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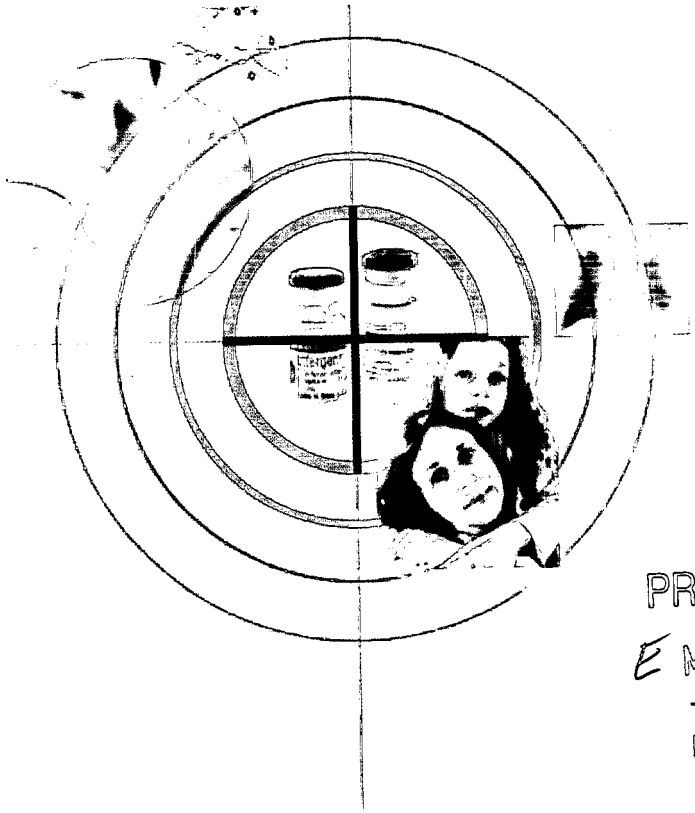
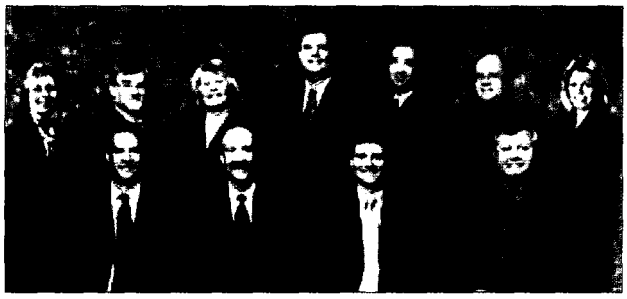
INTERMUNE®

P.E 12/31/04



2004 ANNUAL REPORT



Front Row: Williamson Z. Bradford, M.D., Ph.D., Vice President of Clinical Science; Steven B. Porter, M.D., Ph.D., Senior Vice President of Clinical Affairs; Thomas R. Kassberg, Senior Vice President of Business Development and Corporate Strategy; Roger L. Hawley, Executive Vice President of Commercial and Technical Operations

Back Row: Cynthia Y. Robinson, Ph.D., Senior Vice President of Therapeutic Area Teams; Howard A. Simon, Esq., SPHR, Senior Vice President of Human Resources and Associate General Counsel; Robin J. Steele, Esq., Senior Vice President, General Counsel and Corporate Secretary; Daniel G. Welch, President and Chief Executive Officer; Lawrence M. Blatt, Ph.D., Senior Vice President of Preclinical and Applied Research; Norman L. Halleen, Senior Vice President of Finance and Chief Financial Officer; Marianne T. Armstrong, Ph.D., Senior Vice President of Regulatory, Medical Affairs and Drug Safety

An article published in the January 2005 issue of CHEST, the journal of the American College of Chest Physicians, provides additional analyses of data from our first Phase III trial of Actimmune for IPF. These analyses conclude that survival is the preferred outcome measure for future studies of Actimmune in patients with IPF and support the design of our ongoing Phase III INSPIRE Trial, a 600-patient, placebo controlled study with survival as its primary endpoint. We anticipate enrollment of the INSPIRE Trial to be completed by the end of 2005 and two-year treatment data to be reported in early 2008.

In 2004, the FDA and the European Medicines Agency (EMEA) granted orphan drug designation for pirfenidone for the treatment of IPF in the United States and Europe, respectively. Orphan drug designation provides a period of market exclusivity for pirfenidone in these markets. During 2004, we made significant progress in our pirfenidone development program, including completing an analysis of prior pirfenidone trial data, negotiating a data-sharing agreement with Shionogi & Co., LTD, and conducting an end-of phase II meeting with the FDA. As a result of this productive meeting with the FDA, we now plan to move forward with a Phase III development program for pirfenidone in IPF.

Strengthening Financials and Leveraging Assets In 2004, we created a new revenue growth brand in Infergen, and we continued to apply fiscal discipline throughout the organization, focusing development on our two core therapeutic areas. We reduced our 2004 net loss by $38 million, a 39% reduction over 2003, and we strengthened our balance sheet by replacing a $150 million high-interest convertible note due in 2006 with a $170 million lower interest convertible note due in 2011. In doing so, we reduced our annual interest expense by over $8 million and deferred our payment obligations by 5 years.

We are investing heavily in InterMune's future. At the end of 2004, we had three Phase III and one Phase IIb clinical trials underway. Still, there are other exciting product candidates in our pulmonology and hepatology portfolios that merit investment. Therefore, we are seeking partnerships to increase the speed and mitigate the risk and expense of some of these programs.

While cancer is outside of our two areas of therapeutic focus, we decided to continue a Phase III trial evaluating Actimmune in ovarian cancer because it required relatively little additional investment. An interim analysis of progression-free survival is planned for the second half of 2005, and the results of this analysis will guide further investment decisions.

Importantly, we significantly strengthened our leadership team in 2004. During the year, we added seven new senior executives to our Executive Committee and recruited 19 Vice President and Director level professionals. I am confident that InterMune now has the depth and breadth of experienced leadership to deliver on our exciting opportunities.

2005 – A Year for Execution Armed with promising clinical data for our compounds, solid revenue growth of our Infergen brand, and a new and very experienced leadership team, we believe InterMune is poised for success in 2005. Looking ahead, we expect a year of strong growth in Infergen sales and meaningful progress in our late-stage clinical development programs. We will remain focused on developing two very exciting pipelines, the first in HCV and the second in IPF, to meet the unmet needs of patients who suffer from these deadly diseases.

We appreciate your continued support and confidence, and look forward to updating you throughout the year.

Sincerely,

Daniel G. Welch
President and Chief Executive Officer

2004 was an important rebuilding year for InterMune, and I am very pleased with the progress we made. During the year, we:

- Successfully narrowed our therapeutic focus to two areas: hepatology and pulmonology
- Significantly advanced our late-stage clinical development programs
- Published and presented important data demonstrating the potential of the compounds in our pipeline to help patients with serious unmet medical needs
- Turned Infergen® (interferon alfacon-1) into a revenue growth brand
- Strengthened our financial position
- Completed the transformation of our executive team

An Aggressive Approach to Hepatitis C Nonresponders It is estimated that there are currently four million people infected with the hepatitis C virus (HCV) in the United States, making it much more common than the human immunodeficiency virus (HIV). Current first-line therapy for HCV is treatment with a pegylated interferon alpha 2 plus ribavirin, which provides a cure for approximately 50% of patients. Those patients who do not respond to this first-line therapy are called nonresponders. There are approximately 200,000 nonresponders in the United States, and this number is growing by an estimated 50,000 patients each year.

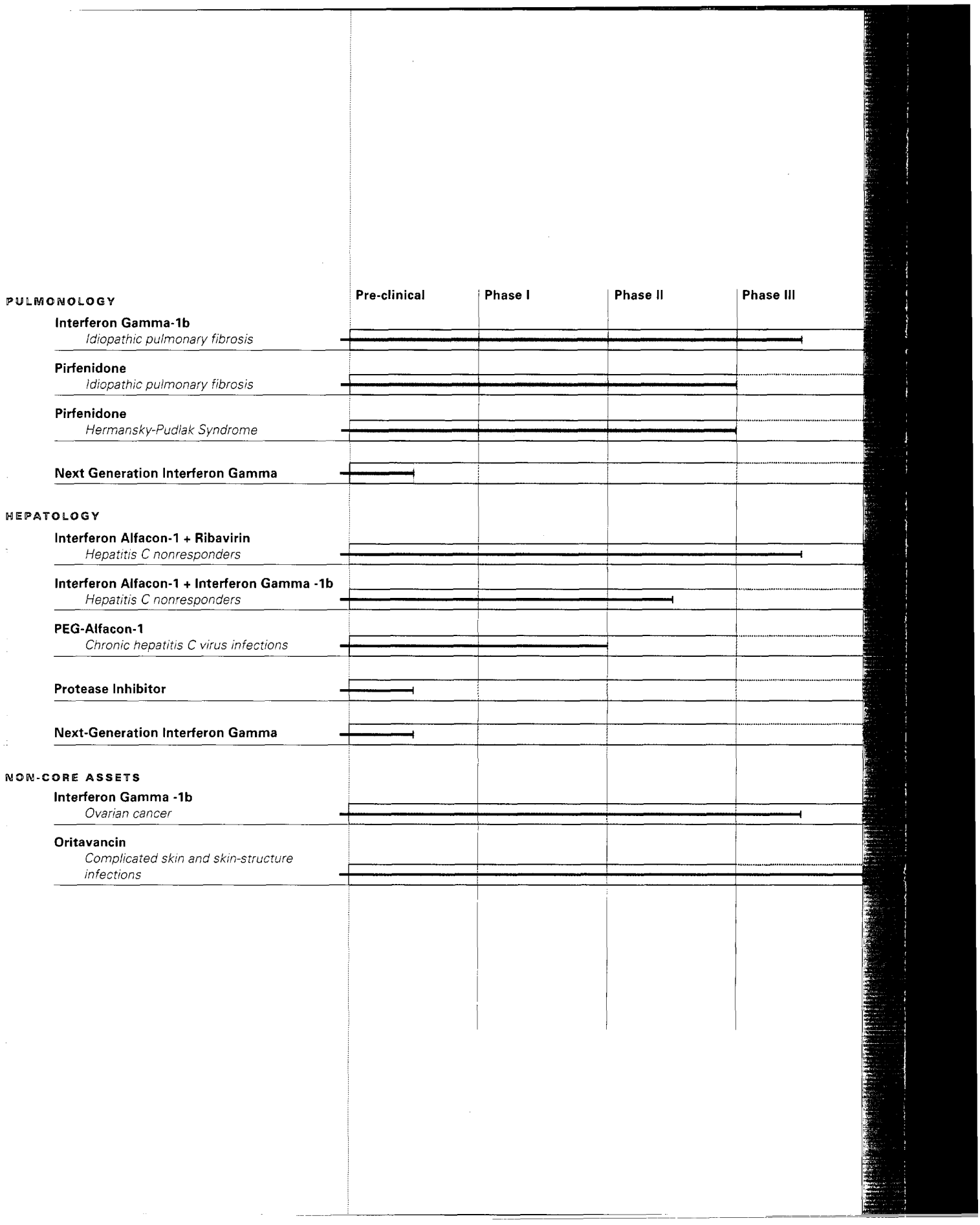
We took bold steps last year to create value in our hepatology pipeline and to expand the options for patients suffering from chronic HCV infections. Three times a week dosing of Infergen is currently indicated for the treatment of adults with chronic HCV. Infergen is also the only Food and Drug Administration (FDA) approved interferon alpha with data in its label regarding the treatment of patients who failed to adequately respond to prior interferon alpha therapy. In 2004, we launched a significant effort to position Infergen for use by nonresponders and transformed this brand into an important revenue contributor for InterMune. Infergen revenue in 2004 was $22 million, a 140% increase over 2003.

During the first half of 2004, we initiated two very important clinical trials to evaluate the daily dosing of Infergen for the treatment of nonresponders: the Phase III DIRECT Trial of daily Infergen plus ribavirin and the Phase IIb trial of daily Infergen plus Actimmune® (interferon gamma-1b), with and without ribavirin. Several investigator-initiated studies suggest that daily Infergen, in combination with ribavirin, could potentially provide a cure for nonresponders. Based on this data, we initiated the 510-patient Phase III DIRECT Trial in June 2004. We anticipate enrollment of this trial to be completed in the third quarter of 2005 and 72-week data to be reported in the first half of 2007.

