2,729,392	$ 2.34	986,041	$1.43

The total options outstanding and exercisable under the Plan as of December 31, 2003 are as follows:

	Options Outstanding			Options Exercisable	
Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.50	21,001	4.87	$ 0.50	21,001	$ 0.50
$1.15	133,593	6.26	$ 1.15	120,121	$ 1.15
$1.25	1,816,632	8.12	$ 1.25	801,893	$ 1.25
$2.50	72,169	8.23	$ 2.50	28,714	$ 2.50
$5.00	614,997	9.65	$ 5.00	—	$ 5.00
$6.88-$7.50	46,000	8.18	$ 7.45	4,312	$ 7.50
$13.57-$16.00	25,000	9.90	$14.35	10,000	$15.51
	2,729,392	8.37	$ 2.34	986,041	$ 1.43

The per share weighted average grant date fair value of options granted at market value under the Plan during 2003, 2002 and 2001 was $11.68, $0.89 and $0.22, respectively. The per share weighted average grant date fair value of options granted below market value under the Plan during 2003 and 2002 was $11.21 and $4.32, respectively.

Stock-Based Compensation

In connection with certain option grants to employees, the Company recognized $8,317,386, $1,841,472 and $0 of deferred stock-based compensation for the years ended December 31, 2003, 2002 and 2001, respectively, for the excess of the fair value of the Company's common stock over the exercise price of the option at the date of grant. Of these amounts, the Company recognized stock-based compensation expense of $3,412,815, $392,119 and $0 for the years ended December 31, 2003, 2002 and 2001, respectively. Stock-based employee compensation expense is recognized over the option vesting period using the multiple option method as prescribed by FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans, an Interpretation of APB Opinions No. 15 and 25* ("FIN 28").

During the years ended December 31, 2003, 2002 and 2001, the Company granted 47,000, 34,425 and 73,000 options, respectively, to consultants. The Company recorded deferred stock-based compensation of $878,373, $446,524 and $82,346 related to such grants in 2003, 2002 and 2001, respectively, of which $779,441, $289,124 and $37,996 was recognized in operations in 2003, 2002 and 2001, respectively. The fair values of these options are calculated at each reporting date using the Black-Scholes option-pricing model. As a result, the stock-based compensation expense will fluctuate as the fair value of the Company's common stock fluctuates. The Company believes that the fair values of the options are more reliably measurable than the fair value of the services received. The following weighted average assumptions were used in the Black-Scholes option-pricing model:

	2003	2002	2001
Risk-free interest rate	2.74-3.36%	3.06%	5.85%
Expected life (in years)	10	10	10
Expected volatility	100%	100%	100%
Expected dividend yield	0%	0%	0%

401(k) Plan

The Company's employee savings and retirement plan is qualified under Sections 401(a) and 401(k) of the Internal Revenue Code of 1986, as amended. Eligible employees may elect to defer their current compensation up to the statutorily prescribed annual limits and have the amount of such reduction contributed to the 401(k) Plan. As of December 31, 2003, the Company had not made any matching or additional contributions to the 401(k) Plan on behalf of its employees.

Employee Stock Purchase Plan

The Company adopted an employee stock purchase plan in 2003, in which substantially all of its employees are eligible to participate. The Board of Directors has the authority to set the terms of an offering and may specify offering periods of up to 27 months. The plan allows participants to purchase Myogen common stock through payroll deductions at a price 15% less than the lower of the closing price for the beginning of the offering period or the purchase date. As of December 31, 2003, the plan allowed for the issuance of 100,000 shares of common stock to eligible employees. If an offering is approved, participants may contribute up to 15% of their annual compensation to the plan, subject to certain limitations. During 2003, no shares were issued pursuant to this plan, and no offering was approved as of December 31, 2003.

12. Income Taxes

The components of loss before income taxes consisted of the following for the years ended:

	December 31,		
	2003	2002	2001
Domestic	$(43,201,630)	$(28,084,751)	$(17,189,218)
Foreign	93,143	55,476	77,866
Loss before income taxes	$(43,108,487)	$(28,029,275)	$(17,111,352)

The current provision for income taxes for the years ended December 31, 2003, 2002 and 2001 consisted of foreign expense of $39,346, $18,304 and $3,147, respectively.