There is promising in vitro and independent clinical data that support the synergistic effect of two of our products, Infergen and Actimmune, in combination. This data has been presented at medical conferences and is the scientific rationale behind our Phase IIb trial of the combination of daily Infergen and Actimmune, with and without ribavirin, for the treatment of nonresponders. We initiated this 280-patient trial in May 2004, and we expect enrollment to be completed in the third quarter of 2005 and 72-week data to be reported in 2007.

During 2004, we made great progress on our new research program to discover and develop novel HCV protease inhibitors. We believe this class of compounds, which may inhibit replication of the HCV virus, could prove to be an important component of first-line treatment of HCV patients. In connection with this program, we signed a licensing agreement with Chiron Corporation and extended our discovery collaboration with Array BioPharma Inc. in the second half of 2004. At the American Association for the Study of Liver Diseases medical conference in November 2004, we presented preclinical data on the discovery and characterization of a number of potent and selective small molecule inhibitors of the HCV protease arising out of this research effort.

Committed to Innovative Therapies for Idiopathic Pulmonary Fibrosis (IPF) In the area of pulmonology, InterMune is committed to serving the needs of IPF patients by advancing diagnosis and disease awareness and by developing and commercializing innovative medicines to treat this condition. IPF, which afflicts approximately 83,000 patients in the United States, is characterized by progressive scarring, or fibrosis, of the lungs and typically results in death within two to five years of diagnosis. There is currently no FDA approved therapy for the treatment of IPF. We are developing both Actimmune and pirfenidone, an oral small molecule compound, for the treatment of this deadly disease.


Pre-clinical
Phase I
Phase II
Phase III
PULMONOLOGY
Interferon Gamma-1b
Idiopathic pulmonary fibrosis
Pirfenidone
Idiopathic pulmonary fibrosis
Pirfenidone
Hermansky-Pudlak Syndrome
Next Generation Interferon Gamma
HEPATOLOGY
Interferon Alfacon-1 + Ribavirin
Hepatitis C nonresponders
Interferon Alfacon-1 + Interferon Gamma -1b
Hepatitis C nonresponders
PEG-Alfacon-1
Chronic hepatitis C virus infections
Protease Inhibitor
Next-Generation Interferon Gamma
NON-CORE ASSETS
Interferon Gamma -1b
Ovarian cancer
Oritavancin
Complicated skin and skin-structure infections

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2004

or

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

For the transition period from to

Commission file number 0-29801

INTERMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3296648**
(State or other jurisdiction of incorporation or organization)	(IRS Employer identification No.)

3280 Bayshore Boulevard
Brisbane, CA 94005
(Address of principal executive offices)

(415) 466-2200
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 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 (§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 Exchange Act Rule 12b-2). Yes ☒ No ☐

As of June 30, 2004, the aggregate market value (based upon the closing sales price of such stock as reported in the NASDAQ National Market on such date) of the voting stock held by non-affiliates of the registrant was $205,614,952. Excludes an aggregate of 19,152,753 shares of the registrant's common stock held by officers and directors and by each person known by the registrant to own 5% or more of the registrant's outstanding common stock as of June 30, 2004. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. As of February 28, 2005, the number of outstanding shares of the registrant's common stock was 32,583,226 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

INTERMUNE, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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PART I

ITEM 1. BUSINESS

Forward Looking Statements

This Annual Report on Form 10-K (the "Report") contains certain information regarding our financial projections, plans and strategies that are 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 statements involve substantial risks and uncertainty. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "plan," "could," "should" and "continue" or similar words. These forward-looking statements may also use different phrases.

We have based these forward-looking statements on our current expectations and projections about future events. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include, among other things, statements which address our strategy and operating performance, and events or developments that we expect or anticipate will occur in the future, including, but not limited to, statements in the discussions about:

- product and product candidate development;
- governmental regulation and approval;
- sufficiency of our cash resources;
- future revenues, including those from product sales and collaborations, and future expenses;
- pending securities and shareholder derivative class action litigation;
- our research and development expenses and other expenses; and
- our operational and legal risks.

You should also consider carefully the statements under the heading "Risk Factors" below, which address additional factors that could cause our results to differ from those set forth in the forward-looking statements. Any forward-looking statements are qualified in their entirety by reference to the factors discussed in this Report, including those discussed in this Report under the heading "Risk Factors" below. Because of the factors referred to above, as well as the factors discussed in this Report under the heading "Risk Factors" below, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statement. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. When used in the Report, unless otherwise indicated, "InterMune," "we," "our" and "us" refers to InterMune, Inc.

Overview

We are an independent biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology. Pulmonology is the field of medicine concerned with the diagnosis and treatment of pulmonary, or lung, conditions. Hepatology is the field of medicine concerned with the diagnosis and treatment of disorders of the liver. We were incorporated in California in 1998 and reincorporated in Delaware in 2000 upon becoming a public company. On April 26, 2001, we

changed our name from InterMune Pharmaceuticals, Inc. to InterMune, Inc. During 2003 and 2004, we began reorganizing our business by curtailing new investment in non-core areas and focusing our commercial and development efforts in pulmonology and hepatology. Our revenue base is provided primarily from sales of our two core marketed products, Actimmune and Infergen. We also have a number of advanced-stage clinical programs addressing a range of unmet medical needs with attractive potential commercial markets as well as two non-core assets that we are seeking to divest during 2005. We have sustained losses in every year since inception and, as of December 31, 2004, we had an accumulated deficit of $455.6 million.

Our total revenues and net loss for each of the years ending, and our total assets as of, December 31, 2004, 2003, and 2002 are summarized in the following table:

	2004	2003	2002
		(in thousands)	
Total Revenues	$150,987	$154,138	$ 111,965
Net Loss	(59,478)	(97,001)	(144,309)
Total Assets	266,011	288,501	384,881

Marketed Products

Our three marketed products are Actimmune® (interferon gamma-1b), approved for the treatment of patients with severe, malignant osteopetrosis and chronic granulomatous disease ("CGD"), Infergen® (consensus interferon alfacon-1), approved for the treatment of patients with compensated liver disease who have chronic hepatitis C virus ("HCV"), infections, and Amphotec® (amphotericin B cholesteryl sulfate complex for injection), approved for the treatment of invasive aspergillosis. For the year ended December 31, 2004, Actimmune accounted for approximately 83% of our product revenues, and substantially all of those revenues were derived from physicians' prescriptions for the off-label use of Actimmune in the treatment of idiopathic pulmonary fibrosis ("IPF").

Co-Promotion

On March 26, 2004, we entered into an agreement with Baxter Healthcare Corporation ("Baxter") under which we co-promote Baxter's product Aralast® in the United States for the treatment of patients with hereditary emphysema. Under this agreement, we are compensated by Baxter based upon a percentage of Aralast sales. We are required to make a certain minimum number of visits to physicians' offices on an annual basis to discuss Aralast, and among those visits a certain minimum number must be to offices of pulmonologists.

Product Development

Drug development in the United States is a process that includes several steps required by the United States Food and Drug Administration ("FDA"). The process begins with the filing of an Investigational New Drug Application ("IND"), which if successful, allows for the opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of clinical trials prior to approval: Phase I, II and III. Within the pharmaceutical industry, clinical development takes approximately seven years of a drug's total development time. The FDA may require, or companies may pursue, additional clinical trials, known as Phase IV clinical trials, after a product is approved. The results of Phase IV clinical trials can confirm the effectiveness of a drug and can provide important safety information to supplement the FDA's voluntary adverse drug reaction reporting system. The most significant costs associated with clinical development are Phase III clinical trials, as they tend to be the longest and largest

studies conducted during the drug development process. It is possible for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous Phase III clinical trial.

The successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate and are difficult to accurately predict. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our business. In responding to a New Drug Application ("NDA"), a Biologic License Application, ("BLA"), or an NDA or BLA supplement, the FDA may grant marketing approval (i.e., a license), request additional information or refuse to approve the application if it determines that the application does not provide an adequate basis for approval.

We have a late-stage development pipeline in the areas of pulmonology, hepatology and ovarian cancer.

- Pulmonology

In pulmonology, we are developing two therapies for the treatment of IPF, and one therapy for pulmonary fibrosis associated with Hermansky-Pudlak Syndrome ("HPS"). IPF is a fatal disease characterized by progressive scarring, or fibrosis, of the lungs, which leads to the deterioration and destruction of lung function. There is no FDA approved therapy for IPF. Based on available data, we believe that there are approximately 83,000 patients with IPF in the United States. We are developing two clinically advanced compounds for the treatment of IPF, Actimmune and pirfenidone. We initiated a second Phase III clinical trial of Actimmune for the treatment of patients with IPF (the "INSPIRE" trial) in December 2003. We have rights to develop and commercialize Actimmune for a broad range of diseases in the United States, Canada and Japan. We are collaborating with Boehringer Ingelheim International GmbH ("BI International"), which has similar rights in Europe and the rest of the world, to develop and commercialize interferon gamma-1b under the trade name Imukin®. Actimmune has been granted orphan drug designation for IPF in the United States. In 2004 the FDA and the European Medicines Agency ("EMEA") granted us orphan drug designation for pirfenidone for the treatment of IPF. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. This designation provides seven years of market exclusivity in the United States upon the FDA's first approval of the product for the orphan designation provided that the sponsor complies with certain FDA specified conditions.

We are also developing pirfenidone for pulmonary fibrosis associated with HPS, a fatal, fibrotic lung disease caused by genetic factors for which there is no FDA approved therapy.

- Hepatology

In hepatology, we are focused on expanding treatment options for patients suffering from chronic HCV infections. Patients who have never been treated with interferons are referred to as "naïve" patients. We are developing once-daily Infergen in combination with ribavirin therapy for the treatment of patients suffering from chronic HCV infections who have failed to respond to a first line therapy of pegylated interferon-alpha 2 in combination with ribavirin therapy. Approximately 50% of naïve patients show a sufficient and sustained virologic response (the most commonly used measure of treatment effectiveness) to this initial treatment. The remaining 50% of patients that do not show a sufficient and sustained virologic response to pegylated interferons plus ribavirin are referred to as hepatitis C "nonresponders". We believe that there are approximately 200,000 hepatitis C nonresponders in the United States. We initiated our first Phase III trial of once-daily treatment with Infergen in combination with ribavirin

therapy for hepatitis C nonresponders (the "DIRECT" trial) in June 2004. In addition, we are developing once-daily Infergen in combination with Actimmune, with and without ribavirin, for the treatment of hepatitis C nonresponders. We initiated a Phase IIb clinical trial of this combination in May 2004.

We completed our Phase I trial of a pegylated form of Infergen, PEG-Alfacon-1, for the treatment of chronic HCV infections in 2003. The PEG-Alfacon-1 development program would be lengthy and very expensive, and the duration and expense carry significant risk. Accordingly, development is on hold as we consider alternative development plans, including business collaborations that could increase the speed and decrease our risk and expense for this program. Once we have completed our analysis of alternative development plans and assessed the value that a partnership could bring to PEG-Alfacon-1, we will announce our plans, which may be to discontinue the program if we are unable to enter into a collaboration on favorable terms.

In September 2002 we entered into a drug discovery collaboration agreement with Array BioPharma, Inc. ("Array") to discover certain novel small molecule NS-3 protease inhibitors for the treatment of hepatitis C. We have completed several preclinical studies on a series of compounds and have identified several lead compound candidates. We are in active discussions with a number of potential development partners for this program. In late 2004, we entered into an agreement with Array that allows us to initiate a second research collaboration in early 2005 with respect to a different HCV target.

- Ovarian Cancer

We are also evaluating Actimmune in patients with ovarian cancer in an ongoing Phase III trial (the "GRACES" trial). We will make a decision as to the future of this program based on the outcome of a planned interim analysis of progression-free survival, which we anticipate in the second half of 2005.

- Other Assets

Our oritavancin and Amphotec assets do not fit within our core focus areas of pulmonology and hepatology. Therefore, we are attempting to divest these non-core assets.

Product Development Status

The following chart shows the status of our product development programs as of December 31, 2004:

	Preclinical	Phase I	Phase II	Phase III
Pulmonology				
Actimmune *Idiopathic pulmonary fibrosis*				X
Pirfenidone *Idiopathic pulmonary fibrosis*			X	
Pirfenidone *Pulmonary fibrosis associated with Hermansky-Pudlak Syndrome*			X	
Next Generation Interferon Gamma	X			
Hepatology				
Daily Infergen + ribavirin *Hepatitis C nonresponders*				X
Daily Infergen + Actimmune +/- ribavirin *Hepatitis C nonresponders*			X (IIb)	
PEG-Alfacon-1 *Chronic hepatitis C virus infections*		X		
NS-3 Protease Inhibitor program	X			
Other Assets				
Actimmune + Standard-of-Care Chemotherapy *Ovarian cancer*				X
Oritavancin *Complicated skin and skin structure infections*				X

Our Strategy

We intend to use our current capital resources and the anticipated revenues provided by the sales of our marketed products to fund the development of our advanced-stage pipelines in pulmonology and hepatology. We also intend to capture value by divesting certain of our non-core assets. Our development programs are lengthy and expensive. We intend to seek development partners for certain of these programs and to raise additional capital as needed to fund their continued development.

Our strategy for achieving these objectives include:

Focusing our development efforts in the areas of pulmonology and hepatology. Historically, InterMune pursued developing opportunities in the areas of pulmonology, hepatology, infectious disease and oncology. During 2003 and 2004, we narrowed our focus to development and commercial efforts in pulmonology and hepatology in order to more effectively compete, manage our resources and sustain our business.

Expanding the number of indications for which the FDA approves Actimmune and Infergen as a treatment, and obtaining FDA approval for our other compounds in pulmonology and hepatology. We are developing Actimmune, Infergen, pirfenidone and our NS-3 protease inhibitors for a number of diseases for which preclinical studies and clinical trials have shown evidence that they may be potentially effective treatments. Some of the diseases for which Actimmune may demonstrate therapeutic activity include IPF (as a monotherapy) and HCV infections (in combination with Infergen). We believe that pirfenidone may

have potential as a treatment for IPF and for pulmonary fibrosis associated with HPS. We believe that daily Infergen in combination with Actimmune, with or without ribavirin, may have the potential to treat these hepatitis C nonresponders. We believe that daily Infergen in combination with Actimmune with or without ribavirin may have potential to treat these hepatitis C nonresponders. We believe that PEG-Alfacon-1 may have potential to compete with other pegylated interferon-alpha therapies in treating patients with chronic HCV infections. We also believe that our NS-3 protease inhibitors may have potential to treat patients with HCV infections.

Increasing sales of certain marketed products. Actimmune is approved by the FDA for the treatment of patients with CGD and severe, malignant osteopetrosis. We are continuing our marketing efforts in these small, but important, patient populations. Infergen is approved by the FDA for the treatment of hepatitis C. In late 2004, we expanded our efforts to support Infergen for the treatment of adult patients with compensated liver disease who have hepatitis C. In particular, we hired 31 dedicated sales representatives to create a specialty hepatology sales force, such that now we have 110 representatives selling Infergen. We also continue to increase our visibility at major medical meetings and sponsored independent medical education symposia and seminars. We believe that the unmet need for effective treatments for hepatitis C nonresponders provides an opportunity for revenue growth.

Establishing appropriate alliances. One of our important organizational strengths is our commercial infrastructure. We believe that we can leverage our commercial organization and create an opportunity for revenue growth and expense reduction by establishing appropriate alliances in pulmonology and hepatology. We believe that our commercial expertise and resources for such alliances will make us an attractive potential partner. In particular, in March 2004 we entered into a Co-Promotion Agreement with Baxter to co-promote their product Aralast to pulmonologists. We are seeking development partners for certain pulmonology and hepatology programs in order to accelerate our development efforts, offset our expenses, mitigate our risk, maximize the value of our programs and create value for our stockholders. Currently, these potential co-development programs include our NS-3 protease inhibitor program, Peg-Alfacon-1 and pirfenidone.

Investing in preclinical and applied research. We have a preclinical and applied research group focused on the preclinical development of compounds in pulmonology and hepatology. These compounds include our NS-3 protease inhibitor program for the treatment of hepatitis C. This group seeks to characterize mechanisms of action and biological, toxicology and pharmacology profiles of our product development candidates. Further, we expect that this group will explore expanded indications and additional formulations to enable us to continue the development of our marketed and late-stage products.

Divesting other assets. Our oritavancin and Amphotec assets do not fit within our core focus areas of pulmonology and hepatology. Therefore, we are attempting to divest these non-core assets.

Marketed Products

We have three marketed products: Actimmune, Infergen and Amphotec.

Actimmune (interferon gamma-1b)

Actimmune is approved by the FDA for the treatment of two rare congenital disorders: CGD and severe, malignant osteopetrosis.

Chronic granulomatous disease. CGD is a life-threatening congenital disorder that causes patients, mainly children, to be vulnerable to severe, recurrent bacterial and fungal infections. This results in frequent and prolonged hospitalizations and commonly results in death. In 1990, Actimmune was approved by the FDA for reducing the frequency and the severity of serious infections associated with CGD, and is the only FDA approved drug for this disease. We have been marketing Actimmune for the treatment of CGD since 2000.

Severe, malignant osteopetrosis. Severe, malignant osteopetrosis is a life-threatening, congenital disorder that primarily affects children. This disease results in increased susceptibility to infection and an overgrowth of bony structures that may lead to blindness and/or deafness. In 2000, Actimmune was approved by the FDA for delaying time to disease progression in patients with severe, malignant osteopetrosis, and is the only FDA approved drug for this disease.

We have the exclusive rights to develop and commercialize Actimmune for a broad range of diseases in the United States, Canada and Japan. We are collaborating with BI International, which is developing and commercializing interferon gamma-1b in Europe and the rest of the world under the trade name Imukin. See "License and Other Agreements." Substantially all of our revenues from sales of Actimmune are derived from off-label uses of Actimmune rather than the treatment of osteopetrosis or CGD.

Infergen (interferon alfacon-1)

Chronic HCV infections. Almost 4,000,000 individuals in the United States have the antibody to the hepatitis C virus, indicating ongoing or previous infection with the virus. If left untreated, infection with HCV can lead to liver fibrosis, cirrhosis and hepatocellular carcinoma. HCV infections are the second leading cause of liver cirrhosis and the leading indication for liver transplantation in the United States. As a result of persistent infection and progressive liver damage, an estimated 8,000 deaths are attributable to chronic HCV infections in the United States annually.

Infergen was approved by the FDA in 1997 for the treatment of chronic HCV infections in adult patients with compensated liver disease, and is the only interferon alpha approved for the treatment of chronic HCV infections with data in its label regarding the treatment of patients who have failed prior treatment with interferon alphas. The current initial standard of care for chronic HCV infections in adults is treatment with pegylated interferon alpha in combination with ribavirin. We cannot confirm the number of persons who have failed prior treatment with interferon alphas, but it is estimated to be approximately 200,000. In 2004 we expanded our promotional efforts for Infergen by creating a dedicated specialty hepatology sales force of 31 new sales representatives.

We have the exclusive rights to develop and commercialize Infergen in the United States and Canada. See "License and Other Agreements."

Development Programs

PULMONOLOGY

InterMune is developing two compounds for the treatment of IPF—Actimmune and pirfenidone.

Idiopathic Pulmonary Fibrosis. IPF is a disease characterized by progressive scarring, or fibrosis, of the lungs, which leads to their deterioration and destruction. The cause of IPF is unknown. The prognosis is poor for patients with IPF, which occurs primarily in persons 40 to 70 years old. Based on the published literature, median survival time from diagnosis is two to five years in patients with IPF, and most patients die from the complications associated with IPF. We believe that there are approximately 83,000 patients with IPF in the United States, approximately two-thirds of whom have mild-to-moderate disease severity.

There is no FDA approved therapy available for the treatment of IPF. Although no data exists supporting the use of these products, the American Thoracic Society ("ATS") recommends the use of corticosteroids and immunosuppressants in IPF patients if warranted, both of which have significant adverse side effects and have not been proven to be efficacious. As a last resort, a small percentage of patients undergo lung transplantation, but donors are limited. Many patients are of advanced age and not eligible for a lung transplant and many patients die while awaiting a transplant.

Actimmune for Idiopathic Pulmonary Fibrosis

We are developing Actimmune for the treatment of IPF. We reported data from our Phase III clinical trial of Actimmune for the treatment of IPF (GIPF-001) in August 2002. Although this trial failed to meet its primary endpoint, it provided us with information regarding the disease, appropriate clinical endpoints and the treatment effect of Actimmune on patients. Based on analysis of this data, we initiated a second Phase III clinical trial of Actimmune for the treatment of IPF (GIPF-007, or the "INSPIRE" trial) in December 2003.

GIPF-001. In August 2002, we reported data from our Phase III clinical trial of Actimmune for the treatment of patients with documented IPF who had not responded to previous treatment with corticosteroids and who had evidence of deteriorating lung function. This study was a randomized, double-blind, placebo-controlled Phase III clinical trial of 330 patients conducted at 58 centers in the United States, Canada, Europe and South Africa. Patients were randomized to receive either 200 micrograms of Actimmune subcutaneously three times per week or placebo. All patients were to remain in the trial until the last patient received 48 weeks of therapy. There was no significant effect on the primary endpoint of progression-free survival time or on secondary endpoints of lung function and quality of life. However, there was a trend towards enhanced survival among patients receiving Actimmune. In the overall population, there were 16/162 deaths in the Actimmune-treated group (9.9%) compared to 28/168 deaths in the placebo group (16.7%), representing a 40% reduction in the risk of death in patients treated with Actimmune than those treated with the placebo ($p = 0.084$). Actimmune was generally well tolerated, but 24/162 of the treated patients (14.8%) experienced pneumonias while only 12/168 of the placebo group (8.3%) experienced pneumonias, although the incidence of severe or life-threatening respiratory infections was similar in the two groups. The most commonly observed side effects were flu-like symptoms, including fever, headache and chills.

GIPF-007—the INSPIRE Trial. The results of the GIPF-001 trial suggested that the survival benefit was more pronounced in patients with less severe impairment in lung function. Accordingly, we designed a study to further investigate Actimmune in this patient group. In December 2003, we initiated GIPF-007, the INSPIRE trial, a randomized, double-blind, placebo-controlled Phase III clinical trial. The trial is designed to evaluate the safety and efficacy of Actimmune in IPF patients with less severe impairment in lung function. The primary endpoint of the trial is survival time. We expect to enroll 600 patients in the INSPIRE trial at approximately 70 to 80 centers in the United States, Europe and Canada. Patients will be randomized at a ratio of 2:1 to receive either 200 micrograms of Actimmune three times a week or a placebo, and each patient enrolled will be followed for at least 24 months. We anticipate that the trial will be fully enrolled by December 31, 2005.

Pirfenidone for Idiopathic Pulmonary Fibrosis and HPS

Pirfenidone is an orally active, small molecule drug that appears to inhibit collagen synthesis, down-regulate production of multiple cytokines and block fibroblast proliferation and stimulation in response to cytokines. Pirfenidone, which may have activity in multiple fibrotic indications, is currently in clinical development for the treatment of IPF and HPS. In May 2003, we concluded a 55-patient, proof-of-concept Phase II clinical trial of pirfenidone in IPF originally initiated by Marnac. We stopped this trial early to expedite the collection of preliminary safety and efficacy data and our assessment of whether this data supports pirfenidone as a product candidate with potential benefits to IPF patients.

In 2004, we completed the data analysis and preclinical work necessary to design and conduct a pirfenidone registration program for IPF. An end of Phase II meeting was held with the FDA at the end of 2004 during which the FDA provided us with comments and suggestions regarding our proposed clinical development plan for pirfenidone. We plan to announce our plans regarding the clinical program for pirfenidone in the first half of 2005. In 2004, the FDA and the EMEA granted orphan drug designation for pirfenidone for the treatment of IPF in the United States and Europe, respectively.

Next-Generation Interferon Gamma

We have a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc., to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune. We plan to take forward into clinical development selected modified interferon gamma product candidates created by Maxygen that meet these criteria. See "License and Other Agreements."

HEPATOLOGY

Our second area of focus is developing therapeutics in the area of hepatology. Our clinical efforts in hepatology are currently directed at expanding treatment options for patients suffering from HCV infections.

Hepatitis C Virus Infections—Nonresponder Patients. Patients who have never been treated with interferons, also called "naïve" patients, are treated with a first line therapy of pegylated interferon-alpha 2 in combination with ribavirin therapy, the current standard of care. Approximately 50% of these naive patients show a sustained virologic response (the most commonly used measure of treatment effectiveness) with this treatment. The remaining 50% of patients, who do not show a sustained virologic response to pegylated interferons plus ribavirin, are known as hepatitis C "nonresponders". We believe that the hepatitis C nonresponder patient population currently numbers approximately 200,000 in the United States. Retreatment of hepatitis C nonresponders with pegylated interferon-alpha 2 and ribavirin therapy has poor response rates. However, some nonresponders who are treated with Infergen show an improved response. In the fourth quarter of 2003 and throughout 2004, we expanded our promotion of Infergen into the hepatitis C nonresponder patient population.