The income tax effects of temporary differences that give rise to significant portions of the Company's net deferred tax assets are as follows:

	December 31, 2003	December 31, 2002
Deferred tax assets:		
Net operating loss carryforwards	$ 31,485,487	$ 18,795,933
Amortization of intangibles	4,894,938	3,981,158
Research and development credits	1,423,790	200,000
Deferred revenue	1,283,655	—
Other	491,055	35,812
Total deferred tax assets	39,578,925	23,012,903
Deferred tax liabilities:		
Depreciable assets	(88,216)	(36,340)
Total deferred tax liabilities	(88,216)	(36,340)
Net deferred tax assets, before valuation allowance	39,490,709	22,976,563
Valuation allowance	(39,490,709)	(22,976,563)
Net deferred tax assets	$ —	$ —

The Company's ability to realize the benefit of its deferred tax assets will depend on the generation of future taxable income through profitable operations. Due to the uncertainty of achieving profitable operations, the Company has recorded a full valuation allowance against its deferred tax assets.

The provision for income taxes differs from the amount computed by applying the federal income tax rate of 35% for 2003, 2002 and 2001 to the loss before income taxes as follows for the years ended:

	December 31, 2003	December 31, 2002	December 31, 2001
U.S. federal income tax benefit at statutory rates	$(15,087,971)	$(9,810,246)	$(5,988,973)
Permanent differences	1,063,470	123,481	9,848
Research and development credits	(1,223,790)	(200,000)	—
Change in income tax rate	—	—	(150,022)
Foreign income taxes greater than 35%	6,748	(1,110)	(10,906)
State income tax benefit, net of federal benefit	(1,233,257)	(891,375)	(549,016)
Change in valuation allowance	16,514,146	10,797,554	6,692,216
	$ 39,346	$ 18,304	$ 3,147

As of December 31, 2003, the Company had $82.3 million of net operating loss carryforwards and $1.4 million of research and development credits available to offset future regular and alternative taxable income. These net operating loss carryforwards and research development credits will expire beginning in 2011 and 2019, respectively. The Internal Revenue Code places certain limitations on the annual amount of net operating loss carryforwards which can be utilized if certain changes in the Company's ownership occur. Changes in the Company's ownership may limit the use of such carryforward benefits.

13. Royalty and License Commitments

From time to time, the Company enters into royalty and license agreements (the "Agreements") with universities, companies, research groups and others, resulting in certain commitments. The Company may terminate such Agreements at any time, generally with 30 days to 6 months written notice. The Company has expensed $7,442,000, $3,621,000 and $5,489,000 related to the Agreements for the years ended December 31, 2003, 2002 and 2001, respectively.

The Agreements are summarized as follows:

In September 1998, the Company entered into a license agreement with University License Equity Holdings, Inc., (formerly University Technology Corporation), ("ULEHI") under which ULEHI granted to the Company an exclusive, worldwide license to practice, develop and use certain of ULEHI's technology and licensed patent rights to develop and market licensed products. In exchange for the license agreement, the Company made a small upfront payment and issued 46,542 shares of its common stock valued at $0.50 per share. Under the license agreement, the Company will be required to pay an annual license maintenance fee and quarterly royalty payments based on a percentage of net quarterly product sales. The terms of the agreement also require the Company to pay for all costs related to obtaining and maintaining patents on the technology. As of December 31, 2003, no royalty payments have been made and no royalty payments are due. The Company incurred a $25,000 sublicense fee to ULEHI under this agreement, which is accrued at December 31, 2003. This agreement was amended in November 2003 to modify the royalty structure and to include milestone payments for any drugs developed from the licensed technology, up to a maximum of $400,000 in the case of a drug for which an application for marketing approval is filed.

In October 1998, the Company entered into a license agreement with Hoechst Marion Roussel, Inc., now Aventis, to obtain an exclusive worldwide license for the right to develop and commercialize enoximone. On November 23, 1999, the Company and Aventis amended the licensing agreement, reducing annual payments required under the agreement. As of December 31, 2003, the Company has made $5.5 million in license payments under this agreement. No additional milestone payments are due under this agreement. The Company pays Aventis royalties based on sales.