Daily Infergen in Combination with Ribavirin for Hepatitis C Nonresponders

Data from investigator sponsored trials has been previously presented at meetings of the American Association for the Study of Liver Diseases ("AASLD"). These data show a sustained virologic response in hepatitis C nonresponders in response to treatment with a daily regimen of Infergen in combination with ribavirin. These data suggest that the daily usage of Infergen in combination with ribavirin may provide potential benefits for the hepatitis C nonresponder population. In 2004 we initiated a Phase III trial (the "DIRECT" trial) of once daily Infergen in combination with ribavirin for the treatment of hepatitis C nonresponders. We anticipate that enrollment of the DIRECT trial will be complete by the third quarter of 2005.

Daily Infergen in Combination with Actimmune for Hepatitis C Nonresponders

In vitro analysis of the combination of daily Infergen and Actimmune cell based models of viral infection and replication as well as gene induction using global transcriptional profiling showed very strong synergistic effects for a range of varying doses of combination therapy relative to Infergen monotherapy. Analysis of gene expression showed that several genes that undertake critical cellular processes were not significantly upregulated by either drug alone, but were upregulated by the combination of Infergen and Actimmune.

In addition, investigator sponsored trials have evaluated the effectiveness of combination therapy with daily Infergen and Actimmune with or without ribavirin in a small number of hepatitis C nonresponders and determined that a significant sustained virologic treatment response is possible with an appropriate treatment regimen in this population. To further explore this potential, we initiated a U.S. Phase IIb trial in 2004 to evaluate various combination doses of daily Infergen and Actimmune with and without ribavirin for the treatment of hepatitis C nonresponders. Information from this trial is required to assess safety, tolerability and appropriate combination dosing to progress to a Phase III program.

PEG-Alfacon-1 for Chronic Hepatitis C Virus Infections

To further expand the limited treatments for HCV infections, we have derived a pegylated form of Infergen, PEG-Alfacon-1, which is being designed to offer patients an alternative therapy with less frequent dosing than non-pegylated interferons, including Infergen. In late 2003, we completed a Phase I clinical trial to evaluate PEG-Alfacon-1 as a potential treatment for chronic HCV infections. We plan to present the data from our Phase I clinical trial at an upcoming medical conference in 2005.

The PEG-Alfacon-1 development program will be lengthy and very expensive, and the duration and expense carry significant risk. Accordingly, we are considering alternative development plans and business collaborations that could increase the speed and decrease our risk and expense for this program. Once we have completed our analysis of alternative development plans and assessed the value that a partnership could bring to PEG-Alfacon-1, we will announce our plans, which may be to discontinue the program if we are unable to enter into a collaboration on favorable terms.

ONCOLOGY

Actimmune for Oncology

Ovarian cancer. Ovarian cancer is the third most common cancer in women, afflicting approximately 100,000 women and causing approximately 14,000 deaths in the United States per year. We believe that approximately 25,000 new cases are diagnosed annually in the United States. Current treatment with chemotherapy is suboptimal, with a five-year survival rate of only 44%. In preclinical *in vitro* and *in vivo* studies, Actimmune has been shown to be directly toxic to ovarian cancer cells and to stimulate the body's immune system to enhance the removal of cancer cells. A European study of 148 women published in the March 2000 issue of *The British Journal of Cancer* showed that the addition of Actimmune to chemotherapy delayed the time to disease progression from an average of 17 months to 48 months.

We are currently conducting an 847-patient Phase III clinical trial of Actimmune (the "GRACES" trial) in combination with carboplatin and paclitaxel for the first-line treatment of ovarian cancer in women who have undergone surgical resection. Enrollment of this clinical trial was completed during the first half of 2004 and we anticipate that a planned interim analysis regarding progression-free survival will be completed in late 2005. A decision as to the future of this trial will be made after completion of the progression-free survival analysis.

OTHER ASSETS

Our oritavancin and Amphotec assets do not fit within our core focus areas of pulmonology and hepatology. Therefore, we are attempting to divest these assets.

Oritavancin

Oritavancin is a semi-synthetic glycopeptide antibiotic in development for the treatment of a broad range of infections caused by gram-positive bacteria, including those resistant to other glycopeptides. Oritavancin has demonstrated the ability to kill most strains of gram-positive bacteria, while other glycopeptides and many other agents merely suppress them. Oritavancin may be effective in the treatment of a range of infections caused by gram-positive bacteria. We have worldwide rights to oritavancin.

In two Phase III clinical trials with oritavancin for the treatment of complicated skin and skin-structure infections ("CSSSIs"), oritavancin achieved the primary efficacy endpoint and demonstrated that oritavancin was as effective as the comparator regimen of vancomycin followed by cephalexin, which is a commonly used regimen. However, the FDA requested an additional clinical safety study be completed prior to the submission of a New Drug Application, or NDA, for oritavancin for the treatment of CSSSIs. We do not intend to market or co-market oritavancin. We are attempting to divest oritavancin and are currently in discussions with a number of potential buyers. However, there are no assurances that we will

succeed in divesting this asset during 2005 or at all. We expect that our investment in oritavancin in 2005 will decrease as compared to our investment in 2004.

Amphotec

Amphotec is an FDA approved lipid-form of amphotericin B indicated for the treatment of invasive aspergillosis in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate in effective doses, and in patients with invasive aspergillosis where prior amphotericin B deoxycholate has failed. Systemic fungal infections that do not respond to initial treatment with standard antifungal treatment regimens are typically treated with amphotericin B, the active ingredient in Amphotec. We estimate that there are approximately 200,000 cases of systemic fungal infections each year in the United States. Worldwide sales of all amphotericin B-based products are approximately $350 million per year. This product is approved in the United States under the name Amphotec and in more than 40 other countries under the name Amphocil®. We are attempting to divest Amphotec and are currently in discussions with a number of potential buyers. However, there are no assurances that we will succeed in divesting this asset during 2005 or at all. We expect that our investment in Amphotec in 2005 will decrease as compared to our investment in 2004.

License and Other Agreements

Genentech, Inc. License Agreement (Actimmune)

In 1998, we obtained a license under Genentech's patents relating to Actimmune. The license from Genentech terminates on the later of May 5, 2018 or the date that the last of the patents licensed under the agreement expires. Our licensed Actimmune rights include exclusive and non-exclusive licenses. The exclusive licenses include the right to develop and commercialize Actimmune in the United States and Canada for the treatment and prevention of all human diseases and conditions, including infectious diseases, pulmonary fibrosis and cancer, but excluding arthritis and cardiac and cardiovascular diseases and conditions. The non-exclusive licenses include the right to make or have made Actimmune for clinical and commercial purposes within our field of use in the United States and Canada. In Japan, we have the exclusive license rights to commercialize Actimmune for the treatment and prevention of all infectious diseases caused by fungal, bacterial or viral agents, including in patients with CGD or osteopetrosis. We also have the opportunity, under specified conditions, to obtain further rights to Actimmune in Japan and other countries. In addition, we received an exclusive sublicense under certain of Genentech's patents outside the United States, Canada and Japan under the BI International agreement discussed below. Under the Genentech license, we pay Genentech royalties on the revenue from sales of Actimmune and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the filing for FDA approval to market Actimmune for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune for the treatment of particular categories of diseases and the achievement of certain annual revenue targets for Actimmune. We had made royalty payments of approximately $13.7 million, but no milestone payments, under this agreement in the aggregate through December 31, 2004. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $3.2 million. We must satisfy specified diligence obligations under the agreement with Genentech to maintain our license from Genentech. In particular, we are obligated under the agreement to develop and commercialize Actimmune for a number of diseases. In addition, the agreement specifies deadlines for achieving a number of milestones related to clinical development of Actimmune for such diseases, and we are obligated to use our best efforts to meet these deadlines, to the extent reasonably allowed by our financial resources. Our rights to Actimmune under this agreement could revert to Genentech if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

Boehringer Ingelheim International GmbH (Imukin)

In 2001, we formed a collaboration with BI International to clinically develop and seek regulatory approval for interferon gamma-1b, the active ingredient in Actimmune, in certain diseases, and to commercialize a liquid formulation of interferon gamma-1b under one or more of BI International's trade names, including Imukin, in Europe and other major markets of the world (other than the United States, Canada and Japan). Under the agreement, the parties will seek to develop and obtain regulatory approval for the use of Imukin in the treatment of a variety of diseases, including IPF, ovarian cancer, CGD and osteopetrosis. The agreement provides that we will fund and manage clinical and regulatory development of interferon gamma-1b for these diseases in the countries covered by the agreement. BI International will pay us royalties on sales of the product when it meets a specified minimum sales level. BI International has an option to exclusively promote Imukin in all of the major market countries covered by the agreement, and we may opt to promote the product in those countries and for those new diseases for which BI International does not do so. If we opt to promote the product in those countries or for those new diseases for which BI International does not, we will pay royalties to BI International on sales of the product in those countries and/or for those new diseases. We had neither paid nor received any royalties under this agreement through December 31, 2004, and there are no milestone payments under this agreement. The agreement will expire, on a country-by-country basis, upon expiration of the parties' royalty obligations in each country covered by the agreement. Such royalty obligations generally expire fifteen years after regulatory approval of Imukin for certain specified indications in the relevant country. If no such regulatory approvals are granted in a particular country, the royalty obligations in such country will expire in 2016. Prior to such expiration, either party can terminate the agreement for the uncured material breach of the other party or for the insolvency of the other party. In addition, we have the right to terminate the agreement with respect to certain countries at any time subsequent to regulatory approval for IPF.

Connetics Corporation (Actimmune)

Through an assignment and option agreement with Connetics, we paid Connetics $5.7 million to acquire rights to Actimmune and are obligated to pay to Connetics a royalty of 0.25% of our net United States sales for Actimmune until our net United States sales cumulatively surpass $1.0 billion. Above $1.0 billion, we are obligated to pay a royalty of 0.5% of our net United States sales of Actimmune. Through a separate purchase agreement, we paid Connetics $0.4 million to acquire rights related to scleroderma and are obligated to pay Connetics a royalty of 4.0% on our net revenue from sales of Actimmune for the treatment of scleroderma. We had made royalty payments of approximately $0.9 million in the aggregate through December 31, 2004. There are no milestone payments pursuant to this agreement.

Amgen Inc. (Infergen, PEG-Alfacon-1 and interferon gamma)

In 2001, we entered into a licensing and commercialization agreement with Amgen through which we obtained an exclusive license in the United States and Canada to Infergen and the rights to an early stage program to develop a pegylated form of Infergen (PEG-Alfacon-1). Infergen is currently approved in both the United States and Canada to treat chronic HCV infections. Under the agreement, we have the exclusive right to market Infergen and clinically develop it for other indications in the United States and Canada. In December 2004, we amended our Licensing and Commercialization Agreement with Amgen to remove certain non-competition restrictions on Amgen with respect to alpha interferons in exchange for a specified reduction in the royalties payable by us to Amgen on Infergen sales should Amgen engage in certain competitive activities as well as Amgen's consent to transfer the manufacturing of Infergen to a new supplier. (See section entitled "Manufacturing" below). We initially paid Amgen total consideration of $29.0 million for up-front license and other fees and milestones with respect to our license, and are obligated to pay royalties on sales of Infergen. In March 2003, we commenced a Phase I clinical trial for

PEG-Alfacon-1, which required us to make a $1.5 million milestone payment to Amgen pursuant to the terms of the agreement. We may be required to make additional milestone payments to Amgen based on the progress of our PEG-Alfacon-1 clinical development program, and we will be obligated to pay royalties on sales of the resulting product, if any. We had made royalty and milestone payments of approximately $35.9 million under this agreement in the aggregate through December 31, 2004. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of $51.5 million under this agreement. The agreement with Amgen will expire on the date that the last of the Amgen patents licensed under the agreement expires, at which point the exclusive licenses granted to us relating to Infergen and PEG-Alfacon-1 will become fully paid and irrevocable. Prior to such expiration, either party can terminate the agreement for the uncured material breach of the other party, and our rights to Infergen and PEG-Alfacon-1 could revert to Amgen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. In addition, we can at any time discontinue our development and commercialization efforts under the agreement, terminate the agreement, and return to Amgen all rights to Infergen and PEG-Alfacon-1.

In 2002, we acquired certain pending patent applications relating to interferon gamma from Amgen in exchange for $3.5 million, of which $1.5 million was paid in June 2002, and the remaining $2.0 million was paid in January 2003.

Marnac, Inc./KDL GmbH (pirfenidone)

In 2002, we licensed from Marnac, Inc. ("Marnac") and its co-licensor, KDL GmbH ("KDL"), their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and future milestone and royalty payments. Future milestone payments will be based on the progress of clinical development of pirfenidone. We had made no royalty or milestone payments under this agreement through December 31, 2004. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $14.5 million. Our rights to the licensed products under the agreement could revert to Marnac if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. The agreement will expire upon the later of the expiration of the primary patent licensed under the agreement; or on a disease-by-disease and country-by-country basis (as determined by reference to the indications for which pirfenidone is approved in such country) on the later of (i) the expiration of market exclusivity in such country (if any) resulting from the grant of orphan drug designation to pirfenidone for the treatment of a human fibrotic disease; and (ii) the expiration of the last valid and enforceable claim in a issued licensed patent claiming the use of pirfenidone to treat such disease in such country. Following expiration of the agreement, we will retain a fully paid-up, royalty-free, perpetual, irrevocable, sublicenseable license to the patents, know-how, and other intellectual property rights licensed under the Agreement. We may terminate the agreement after giving the requisite notice to Marnac. In the event Marnac or KDL terminate the agreement, we have the right to seek specific performance of the agreement.

Array BioPharma Inc. (small molecule therapeutics)

In 2002, we entered into a drug discovery collaboration agreement to create small molecule therapeutics targeting hepatitis with Array. We will fund drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and will be responsible for all development and commercialization. Array will be entitled to receive milestone payments based on the selection and progress of clinical drug candidates, as well as royalties on net sales of products derived from the collaborative efforts. The original term of this agreement expired in September 2004 and was extended to June 30, 2005, subject to certain conditions. In addition, in December 2004, the

agreement was amended to provide a mechanism for us to purchase certain intellectual property rights arising from the collaboration. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $9.1 million. Total research and development expenses related to this agreement were $5.7 million, $2.1 million, and $0.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. Included in the $5.7 million is a one-time non-refundable fee of $2.5 million paid in connection with securing the right to purchase Array's ownership interest in certain collaboration patents.

Shearwater Corporation (PEG-Alfacon-1)

In June, 2002 we entered into a development, license and manufacturing agreement with Shearwater Corporation ("Shearwater"), a wholly owned subsidiary of Nektar Therapeutics, to access Shearwater's pegylation technology in order to develop a pegylated version of Infergen. Under the terms of the agreement, we received a co-exclusive license with Maxygen from Shearwater in exchange for an up-front payment of $500,000 and future milestone and royalty payments. We had paid $250,000 in milestone payments, but no royalty payments, under this agreement in the aggregate through December 31, 2004. Assuming that all the milestone payments under this agreement are achieved, we will be required to make additional milestone payments of $8.3 million.

In countries in which patents covering one of our products using Shearwater's pegylation technology have issued or will issue, our royalty obligations will generally expire upon the expiration of all such patents. In other countries, our royalty obligations will continue for a specified period following the first commercial sale of a product using Shearwater's pegylation technology in such country. Our agreement with Shearwater will expire upon the expiration of all royalty obligations under the agreement. We can terminate the agreement (i) if marketing authorization for any of our products using Shearwater's pegylation technology is withdrawn or suspended by regulatory authorities; (ii) if safety or certain other issues associated with the product render further development or marketing unjustified; (iii) if we are unable to market the product due to valid patent infringement claims of third parties; or (iv) if competing products render the marketing of the product not commercially feasible. Prior to the expiration of the agreement, either party can terminate the agreement for the uncured material breach of the other party, and our rights to Shearwater's pegylation technology could revert to Shearwater if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

Maxygen Holdings Ltd. (next-generation interferon gamma)

We have a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc. ("Maxygen"), to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune. We plan to take forward into clinical development selected modified interferon gamma product candidates created by Maxygen that meet these criteria. We have funded Maxygen's optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. Our diligence obligations include a minimum level of clinical development expenditures for an initial period of time, as well as the general obligation to use commercially reasonable efforts to clinically develop, seek regulatory approval for and commercialize a product in specified major market countries. The agreement terms include up-front license fees and full research funding, as well as development and commercialization milestone payments, which are payable based on the progress of our clinical development program for next-generation interferon gamma products and the achievement of certain sales targets with respect to such products. In addition, Maxygen will receive royalties on product sales. We had made payments of approximately $9.6 million under this agreement in the aggregate through December 31, 2004. We paid Maxygen a total of $106,000, $228,000, and $5.1 million for the years ended December 31, 2004, 2003 and 2002,

respectively. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of $43.0 million.

In countries in which patents covering next-generation interferon gamma products have issued or will issue to either us or Maxygen, our royalty obligations will generally expire upon the expiration of all such patents. In other countries, our royalty obligations will continue for a specified period following the first commercial sale of a next-generation interferon gamma product in such country. Our agreement with Maxygen will expire upon the expiration of all royalty obligations under the agreement. Prior to expiration of the agreement, either party can terminate the agreement for the insolvency of the other party, and in the event of a material breach of the agreement by a party, the other party has the right to pursue a remedy through arbitration. If we commit a material breach of the agreement, the remedy selected by the arbitrator may include termination of the licenses granted to us by Maxygen under the agreement. In addition, if we do not meet certain diligence obligations, Maxygen may have the right to terminate the agreement, as well as to obtain royalty-bearing licenses from us that would allow it to continue the development and commercialization of next-generation interferon gamma products.

Eli Lilly & Company (oritavancin)

In 2001, we entered into an asset purchase and license agreement with Eli Lilly & Company ("Eli Lilly") pursuant to which we acquired worldwide rights to oritavancin. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. We are obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for oritavancin in accordance with our proposed development plan and to commercialize oritavancin in accordance with our proposed commercialization plan. In order to partner oritavancin, the agreement requires that we first offer Eli Lilly the opportunity to enter into such a relationship with us, which we have done. Eli Lilly has declined the opportunity to partner with us, and the agreement prohibits us from entering into an agreement with a third party on more favorable terms than those we offered to Eli Lilly. Pursuant to the agreement, we paid Eli Lilly $50.0 million and will be obligated to pay Eli Lilly significant milestone payments and royalties on product sales. Our milestone obligations are based on the progress of our clinical development program for oritavancin and include payments to Lilly for achievement of regulatory approval in various major market countries. We had made no royalty or milestone payments under this agreement through December 31, 2004. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $95.0 million. In September 2002, Eli Lilly exercised its option under the agreement to reduce the agreed percentage of royalties on product sales. The exercise of this option required us to pay $15.0 million to Eli Lilly, and we made the actual payment to Eli Lilly during January 2003. In September 2003, we expensed $10.0 million related to a milestone payment due to Eli Lilly for the completion of the Phase III clinical trials for oritavancin. This amount was recorded as a milestone-based liability at December 31, 2003. However, this payment has not been made to Eli Lilly as a result of an understanding between Eli Lilly and ourselves.

Our agreement with Eli Lilly will expire on a country-by-country basis upon the expiration of all royalty obligations in each country covered by the agreement, at which point we will possess a fully paid, perpetual, irrevocable, and sublicenseable exclusive license to oritavancin. In countries where patents licensed under the agreement have issued or will issue, our royalty obligations will in most cases expire upon the expiration of all such patents. In other countries, our royalty obligations will in most cases continue for a specified period following the first commercial sale of an oritavancin product in such country. Prior to expiration of the agreement, either party can terminate the agreement for the insolvency of the other party or for an uncured material breach by the other party. Our rights to oritavancin could revert to Eli Lilly if we do not meet our diligence obligations under the agreement or otherwise commit a material breach of the agreement. Additionally, if we are acquired by a company with a certain type of competing program and Eli Lilly has notified us prior to the acquisition that it believes in good faith that

its economic interests in oritavancin under the agreement will be harmed in light of the acquisition, Eli Lilly may terminate the agreement and our rights to oritavancin would revert to Eli Lilly. In any event, we may not assign the agreement to a potential acquirer without Eli Lilly's advance, written consent. We are attempting to divest oritavancin and are currently in the process of identifying a buyer for this asset.

ALZA Corporation (Amphotec)

In 2001, we acquired worldwide rights from ALZA, now a subsidiary of Johnson & Johnson) to Amphotec (sold under the trade name Amphocil in certain countries outside the United States). The transaction terms included an up-front product acquisition fee of $9.0 million, milestone payments based upon sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune and royalties payable upon net sales of Amphotec. We had made royalty payments of approximately $1.3 million, but no milestone payments, under this agreement in the aggregate through December 31, 2004. Assuming that all of the milestones under this agreement that we continue to believe are relevant are achieved, we will be required to make milestone payments of $1.0 million. Under the agreement, we obtained access to certain existing distributorships for Amphotec and assumed ALZA's obligations under agreements with its existing Amphotec distributors and service providers. We have diligence obligations under the agreement to set up additional distributorships for Amphotec or establish a sales force and begin to promote Amphotec in specified countries at specified times. Our rights to Amphotec could revert to ALZA if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. We are also subject to certain royalty obligations to the University of California under this agreement. During September 2003, we reduced the remaining carrying value of the intangible asset recorded in 2001 when we acquired Amphotec by recording an impairment charge of $4.8 million. This impairment charge was based on our impairment review of the Amphotec product rights, which took into account that sales levels were lower than expected and that Amphotec is not aligned with our new strategic focus in pulmonology and hepatology. Consequently, we are attempting to divest Amphotec and are in the process of identifying a buyer for this asset. Any such buyer will need to comply with the current and future terms of the agreement with ALZA.

Manufacturing

We contract with qualified third-party manufacturers to produce our products and product candidates. This manufacturing strategy enables us to direct financial resources to the development and commercialization of products rather than diverting resources to establishing a manufacturing infrastructure.

Boehringer Ingelheim Austria GmbH (Actimmune)

In 2000, we entered into an agreement with Boehringer Ingelheim Austria ("BI Austria") for the clinical and commercial supply of Actimmune. The agreement with BI Austria generally provides for the exclusive supply by BI Austria and exclusive purchase by us of Actimmune. We are required to purchase a minimum amount of Actimmune per year, and BI Austria is required to supply Actimmune to us, subject to certain limits. As of December 31, 2004, we were obligated to make minimum purchases of Actimmune from BI Austria in the years 2005 through 2012 of $175.9 million. If BI Austria is not able to supply all of our requirements for Actimmune, we may choose an additional manufacturer. However, we are not entitled to seek such a secondary source until BI Austria has informed us of its unwillingness or inability to meet our requirements. BI Austria may have the right to terminate the agreement if we materially breach the minimum yearly purchase obligation for Actimmune that is specified in the agreement. In the event that we decide that our minimum yearly purchase obligation under the agreement exceeds our annual requirements for Actimmune, the agreement provides a mechanism by which we can decrease on a going-forward basis such purchase obligation, in exchange for appropriate adjustments to the financial

terms of the agreement, to be negotiated by the parties at time of such adjustments. The agreement will expire on December 31, 2012. Prior to this date, either party can terminate the agreement for the insolvency or bankruptcy of the other party or for an uncured material breach by the other party, and either party can terminate the agreement on twelve months notice if the other party assigns the agreement. In addition, we have the right to terminate the agreement immediately in the event that health authorities block the use in clinical trails or the marketing of Actimmune.

Amgen Inc. (Infergen)

In connection with our 2001 agreement with Amgen under which we license Infergen, we entered into a separate Manufacturing and Supply Agreement under which Amgen is obligated to manufacture and supply our requirements of Infergen for our sales in the United States and Canada. There are certain limits on the amount of Infergen that Amgen is required to supply to us. We must purchase Infergen exclusively from Amgen, unless Amgen has materially breached its manufacturing obligations. In late 2004 we amended the Manufacturing and Supply Agreement with Amgen to provide us with the ability to transfer the manufacturing of Infergen to a new contract manufacturer. We are in the process of identifying potential manufacturers and anticipate transferring the manufacturing of Infergen to a new manufacturer within the next three to four years. As of December 31, 2004, we were obligated to make minimum purchases of Infergen from Amgen totaling $33.0 million through 2006. Amgen's supply obligations under the agreement will expire on the earlier of: (i) the date on which we receive regulatory approval to market Infergen obtained pursuant to a supply agreement with a third party, (ii) the date on which we receive regulatory approval to market Infergen manufactured by us or any third party of our choice, (iii) the date as of which we no longer develop or commercialize Infergen in the licensed territory, (iv) the effective date of termination of the agreement with Amgen, or (v) January 1, 2015.