In December 1999, the Company entered into a license agreement with the Board of Regents of the University of Texas System ("UTS") to obtain certain patent and technology rights. Under the agreement, the Company is required to make payments totaling $3.2 million on achieving certain milestone objectives beginning with the initiation of Phase I clinical trials and through the approval of a new drug application for a licensed or identified product. In addition, the Company will be required to pay an annual license fee of $50,000 on each anniversary of the effective date, beginning on the termination of the University of Texas Southwestern Medical Center ("UTSWMC") Sponsored Research Agreement, as defined below. This license agreement is also subject to the terms of the Sponsored Research Agreement entered into concurrently with the Patent and Technology License Agreement, under which the Company currently pays $250,000 per annum through March 31, 2007. As of December 31, 2003, the Company had accrued $162,500 in accounts payable to a related party under this agreement for a sublicense fee.

In January 2000, the Company entered into a Patent License Agreement with the University and the University of North Texas Health Science Center at Fort Worth (UNTHSC) which grants the Company exclusive rights, with the right to sublicense, to certain patents and technology relating to cardiac hypertrophy. This exclusive license may be subject to certain rights of the U.S. Government to the extent any of the licensed subject matter is developed under a governmental funding agreement. In consideration for the license, the Company is obligated to pay an annual license fee of $50,000 per year, a percentage of sublicense revenue and royalties based upon net sales. Additionally, the Company is obligated to make milestone payments for

any drugs developed from the licensed technology, up to a maximum of $3.2 million in the case of a drug for which a marketing application is approved.

In January 2000, the Company issued 803,606 shares of Series B Preferred Stock in connection with the license agreements entered into in December 1999 and January 2000 with the University and UNTHSC.

Concurrent with the UTS licensing agreement, the Company entered into a Sponsored Research Agreement with UTSWMC for a term of three years. As consideration for the research performed by UTSWMC, the Company is required to pay the related expenses, plus other indirect costs of such research. In 2002, total payments made under the agreement and expensed to research and development were $360,000, of which $62,500 was included in accounts payable to a related party at December 31, 2002. This agreement will terminate on March 31, 2007, unless terminated earlier under the terms of the agreement.

In October 2001, the Company entered into an agreement with Abbott Laboratories for the exclusive license to develop and commercialize ambrisentan, an endothelin receptor antagonist compound. Under the agreement, the Company is required to make payments on attainment of certain milestone objectives. In addition, the Company was required to reimburse Abbott for costs related to the development expenditures already incurred by them as of the effective date of the agreement. The Company has made license and cost-reimbursement payments totaling $5.8 million in the past and an additional cost-reimbursement payment for additional feasibility and evaluation studies performed on the Company's behalf of $690,225 is accrued at December 31, 2003. Milestone payments totaling $6.0 million will be made in the future if the agreement remains in effect through the successful commercialization of ambrisentan in pulmonary arterial hypertension.

In June 2003, the Company entered into a license agreement with Abbott under which the Company received an exclusive worldwide license from Abbott to develop and commercialize darusentan. In consideration for the license, the Company paid Abbott initial license fees of $5.0 million and are obligated to make future milestone payments totaling $25.0 million if the Company successfully commercializes the drug for a single indication. Additional milestone payments would be due if the Company commercializes darusentan for additional indications. However, in no event would the Company be obligated to pay more than $50.0 million in total milestone and license fees. In addition, the Company will owe royalties based on net sales of darusentan. If the Company seeks a co-promotion arrangement for darusentan in any country or group of countries, Abbott has the right of first negotiation. Abbott also has the option to be the exclusive development and commercialization partner for darusentan in Japan, upon terms to be negotiated. If the Company does not commercialize darusentan in certain markets, Abbott may market the product on its own in the affected countries, paying the Company a royalty on its sales. The Company must use reasonable commercial diligence to develop and commercialize darusentan and to meet milestones in completing certain clinical work. The term of the agreement is indefinite, however, either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

In February 2002, the Company entered into a Sponsored Research Agreement with the Board of Regents of the University of Wisconsin System ("UWS"), effective October 2001. Under the terms of the agreement, the Company is required to reimburse UWS for all direct and indirect costs of such research up to a maximum amount. Total payments made under the agreement in 2003 and 2002 were $210,657 and $337,050, respectively. This agreement will terminate on March 31, 2005, unless terminated earlier by its terms. The Company has an obligation to pay a total of an additional $294,920 in 2004 and 2005.