Abbott Laboratories, Inc. (oritavancin)

In 2001, we entered into an agreement with Abbott Laboratories, Inc. ("Abbott") to provide the bulk manufacturing of oritavancin active pharmaceutical ingredient (oritavancin API). The agreement will provide us with additional clinical supply, commercial scale-up and production of oritavancin API. Under the agreement, Abbott will be responsible for the technology transfer of the manufacturing process of oritavancin active pharmaceutical ingredient ("API") from Eli Lilly. Abbott will also be responsible for providing the necessary chemical manufacturing control information for our oritavancin regulatory filings with the FDA. We are required either to purchase a minimum amount of oritavancin API during the term of the agreement or to compensate Abbott for any shortfall by paying Abbott the then-current purchase price of the oritavancin API not purchased. The agreement provides for an initial term of seven years after the first commercial sale of a product derived from oritavancin API, and unless terminated by either party with advanced written notice to the other, the agreement will automatically renew for an indefinite number of additional two-year terms. Either party can terminate the agreement for the insolvency or bankruptcy of the other party or for an uncured material breach by the other party, and either party can terminate the agreement on two years prior written notice if the terminating party determines in good faith that the development or commercialization of oritavancin API is not feasible. In addition, we have the right to terminate the agreement if we elect not to launch oritavancin by a specified date.

Cardinal Health PTS, Inc. (oritavancin and pirfenidone)

In 2003, we entered into an agreement with Cardinal Health PTS, Inc. ("Cardinal Health") to supply us with oritavancin drug product. The agreement provides us with analytical development, validation, and stability support for oritavancin drug product. Under the agreement, oritavancin drug product will be manufactured at Cardinal Health's Albuquerque facility. Cardinal Health will also be responsible for providing the necessary manufacturing control information to support our oritavancin regulatory filings

with the FDA. We have the right to cancel at any time, in whole or in part, our order for oritavancin drug product. Upon such cancellation, we will be obligated to pay Cardinal Health an accommodation fee. With respect to batch manufacture services provided by Cardinal Health, the accommodation fee will be based on a percentage of the total batch cost, which percentage will depend on the number of days between the notice of cancellation and the scheduled compounding date. With respect to all other services provided by Cardinal Health, the accommodation fee will include the cost of any services already provided and any costs associated with non-reusable materials purchased by Cardinal Health, as well as all reasonable documented costs incurred by Cardinal Health in connection with such termination. Cardinal Health also formulates and encapsulates the API in the manufacturing process for pirfenidone. As of March 1, 2005, there would be no material accommodation fee payable to Cardinal Health if we terminated this agreement.

Ben Venue Laboratories Supply Agreement (Amphotec)

We presently have an agreement with Ben Venue Laboratories, Inc. ("Ben Venue") for the manufacture of Amphotec for all purposes. Under this agreement, we are required to provide Ben Venue with periodic forecasts of our needs. Ben Venue will fulfill our orders that meet certain variation limits from the forecast. The agreement provides for an initial term, which has expired, and for the automatic renewal of the agreement for successive two-year terms, which will continue indefinitely unless terminated by either party with advanced written notice to the other. Either party can terminate the agreement for the insolvency or bankruptcy of the other party or for an uncured material breach by the other party. In addition, we have the right to terminate the agreement if we are acquired by a third party that has the interest and capability to supply finished parenteral dosage forms (i.e. forms of the drug in which it is taken into the body or administered in a manner other than through the digestive tract) of Amphotec.

ACIC Fine Chemical, Inc. and Signa C.V. (pirfenidone)

On May 13, 2004 we entered into a Purchase Agreement with ACIC Fine Chemicals Inc. ("ACIC") to supply us with a finite amount of API for manufacturing of pirfenidone. Under a separate agreement with Signa C.V. ("Signa"), ACIC sub-contracts the actual manufacturing of this finite amount of API for pirfenidone to Signa. We acquire the API for pirfenidone from ACIC on a purchase order basis under the agreement. We are not obligated to purchase any minimum amount of product under this agreement

Patents and Proprietary Rights

Based on our own internal research efforts, we have filed numerous patents relating to the use of interferons to treat a variety of diseases in the areas of pulmonology, hepatology and oncology. In addition, we have filed for patents on a number of small molecules in hepatology and pulmonology.

Actimmune

We have acquired an exclusive license under certain Genentech patents to develop, make, use and sell interferon gamma-1b, the active ingredient in Actimmune, in particular fields in the United States, Canada and Japan under our license agreement with Genentech. This license agreement covers more than 12 United States patents and related foreign patents and/or patent applications filed in Japan and Canada. Certain of the United States patents covering DNA vectors and host cells relating to interferon gamma-1b have or will expire in 2005 and in 2006 without material impact to our business. In addition, a United States patent relating to the composition of interferon gamma-1b expires in 2014. Other material United States patents expire between 2009 and 2013. Under the Genentech license, we pay Genentech royalties on the sales of Actimmune, and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the filing for FDA approval to market Actimmune for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune for the treatment of particular categories of diseases and the achievement of certain annual sales targets for Actimmune.

Infergen

We have acquired an exclusive license under certain Amgen patents to develop, use and sell Infergen in the United States and Canada and to develop new forms of Infergen's active ingredient, interferon alfacon-1, including pegylated forms of interferon alfacon-1, under our license and commercialization agreement with Amgen. The agreement covers nine United States patents, one Canadian patent and several pending patent applications. Two of Amgen's United States patents relating to interferon alfacon-1 expired in 2004. However, the United States Patent and Trademark Office recently issued a Certificate of Extension of Patent Term, officially extending the term of this patent by five years to 2009. This extension gives us the right to exclude others from marketing interferon alfacon-1 until 2009 for the treatment of chronic HCV infections. After expiration of the extended patent term in 2009, we will rely on a United States patent, which expires in 2011, related to the use of interferon alfacon-1 at a dose within the range of 2 million to 30 million units of interferon alfacon-1 per administration for the treatment of chronic HCV infections to block others from marketing interferon alfacon-1 for the treatment of chronic HCV infections at these doses. Under our license to the Amgen patents, we may be required to make milestone payments to Amgen based on the progress of our PEG-Alfacon-1 clinical development program, and we may be obligated to pay royalties on sales of the resulting product, if any.

Pirfenidone

We have acquired an exclusive license under certain Marnac/KDL patents and patent applications relating to the manufacture, use and sale of pirfenidone for antifibrotic use worldwide, excluding Japan, Korea and Taiwan. The Marnac/KDL patent in the United States will expire in 2011. When this patent expires in 2011, we will not be able to use this patent to block others from marketing pirfenidone for the treatment of fibrotic disorders in the United States. Under the terms of this license, we are required to pay Marnac and KDL milestone payments based on the progress of clinical development of pirfenidone, as well as royalties on future sales. For a description of certain intellectual property issues relating to this license, please see the risk factor titled, "Over time, we will lose our ability to rely on the intellectual property we currently own to prevent competing products, which may impair our ability to generate revenues".

NS-3 Protease Inhibitors

In late 2004, we purchased from Array certain co-ownership rights in patents relating to our NS-3 protease inhibitor program such that we hold exclusive ownership rights in the patent applications arising out of our collaboration with Array.

Oritavancin

We have acquired an exclusive license under certain Eli Lilly patents to develop, make, use and sell oritavancin worldwide for any human disease under our asset purchase and license agreement with Eli Lilly. This agreement covers 38 United States patents, one United States patent application and corresponding foreign patents and patent applications. Certain United States and foreign patents related to the oritavancin molecule expire in 2015. Other material patents included in the licensed portfolio expire between 2014 and 2018. Pursuant to this agreement, we are obligated to pay Eli Lilly significant milestone payments and royalties on product sales. Our milestone obligations are based on the progress of our clinical development program for oritavancin and include payments to Eli Lilly for achievement of regulatory approval in various major market countries.

Amphotec

We have acquired certain ALZA patents and patent applications relating to the manufacture, use and sale of Amphotec in particular fields worldwide under our product acquisition agreement with ALZA. In

January 2001, ALZA assigned to us three United States patents and 14 related foreign patents. Two of the patents relating to the composition of Amphotec expire in 2007. The third patent relating to a method of using Amphotec to treat fungal infections expires in 2008. In exchange for receiving rights to these patents, we are required to pay ALZA milestone payments based on sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune, and royalties based on net sales of Amphotec.

Other Intellectual Property

We hold additional intellectual property in our core therapeutic areas. For example, in 2002, we acquired certain pending patent applications relating to interferon gamma from Amgen. In addition, we have filed numerous patent applications relating to the use of interferons and small molecules for the treatment of various diseases in the areas of pulmonology, HCV and oncology. To date, none of these patent applications have issued.

Competition

We believe our products generally compete on the basis of their performance and their price.

Actimmune for CGD and Severe Malignant Osteopetrosis

Actimmune is the only FDA approved therapy for CGD and severe, malignant osteopetrosis, and we are not aware of any competitive products available or in development for these indications. However, in general, our products and product candidates face competition from other currently available or development-stage therapies.

Actimmune and Pirfenidone for IPF

There is no FDA approved therapy available for the treatment of IPF. We believe that the primary competition for Actimmune or pirfenidone, if either is approved by the FDA for the treatment of IPF, will initially consist of products that are approved for other indications and for which clinical development for IPF is contemplated or underway, such as Enbrel®, Gleevec® and Tracleer®.

Infergen for HCV

Infergen competes with other forms of interferon alpha, such as PEG-Intron® and Intron A®, which are marketed by Schering-Plough, and Pegasys® and Roferon-A®, which are marketed by Roche Laboratories. These competitive products, which are marketed in combination with ribavirin therapy, dominate the chronic HCV infection market. Pegylated interferon alpha products have an advantage over non-pegylated products because they circulate longer in the body, permitting a less frequent dosing schedule and potentially enhancing efficacy in chronic hepatitis C patients who have not yet been treated with an interferon-based treatment regiment. As a result, these competing products may impede Infergen's ability to gain acceptance with physicians for the treatment of naive patients with chronic Hepatitis C and thus our ability to generate revenue from sales. Additional therapies, such as Enbrel, Aranesp® and Neulasta®, may also be in development for use in conjunction with interferon alpha products for the treatment of HCV infections.

Several other companies are also currently developing targeted antiviral orally available treatments for chronic Hepatitis C. We do not know if any of these treatments will be successful. If they are proven effective, these targeted antiviral orally available treatments may impede the growth of Infergen when and if they are introduced into the market.

Amphotec for Systemic Fungal Infections

The primary competition for Amphotec is Ambisome®, marketed by Gilead Sciences; Abelcet®, marketed by Enzon; and Vfend®, marketed by Pfizer. These competitive products dominate the invasive aspergillosis market.

Sales & Marketing, Medical Affairs and Product Distribution

Clinical Specialists

We have 110 field-based sales representatives that we refer to as clinical specialists. These clinical specialists report to 11 field-based regional sales directors. Our clinical specialists are organized into two groups. The first of these groups contain 79 clinical specialists and are referred to as our "full-line" clinical specialists. These full-line clinical specialists focus on supporting our two primary therapeutic areas, pulmonology and hepatology. The second group consists of 31 clinical specialists who focus on supporting only hepatology.

Medical Affairs

We have a Medical Affairs Department, which is comprised of 16 people who provide and maintain current, scientific-based information about pulmonology and hepatology for the benefit of our employees as well as outside persons. Of this group, ten persons are Medical Science Liaisons ("MSL's"). Our MSL's are responsible for maintaining relationships with physicians and key opinion leaders, supporting clinical trial awareness and enrolling and supporting our advisory boards and investigator sponsored trials. Other functions of our Medical Affairs Department are medical education, medical information and administration.

Distribution

In the United States, our products are sold primarily to specialty pharmacies and to distributors who resell them to hospitals, pharmacies and physicians. During the year ended December 31, 2004, the primary specialty pharmacies and distributors for our products were Priority Healthcare Corporation, Caremark, Inc. and Merck Medco, who accounted for 53%, 12% and 10%, respectively, of our total net product sales. In Europe and other parts of the world, Amphotec is sold through a number of distributors and agents.

Sales by Geographic Region

Our net product sales by region for the years ended December 31, were as follows (in thousands):

	2004	2003	2002
United States	$148,594	$151,373	$109,537
Rest of the world	2,393	2,765	2,428
Totals	$150,987	$154,138	$111,965

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. We believe that our products will be regulated as biologics or drugs by the FDA.