During 2002, the Company entered into a collaborative research agreement with an unrelated third party associated with the Company's EMPOWER study. Under this agreement, the Company is entitled to certain milestone payments in conjunction with the Phase III study. As of December 31, 2003, the Company accrued $644,940 under this agreement which is reflected as a reduction in research and development expense as costs

are incurred. In 2003, $355,060 of research and development expenses were reduced under this agreement as the unrelated third party does not obtain any rights to the research or drug candidates.

On October 8, 2003, the Company entered into a research collaboration with the Novartis Institutes for BioMedical Research, Inc. ("Novartis") for the discovery and development of novel drugs for the treatment of cardiovascular disease. In exchange for a $4.0 million upfront payment, a deferred payment of an additional $1.0 million after the first year and an obligation to provide research funding to the Company for a minimum of three years, Novartis has the exclusive right to license drug targets and product candidates developed through the collaboration. Upon execution of a license, Novartis is obligated to fund all further development of the licensed product candidate, make payments to the Company upon the achievement of certain milestones and pay the Company royalties for sales of any products that are successfully commercialized. Upon the completion of Phase II clinical trials of any product candidate Novartis has licensed from the Company, the Company has the option to enter into a co-promotion and profit sharing agreement with them for that product candidate, subject to reimbursement by the Company of a portion of Novartis' development expenses up to that point, the Company's agreement to share the future development and marketing expenses for the relevant product candidate and elimination of the royalty payable to the Company.

14. Related Party Transactions

In October 1998, the Company issued restricted common stock in exchange for notes receivable from two officers which were fully collected in 2002.

During 1998, the Company entered into consulting agreements with three stockholders of the Company. The agreements are renewable annually upon mutual consent. One agreement expired in 1999 and was not renewed. Another agreement terminated in 2003. For the years ended December 31, 2003, 2002 and 2001, the Company incurred consulting fees of $29,831, $33,996 and $33,996 related to these agreements, respectively. In addition, the Company granted to these two stockholders options to purchase a total of 24,000 shares of the Company's common stock at $0.50 per share. For consulting services provided during 2001, certain of such stockholders also received options to purchase 24,000 shares of the Company's common stock at an exercise price of $0.50, vesting over four years. The options were valued on their respective grant dates using the Black-Scholes option-pricing model resulting in an insignificant stock-based compensation charge over the vesting period. During 2003, a new consulting agreement was entered into with one of these stockholders, with a three-year term. The consulting fees will be $24,000 per year and it granted 12,000 options to purchase the Company's common stock at an exercise price of $7.50, vesting over three years. These options were valued on the grant date using the Black-Scholes option-pricing model which resulted in a total value of $133,000, of which $36,000 was recognized as stock-based compensation expense during 2003.

During 1999, the Company entered into separate consulting agreements with two stockholders of the Company. The agreements extend for three years and are renewable annually thereafter upon mutual consent. For the years ended December 31, 2003, 2002 and 2001, the Company incurred consulting fees of $71,250, $86,500 and $74,000, respectively, related to these agreements. One agreement expired in 2002 and was not renewed. The remaining agreement was amended in 2003 to extend the expiration date of the agreement to December 31, 2007 and grant an additional 30,000 options. For consulting services provided prior to 2001, the stockholders also received options to purchase 62,000 shares of the Company's common stock at a weighted average exercise price of $1.10, vesting over four years. The options were valued on their respective grant dates using the Black-Scholes option-pricing model. The options have a total value of approximately $603,000 of which approximately $349,000, $244,000 and $10,000 was recognized as stock-based compensation expense during the years ended December 31, 2003, 2002 and 2001, respectively. The additional 30,000 options granted in 2003 have an exercise price of $7.50, vesting over two years. The options were valued on the grant

date using the Black-Scholes option-pricing model which resulted in a total value of $392,000, of which $141,000 was recognized as stock-based compensation expense during 2003.

Dr. Michael Bristow, the Chief Science and Medical Officer and a Director of the Company, has served as a director of Clinical Cardiovascular Research, LLC for each of the last three years. On December 4, 1998, the Company entered into a Clinical Research Services Master Agreement with Clinical Cardiovascular Research, LLC, as amended, pursuant to which it paid $1,473,977 in 2003, $2,141,461 in 2002 and $2,315,098 in 2001. Such payments are recorded as research and development expense.

The Company has made annual contributions of $268,650, $300,000 and $200,000 for fiscal years ended December 31, 2003, 2002 and 2001, respectively, and a sponsored research payment of $26,200 in the fiscal year ended December 31, 2001 to the University of Colorado to support academic research in heart failure, including research performed by Dr. Michael Bristow. Such contributions and payments were recorded as research and development expense.

15. Business Segments

The Company operates in the United States and in certain countries throughout Europe under one operating segment. All product sales from Inception to December 31, 2003 have occurred in Europe through the Company's subsidiary.

	Years Ended December 31,		
	2003	2002	2001
Sales:			
Germany	$ 720,251	$ 691,683	$ 599,813
Netherlands	796,414	650,524	693,758
United Kingdom	541,963	512,303	370,392
Italy	405,341	190,511	—
France	342,192	267,274	123,364
Other	39,552	30,604	20,657
	$2,845,713	$2,342,899	$1,807,984

	December 31,	
	2003	2002
Long-lived assets:		
United States	$1,234,685	$1,627,684
Europe	69,343	64,247
	$1,304,028	$1,691,931

16. Subsequent Event

In February 2004, the Company made a $1.5 million milestone payment to Abbott as a result of the initiation of its Phase III ARIES trials for ambrisentan.

17. Quarterly Financial Results (Unaudited) (in thousands, except per share data)

2003	March 31,	June 30,	September 30,	December 31,
Revenue:				
Product sales	$ 657	$ 708	$ 707	$ 774
Research and development contracts	—	—	—	1,010
Costs and expenses:				
Cost of product sold	207	227	220	231
Research and development*	6,351	11,219	7,052	12,743
Selling, general and administrative*	932	970	663	1,822
Stock-based compensation	772	493	841	2,086
Net loss	(7,580)	(12,244)	(8,130)	(15,194)
Accretion of dividends	(3,670)	(3,670)	(4,244)	(1,603)
Deemed dividend	—	—	(39,935)	—
Net loss attributable to common stock	$(11,250)	$(15,915)	$(52,309)	$(16,796)
Basic and diluted earnings per common share	$ (10.95)	$ (15.47)	$ (50.29)	$ (0.91)

2002	March 31,	June 30,	September 30,	December 31,
Revenue:				
Product sales	$ 473	$ 549	$ 635	$ 686
Research and development contracts	—	—	—	—
Costs and expenses:				
Cost of product sold	175	261	225	216
Research and development*	4,338	4,940	8,421	7,251
Selling, general and administrative*	1,214	1,033	1,460	943
Stock-based compensation	—	23	291	367
Net loss	(5,026)	(5,446)	(9,518)	(8,058)
Accretion of dividends	(3,671)	(3,671)	(3,671)	(3,671)
Deemed dividend	—	—	—	—
Net loss attributable to common stock	$(8,697)	$(9,117)	$(13,189)	$(11,728)
Basic and diluted earnings per common share	$ (9.06)	$ (8.98)	$ (12.95)	$ (11.48)

* Excludes Stock-based compensation expenses.

In the fourth quarter of 2003, the Company signed a research and development contract which provided upfront payments, license revenues and research funding for a minimum of three years. The research and development contract revenues that were recognized in the fourth quarter of 2003 relate to this agreement and consist of license revenue and research funding. Research and development expenses increased $5.7 million in the fourth quarter 2003 compared to the third quarter 2003 due to the initiation of the Phase III ARIES trials for ambrisentan and costs related to increased duration and enrollment in the other clinical trials. In addition, the fourth quarter 2003 stock-based compensation expense increased $1.2 million compared to the third quarter of 2003. This was primarily a result of a full quarter of amortization related to employee stock option grants that occurred in late August 2003 and an increase in expense related to options granted to non-employees as a result of an increase in the Company's market price for its common stock.