The European Medicines Agency ("EMEA") is a decentralized body of the European Union whose main responsibility is the protection and promotion of public health through the evaluation and supervision of medicines for human use. The EMEA coordinates the evaluation and supervision of medicinal products throughout the 25 EU member states in a network of 42 national competent authorities. We believe that our products will be regulated as biologics or drugs by the EMEA.

The process required by the FDA before our potential products, or previously approved products to be marketed for the treatment of new diseases, may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission of an investigational new drug application ("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; and
- FDA approval of a new biologics license application ("BLA"), a new drug application ("NDA"), or a BLA 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.

Prior to commencing a clinical trial, 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 application. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence such a clinical trial. Further, an independent institutional review board ("IRB") for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences.

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

- Phase I: The drug is initially introduced into 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, optimal dosage and dosage frequency. These Phase II clinical trials may be divided into early Phase II clinical trials, which are referred to as Phase IIa clinical trials, during which pilot studies are performed to determine initial activity and late Phase II clinical trials, which are referred to as Phase IIb clinical trials, that generally consist of controlled trials often involving several hundred patients in traditional drug development programs.
- Phase III: When Phase II clinical trials demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III clinical 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. It is possible for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous and reliable Phase III clinical trial. For example, after Actimmune had shown promising results for the treatment of IPF in a Phase II clinical trials, our initial Phase III study of Actimmune for the treatment of IPF failed to show significant effect on the primary endpoint of progression-free survival or on secondary endpoints of lung function and quality of life.

In the case of products for severe or life-threatening diseases such as IPF, the initial human testing is often conducted in patients rather than in healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase II clinical trials, and thus these trials are frequently referred to as Phase I/II clinical trials.

We may not successfully complete Phase I, Phase II or Phase III clinical trials testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or an IRB 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 are called Phase IV studies. The results of Phase IV studies can confirm the effectiveness of a drug and can provide important safety information to augment the FDA's adverse drug reaction reporting system.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA or NDA, or as part of a BLA or NDA supplement for approval of a new disease if the product is already approved for a disease. The FDA may deny approval of a BLA, NDA or BLA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the BLA, NDA or BLA or NDA supplement does not satisfy the criteria for approval. For example, in two Phase III clinical trials with oritavancin for the treatment of complicated skin and skin-structure infections, or CSSSIs, oritavancin achieved the primary efficacy endpoint and demonstrated that oritavancin was as effective as the comparator regimen of vancomycin followed by cephalexin, which is the commonly used regimen. However, the FDA requested an additional clinical safety study be completed prior to the submission of an NDA for oritavancin for the treatment of CSSSIs.

Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if 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.

A company seeking approval of an abbreviated new drug application ("ANDA"), for the use of an approved drug that is subject to another company's patent may have to certify to that patent and notify the owner of the NDA and patent for such drug that it is seeking approval. If the patent owner or licensee files a patent infringement lawsuit, FDA approval of the ANDA for which certification is made may be deferred pending the outcome of the lawsuit.

The FDA's fast track program is intended to facilitate the development and expedite the review of drugs intended for the treatment of serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs for such conditions. Under this program, the FDA can, for example, review completed portions of a BLA or NDA for a product granted fast track designation before the entire application is complete, thus potentially beginning the review process at an earlier time. We have obtained fast track designation from the FDA for Actimmune in the treatment of IPF. We cannot guarantee that this fast track designation will affect the time of review, or that the FDA will approve the BLA. Fast track products are subject to the same types of post-approval requirements as other products.

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. Government regulation may delay or prevent marketing of potential products or of approved products for new diseases 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 our product candidates or for use of our approved products for new diseases 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 receives regulatory approval, the approval may be significantly limited to specific diseases, patient subgroups 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, initial regulatory approval for any of our product candidates, or additional regulatory approvals for new indications of our approved products, 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 we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with these products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and other government agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the good manufacturing practices regulations and other FDA regulatory requirements.

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. For example, we are aware that physicians are prescribing Actimmune for the treatment of IPF, although we do not promote Actimmune for the treatment of IPF, and the FDA has not approved the use of Actimmune for the treatment of this disease. Substantially all of our Actimmune revenues are derived from physicians' prescriptions for off-label use. 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. Companies cannot promote FDA approved drugs for off-label uses. A company may engage in truthful, non-misleading, and non-promotional speech concerning its products. For example, we may inform physicians that we are conducting a clinical trial to evaluate the safety and effectiveness of Actimmune in unapproved uses, such as our ongoing clinical trials to evaluate Actimmune for the treatment of IPF, ovarian cancer and hepatitis C, and encourage those physicians to refer eligible patients to enroll in the clinical trial. We may also educate physicians about a particular disease state and how that disease is properly diagnosed so that patients who qualify for the clinical trial might be identified. We also may survey physicians who are lawfully prescribing our products for off-label uses to monitor patients' experiences, particularly as to whether safety issues have arisen. We may also, pursuant to FDA policies, respond to unsolicited requests from health care professionals and engage in appropriate scientific exchange of information about unapproved uses. We have engaged in these lawful activities in the past and continue to engage in some of them today. We have polices and procedures in place to regulate the lawful promotion of our marketed products within their labeled indications. Employees are trained to follow these policies and procedures and must certify that they will abide by them. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. While we believe we are currently in compliance with the FDA's regulations relating to off-label promotion, the regulations are subject to varying interpretations, which are evolving. Failure to comply with these requirements in the past or with respect to future activities can result in regulatory enforcement action by the FDA and other governmental bodies, which would have an adverse effect on our revenues, business and financial prospects. On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune, including information regarding the promotion and marketing of Actimmune. We are cooperating with the

Department of Justice in this inquiry. We cannot predict whether the outcome of this inquiry will have a material adverse effect on our business. For a more complete description of this matter see Item 3 "Legal Proceedings" below.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products 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.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA for that orphan indication. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation is the first to subsequently receive FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity for seven years in the United States, (i.e., the FDA may not approve any other applications to market the same drug for the same disease for seven years, except in very limited circumstances). Orphan drug designation exclusivity lasts for 10 years in Europe. We have filed and intend to file for orphan drug designation for those diseases we target that meet the criteria for orphan drug exclusivity. For example, Actimmune has orphan drug exclusivity for severe, malignant osteopetrosis. Actimmune and pirfenidone have been granted orphan drug designation for the treatment of IPF by the FDA, and pirfenidone has been granted orphan drug designation by the EMEA. Although obtaining FDA and EMEA approval to market a product with orphan drug exclusivity can be advantageous, there can be no assurance that we will be granted orphan drug designation for additional diseases or that orphan drug exclusivity will provide us with a material commercial advantage.

Research and Development

We direct financial resources efficiently to goal-oriented projects by reducing the time and infrastructure spent on research and development. We established an in-house applied research group in 2002 to conduct applied research. We also currently contract preclinical research to qualified third-party research organizations such as academic institutions or private contract labs. Our research and development expenses were $81.3 million, $119.9 million and $129.6 million for the years ended December 31, 2004, 2003 and 2002, respectively.

Facilities

All of our facilities and long-lived assets are located in the United States. Our facilities currently consist of 55,898 square feet of office space located at our headquarters location at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this facility. On January 13, 2005, we entered into an operating lease agreement to sublease an additional 12,988 square feet of office space which consists of 11,444 square feet of usable area and 1,544 square feet of common area located at the second floor of 3240 Bayshore Boulevard, Brisbane, CA 94005. We believe that our facilities are adequate for our current needs, and that suitable additional or substitute space will be available in the future to replace our existing facility, if necessary, or accommodate expansion of our operations.

Employees

As of December 31, 2004, we had 326 full-time employees. Of the full-time employees, 108 were engaged in research and development and 218 were engaged in sales, general and administrative positions. We believe our relations with our employees are good.

Available Information

We file electronically with the United States Securities and Exchange Commission ("SEC") our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We make available on our website at http://www.intermune.com, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC. You can also request copies of such documents by contacting our Investor Relations department at (415) 466-2242 or by sending an e-mail to *ir@intermune.com.*

RISK FACTORS

An investment in our common stock is risky. Stockholders and potential investors in shares of our stock should carefully consider the following risk factors, which hereby update those risks contained in the "Risk Factors" section of our Quarterly Report on Form 10-Q that was filed with the SEC on November 9, 2004, in addition to other information and risk factors in this Report. We are identifying these risk factors as important factors that could cause our actual results to differ materially from those contained in any written or oral forward-looking statements made by or on behalf of InterMune. We are relying upon the safe harbor for all forward-looking statements in this Report, and any such statements made by or on behalf of InterMune are qualified by reference to the following cautionary statements, as well as to those set forth elsewhere in this Report.

Risks Related to the Development of Our Products and Product Candidates

We may not succeed in our development efforts or in growing product revenues.

We commenced operations in 1998 and have incurred significant losses to date. Our revenues have been limited primarily to sales of Actimmune derived from physicians' prescriptions for the off-label use of Actimmune in the treatment of IPF. Although we are developing Actimmune for the treatment of idiopathic pulmonary fibrosis (IPF) and ovarian cancer, Actimmune will not be marketed for IPF before 2008, if at all, and will not be marketed for ovarian cancer before 2007, if at all. We market Infergen for the treatment of chronic hepatitis C virus (HCV) infections, but Infergen revenues may fail to grow significantly. We are developing pirfenidone for the treatment of IPF, but pirfenidone will not be marketed for any diseases before 2010, if at all. The development of PEG-Alfacon-1, a pegylated form of Infergen, for the treatment of chronic HCV infections will be lengthy and very expensive and carries significant risk. Accordingly, we are looking for a development partner for PEG-Alfacon-1, and we do not currently expect to develop the program if a partner is not found. Although we market Amphotec for invasive aspergillosis, we do not believe that it will provide sufficient revenue to us in the near future, if ever, and, consequently, we are attempting to divest Amphotec. We have been developing oritavancin for the treatment of complicated skin and skin-structure infections and have completed a Phase II clinical trial of oritavancin for the treatment of bacteremia. However, we have determined that continued development of oritavancin is non-strategic and therefore we are attempting to divest oritavancin. We may be unable to conclude either a sale of Amphotec or oritavancin in the near term or on favorable terms, if at all.

We may fail to develop our products on schedule, or at all, for the reasons stated in this "Risks Related to the Development of Our Products and Product Candidates" section of this Report. If this were to occur, our costs would increase and our ability to generate revenue could be impaired. In addition, we may need to raise capital in amounts greater than we anticipate in order to continue our development activities as planned. If additional capital is not available, we may be forced to curtail our development activities or cease operations.

Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials.

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, we reported that our exploratory Phase II clinical trial evaluating Actimmune for the potential treatment of advanced liver fibrosis caused by HCV in patients who have failed standard antiviral therapy failed to meet

its primary endpoint. As a result, we do not intend to conduct further development of Actimmune for the treatment of liver fibrosis.

We are conducting a second Phase III clinical trial of Actimmune as a treatment for IPF (the "INSPIRE" trial). However, Actimmune may not demonstrate safety or statistically significant efficacy with respect to the primary or secondary endpoints of the protocol of that clinical trial or any additional clinical trial. If the Phase III clinical trial were to fail to demonstrate statistically significant efficacy, we would likely abandon the development of Actimmune for the treatment of IPF, which would seriously harm our business and would result in a significant decline in our expected Actimmune revenue.

We do not know whether our planned clinical trials will begin on time, or at all, or will be completed on schedule, or at all.

The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial for a variety of reasons, including the advanced stage of their disease and medical problems that are not related to our products or product candidates;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- our contract laboratories fail to follow good laboratory practices;
- the interim results of the clinical trial are inconclusive or negative;
- sufficient quantities of the trial drug may not be available; or
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy.

Our development costs will increase if we have material delays in our clinical trials or if we need to perform more or larger clinical trials than planned. For example, our development costs related to Actimmune as a treatment for IPF are increasing due to our need to conduct an additional Phase III clinical trial, as our first Phase III clinical trial of Actimmune for the treatment of IPF failed to show a significant effect on the primary endpoint of progression-free survival or on secondary endpoints of lung function and quality of life. If there are any significant delays for this or any of our other current or planned clinical trials, our financial results and the commercial prospects for our products and product candidates will be harmed, and our prospects for profitability will be impaired.

Preclinical development is a long, expensive and uncertain process, and we may terminate one or more of our current preclinical development programs.

We may determine that certain preclinical product candidates or programs do not have sufficient potential to warrant the allocation of resources toward them. Accordingly, we may elect to terminate our programs for and, in certain cases, our licenses to, such product candidates or programs. If we terminate a preclinical program in which we have invested significant resources, our financial condition and results of operations may be adversely affected, as we will have expended resources on a program that will not

provide a return on our investment and missed the opportunity to have allocated those resources to potentially more productive uses.