INDEX TO EXHIBITS

Exhibit Number	Description
3.1*	Restated Certificate of Incorporation.
3.2*	Amended and Restated Bylaws.
4.1*	Specimen Stock Certificate.
10.1*(1)	2003 Equity Incentive Plan of the Company, Form of Grant Notice and Form of Stock Option Agreement.
10.2*(1)	2003 Employee Stock Purchase Plan of the Company.
10.3*	Series A Preferred Stock Purchase Agreement, dated May 21, 1998 between Myogen and the parties named therein.
10.4*	Series B Preferred Stock Purchase Agreement, dated March 16, 2000 between Myogen and the parties named therein.
10.5*	Series C Preferred Stock Purchase Agreement, dated November 23, 1999, as amended on December 8, 1999, between Myogen and the parties named therein.
10.6*	Series D Preferred Stock Purchase Agreement, dated August 21, 2001, as amended on November 2, 2001 and December 27, 2001, between Myogen and the parties named therein.
10.7*	Series D Preferred Stock Purchase Agreement, dated August 27, 2003, between Myogen and the parties named therein.
10.8*	Third Amended and Restated Investor Rights Agreement, dated August 21, 2001, as amended on August 27, 2003, between Myogen and certain of our stockholders.
10.9*	Third Amended and Restated Stockholders Agreement, dated August 21, 2001, as amended on December 27, 2001, between Myogen and certain of our stockholders.
10.10*(1)	Form of Employment Agreement entered into between Myogen and certain of its executives, including reference schedule.
10.11*	Form of Indemnification Agreement entered into by each of Myogen's Executive Officers and Directors.
10.12*	Lease Agreement between the Company and Church Ranch Business Center, LLC, dated January 1, 2002.
10.13*	Warrant to purchase shares of Series C preferred stock issued to Silicon Valley Bank, dated January 26, 2000.
10.14*	Venture Loan and Security Agreement by and among GATX Ventures, Inc., Silicon Valley Bank and the Company, dated December 6, 2002.
10.15*	Warrant to purchase shares of Series D preferred stock issued to GATX Ventures, Inc., dated December 6, 2002.
10.16*	Warrant to purchase shares of Series D preferred stock issued to Silicon Valley Bank, dated December 6, 2002.
10.17*==	License Agreement between Hoechst Marion Roussel, Inc. and the Company, dated October 1, 1998, as amended November 23, 1999 and June 2, 2003.
10.18*==	License Agreement between Abbott Deutschland Holding GmbH and the Company, dated October 8, 2001.
10.19*==	Intellectual Property License Agreement between the University Technology Corporation and the Company, dated September 1, 1998, as amended January 26, 2001 and November 12, 2002.
10.20*==	Materials Transfer Agreement between the Regents of the University of Colorado and the Company, dated September 4, 1998, as amended January 4, 2001.
10.21*==	Patent and Technology License Agreement between the Board of Regents of The University Of Texas System and the Company, dated December 1, 1999, as amended July 7, 2000 and December 20, 2001.
10.22*==	Exclusive Patent And Technology License Agreement between the Board of Regents of The University of Texas System and the Company, dated January 1, 2002.
10.23*==	License Agreement between Abbott Laboratories and the Company, dated June 30, 2003.

Exhibit Number	Description
10.24*=	Collaboration and Option Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company, dated October 8, 2003.
10.25*=	Form of License, Development and Commercialization Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company.
10.26*=	Materials Transfer Agreement between the Regents of the University of Colorado and the Company, dated September 12, 2003.
10.27	Indemnification Agreement between Kirk K. Calhoun and the Company, dated as of January 16, 2004.
10.28	First Amendment to Lease Agreement between Sevo Miller, Inc., as receiver on behalf of Church Ranch Business Center, LLC, and the Company, dated December 2, 2003.
10.29†	Third Amendment to Intellectual Property License Agreement between University License Equity Holdings, Inc. and the Company, dated November 24, 2003.
10.30†	Amendment No. 3 to Patent and Technology License Agreement between the Board of Regents of the University of Texas System and the Company, dated November 6, 2003.
10.31†	Amendment No. 1 to Patent and Technology License Agreement between the Board of Regents of the University of Texas System and the Company, dated as of February 10, 2004.
10.32†	Patent License Agreement between the University of Texas System, the University of North Texas Health Science Center at Fort Worth and the Company, dated January 13, 2000.
21.1*	List of Subsidiaries.
23.1	Consent of PricewaterhouseCoopers LLP.
24.1	Powers of Attorney. Reference is made to page 52.
31.1	Certification of principal executive officer required by Rule 13a-14(a).
31.2	Certification of principal financial officer required by Rule 13a-14(a).
32.1	Section 1350 Certification.

* Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-108301) and amendments thereto, declared effective October 29, 2003.

(1) Indicates Management Contract or Compensatory Plan or Arrangement.

= We have been granted confidential treatment with respect to the omitted portions of this agreement.

† We have applied for confidential treatment with respect to portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

MYOG
NASDAQ
LISTED

Corporate Information

SAFE HARBOR STATEMENT

This annual report contains forward-looking statements that involve significant risks and uncertainties, including those discussed in this release and others that can be found in the "Risk Factors" section of Myogen's Annual Report on Form 10-K filed on March 1, 2004. Myogen is providing this information as of March 5, 2004 and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

The Company cautions investors not to place undue reliance on the forward-looking statements contained in this document. No forward-looking statement can be guaranteed and actual events and results may differ materially from those projected. The Company's results may be affected by its effectiveness at managing its financial resources, its ability to successfully develop and market current and new products, difficulties or delays in its clinical trials, difficulties or delays in manufacturing its products, and regulatory developments involving current and future products. Delays in clinical trials, whether caused by adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect the Company's financial position and prospects. Results from earlier clinical trials are not necessarily predictive of future clinical results. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue one or more of its drug development or discovery research programs. Myogen is at an early stage of development and may not ever have any products that generate significant revenue.

BOARD OF DIRECTORS

J. William Freytag, Ph.D.
Chairman, President &
Chief Executive Officer

Michael R. Bristow, M.D., Ph.D.
Chief Science &
Medical Officer

Kirk K. Calhoun
Chairman—Audit
Committee

Jerry T. Jackson
Chairman—Nominating &
Corporate Governance
Committee

Daniel J. Mitchell
Sequel Venture Partners

Arnold L. Oronsky, Ph.D.
InterWest Partners

Andrew N. Schiff, M.D.
Perseus-Soros
Biopharmaceutical Fund

Sigrid J. Van Bladel, Ph.D.
New Enterprise Associates

MANAGEMENT TEAM

J. William Freytag, Ph.D.
Chairman, President &
Chief Executive Officer

Michael Bristow, M.D., Ph.D.
Chief Science &
Medical Officer

Michael Gerber, M.D.
Senior Vice President,
Clinical Development &
Regulatory Affairs

Richard Gorczynski, Ph.D.
Senior Vice President,
Research & Development

John Julian
Senior Vice President,
Commercial Development

Joseph Turner
Senior Vice President,
Finance & Administration
and Chief Financial Officer

INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP
Denver, Colorado

GENERAL COUNSEL

Cooley Godward, LLP
Broomfield, Colorado

CORPORATE HEADQUARTERS

7575 W. 103rd Avenue
Suite 102
Westminster, CO 80021
303.410.6666

TRANSFER AGENT AND REGISTRAR

Communications concerning stock transfer requirements, lost certificates and change of address should be directed to Computershare Trust Company, Inc., 350 Indiana Street, Suite 800, Golden, CO 80401, 303.262.0600, www.computershare.com.

STOCKHOLDER INQUIRIES

Inquiries from our stockholders and potential investors regarding our Company are always welcome. Please direct your requests for information to:
Derek Cole, Director,
Investor Relations
Myogen, Inc.
7575 W. 103rd Avenue,
Suite 102
Westminster, Colorado
80021 USA
303.410.6666
Derek.cole@myogen.com

WEBSITE

www.myogen.com

STOCK LISTING

Myogen, Inc. common stock is listed on the Nasdaq National Market under the ticker symbol MYOG.

ANNUAL MEETING

The next annual meeting of stockholders will be held on May 12, 2004, 9:00 a.m. (Mountain) at The Westin Westminster, 10600 Westminster Boulevard, Westminster, Colorado.

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