We will not be able to recover our total investment in our non-core assets through divestiture, which could harm our business and our results of operations.

In 2003, we reorganized our business by curtailing investment in non-core areas and focusing our commercial and development efforts in pulmonology and hepatology. As a result, we are in the process of attempting to divest oritavancin and Amphotec. We are also evaluating Actimmune in ovarian cancer in an ongoing Phase III trial. We will make a decision as to the future of this program when we receive data from a planned interim analysis of progression-free survival, which we anticipate in the second half of 2005. We have spent significant resources in the acquisition and development of these assets. We may in the future determine that additional product candidates or programs are not consistent with our future business strategy. We may not be able to recover our investment in some or all of these assets in full. In such event, we will have expended resources on programs that will not provide a full return on our investment and missed the opportunity to have allocated those resources to potentially more productive uses.

Risks Related to Government Regulation and Approval of our Products and Product Candidates

If we fail to comply or have failed in the past to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, it could result in regulatory enforcement action by the FDA or other governmental authorities, which would harm our business.

Physicians may prescribe commercially available drugs for uses that are not described in the product's labeling and that differ from those uses tested by us and approved by the FDA. Such off-label uses are common across medical specialties. For example, even though the FDA has not approved the use of Actimmune for the treatment of IPF, we are aware that physicians are prescribing Actimmune for the treatment of IPF. Substantially all of our Actimmune revenues are derived from physicians' prescriptions for off-label use. We are also aware that physicians are prescribing Infergen in combination with ribavirin therapy and prescribing daily administration of Infergen for the treatment of chronic HCV infections, even though the FDA has not approved this combination or dosing regimen for the treatment of chronic HCV infections. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA and other governmental agencies do, however, restrict manufacturers' communications on the subject of off-label use. Companies may not promote FDA approved drugs for off-label uses. Accordingly, we may not promote Actimmune for the treatment of IPF, or Infergen in combination with ribavirin therapy, or the daily Infergen regimen for the treatment of chronic HCV infections. The FDA and other governmental authorities actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has sought large civil and criminal fines against manufacturers for alleged improper promotion, and the FDA has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunction under which certain promotional conduct is changed or curtailed. We are aware of at least one instance in which the Office of the Inspector General has sought criminal penalties and a corporate integrity agreement against a pharmaceutical manufacturer requiring that company to pay substantial fines and to monitor certain promotional activities to ensure compliance with FDA regulations. We engage in medical education activities that are subject to scrutiny under the FDA's regulations relating to off-label promotion. While we believe we are currently in compliance with these regulations, the regulations are subject to varying interpretations, which are evolving.

On March 19, 2004, plaintiff Joan Gallagher filed an action against InterMune and certain individuals in the United States District Court for the Eastern District of Pennsylvania for wrongful termination.

Ms. Gallagher alleges that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Among other things, Ms. Gallagher alleges that we engaged in deceptive practices, such as establishing a patient registry to market Actimmune for unapproved indications and structuring our compensation systems to advance the allegedly unlawful marketing. See "Item 3. Legal Proceedings" for a more complete description of this case.

In addition, we are defending a federal class action stockholder lawsuit alleging that we, our former chief executive officer and former chief financial officer made certain false and misleading statements in violation of the federal securities laws. In connection with this lawsuit, the plaintiff has made allegations with respect to our alleged off-label promotion of Actimmune. See "Item 3. Legal Proceedings" for a more complete description of this case.

If the FDA or any other governmental agency initiates an enforcement action against us and it is determined that we violated prohibitions relating to off-label promotion in connection with past or future activities, we could be subject to civil and/or criminal sanctions such as those noted above in this risk factor, any of which would have an adverse effect on our revenues, business and financial prospects. On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune, including information regarding the promotion and marketing of Actimmune. We are cooperating with the Department of Justice in this inquiry. We cannot predict whether the outcome of this inquiry will have a material adverse effect on our business.

In addition, some of the agreements pursuant to which we license our products, including our license agreement relating to Actimmune, contain provisions requiring us to comply with applicable laws and regulations, including the FDA's restriction on the promotion of FDA approved drugs for off-label uses. As a result, if it were determined that we violated the FDA's rules relating to off-label promotion in connection with our marketing of Actimmune, we may be in material breach of our license agreement for Actimmune. If we failed to cure a material breach of this license agreement, we could lose our rights to Actimmune under the agreement.

If the FDA imposes significant restrictions or requirements related to our products for any disease or withdraws its approval of any of our products for any disease for which they have been approved, our revenues would decline.

The FDA and foreign regulatory authorities may impose significant restrictions on the use or marketing of our products or impose additional requirements for post-approval studies. Later discovery of previously unknown problems with any of our products or their manufacture may result in further restrictions, including withdrawal of the product from the market. In this regard, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of observations." While we believe that all of these observations have been appropriately corrected without further comment or action from the FDA, failure to correct any deficiency could result in manufacturing delays. Our existing approvals for diseases, and any new approval for any other disease that we target, if granted, could be withdrawn for failure to comply with regulatory requirements or to meet our post-approval commitments. For example, we have ongoing Phase IV post-marketing commitments to the FDA relating to Actimmune for the treatment of osteopetrosis and Infergen for the treatment of HCV. Our failure to adequately address these ongoing Phase IV commitments could result in a regulatory action or restriction, such as withdrawal of the relevant product's approval by the FDA. If approval for a disease is withdrawn, we could no longer market the affected product for that disease. In addition, governmental

authorities could seize our inventory of such product, or force us to recall any product already in the market, if we fail to comply with FDA or other governmental regulations.

For a description of restrictions relating to the off-label promotion of our products, please see the risk factor titled, "If we fail to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, it could result in regulatory enforcement action by the FDA or other governmental authorities, which would harm our business" above.

If our clinical trials fail to demonstrate to the FDA and foreign regulatory authorities that any of our products or product candidates are safe and effective for the treatment of particular diseases, the FDA and foreign regulatory authorities may require us to conduct additional clinical trials or may not grant us marketing approval for such products or product candidates for those diseases.

Our failure to adequately demonstrate the safety and effectiveness of any of our products or product candidates for the treatment of particular diseases will delay or prevent our receipt of the FDA's and foreign regulatory authorities' approval and, ultimately, may prevent commercialization of our products and product candidates for those diseases.

The FDA and foreign regulatory authorities have substantial discretion in deciding whether, based on the benefits and risks in a particular disease, any of our products or product candidates should be granted approval for the treatment of that particular disease. Even if we believe that a clinical trial has demonstrated the safety and statistically significant efficacy of any of our products or product candidates for the treatment of a disease, the results may not be satisfactory to the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted by the FDA and foreign regulatory authorities in different ways, which could delay, limit or prevent regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our products or product candidates involved will be harmed, and our prospects for profitability will be impaired.

For example, we reported results from our confirmatory pivotal Phase III clinical trial of oritavancin for the treatment of complicated skin and skin-structure infections, or CSSSIs. However, in two additional small clinical pharmacology trials, we observed adverse events, primarily phlebitis and rash that were inconsistent with the safety profile observed in prior clinical trials of oritavancin. Since the cause of the inconsistency is unknown, the FDA has requested an additional clinical safety trial be completed prior to the submission of a New Drug Application ("NDA"), for oritavancin. Because of the need to perform an additional clinical trial, further development of oritavancin for the treatment of CSSSIs will require additional investment, and FDA approval of oritavancin for the treatment of CSSSIs has been delayed and remains uncertain.

The pricing and profitability of our products may be subject to control by the government and other third-party payors.

The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. For example, in most foreign markets, the pricing and/or profitability of prescription pharmaceuticals are subject to governmental control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control. For example, federal legislation was enacted on December 8, 2003 that provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new Medicare benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care

organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. These new and any future cost-control initiatives could decrease the price that we would receive for Actimmune, Infergen, Amphotec or any other products we may develop in the future, which would reduce our revenues and potential profitability.

Our failure or alleged failure to comply with anti-kickback and false claims laws could result in civil and/or criminal sanctions and/or harm our business.

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Subject to certain exceptions, the anti-kickback laws make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify "safe harbors" or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of Medicaid rebate information and other information affecting federal and state and third-party payment for our products, and the sale and marketing of our products, could become subject to scrutiny under these laws. For example, we are one of what we believe to be a number of companies that received letters from the Office of the Florida Attorney General in 2003 directing us to keep certain records relating to its Medicaid rebate reporting until the Office of the Florida Attorney General has concluded an investigation that was initiated by the state following large false claims act settlements by other manufacturers. We have not been asked to produce any records or otherwise been advised of the nature of the allegations against us, if any. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid).

In addition, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their "off-label" promotion of drugs. For information regarding allegations with respect to "off-label" promotion by us, please see "If we fail to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, it could result in regulatory enforcement action by the FDA or other governmental authorities, which would harm our business" above.

If the government were to allege that we were, or convict us of, violating these laws, there could be a material adverse effect on us, including a substantial fine, decline in our stock price, or both. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

Risks Related to Manufacturing and Our Dependence on Third Parties

The manufacturing and manufacturing development of our products and product candidates present technological, logistical and regulatory risks, each of which may adversely affect our potential revenues.

The manufacturing and manufacturing development of pharmaceuticals, and, in particular, biologicals, are technologically and logistically complex and heavily regulated by the FDA and other governmental authorities. The manufacturing and manufacturing development of our products and product candidates present many risks, including, but not limited to, the following:

- It may not be technically feasible to scale up an existing manufacturing process to meet demand or such scale-up may take longer than anticipated; and
- Failure to comply with strictly enforced good manufacturing practices regulations and similar foreign standards may result in delays in product approval or withdrawal of an approved product from the market. For example, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of observations." While we believe that all of these observations have been appropriately corrected without further comment or action from the FDA, failure to correct any deficiency could result in manufacturing delays.

Any of these factors could delay clinical trials, regulatory submissions and/or commercialization of our products for particular diseases, interfere with current sales, entail higher costs and result in our being unable to effectively sell our products.

Our manufacturing strategy, which relies on third-party manufacturers, exposes us to additional risks as a result of which we may lose potential revenues.

We do not have the resources, facilities or experience to manufacture any of our products or product candidates ourselves. Completion of our clinical trials and commercialization of our products requires access to, or development of, manufacturing facilities that meet FDA standards to manufacture a sufficient supply of our products. The FDA must approve facilities that manufacture our products for commercial purposes, as well as the manufacturing processes and specifications for the product. We depend on third parties for the manufacture of our product candidates for preclinical and clinical purposes, and we rely on third parties with FDA approved manufacturing facilities for the manufacture of our products for commercial purposes. These third parties include BI Austria, Amgen, Abbott, Cardinal Health, Ben Venue and Signa. We have long-term supply contracts with BI Austria for Actimmune, with Amgen for Infergen and with Abbott for oritavancin. However, if we do not perform our obligations under these agreements, they may be terminated.

Our manufacturing strategy for our products and product candidates presents many risks, including, but not limited to, the following:

- If market demand for our products is less than our purchase obligations to our manufacturers, we may incur substantial penalties and substantial inventory write-offs;
- Manufacturers of our products are subject to ongoing periodic inspections by the FDA and other regulatory authorities for compliance with strictly enforced good manufacturing practices regulations and similar foreign standards, and we do not have control over our third-party manufacturers' compliance with these regulations and standards;
- When we need to transfer between manufacturers, the FDA and foreign regulatory authorities must approve the new manufacturers' facilities and processes prior to our use or sale of products it manufactures for us. This requires new testing and compliance inspections. Delays in transferring manufacturing technology between third parties could delay clinical trials, regulatory submissions and commercialization of our product candidates. For example, we have transferred the

manufacturing of oritavancin from Eli Lilly to a third-party manufacturer and our third-party manufacturer's finished product has not yet demonstrated a comparable safety profile to that demonstrated by Eli Lilly's oritavancin product. If the finished oritavancin product of our third-party manufacturer does not have a comparable safety profile to that demonstrated by Eli Lilly's oritavancin product, our ability to divest oritavancin may be adversely affected;

- Our manufacturers might not be able or refuse to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand;
- We may not have intellectual property rights, or may have to share intellectual property rights, to any improvements in the manufacturing processes or new manufacturing processes for our products;
- Our product costs may increase if our manufacturers pass their increasing costs of manufacture on to us;
- If third-party manufacturers do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to obtain or maintain regulatory approvals for our products and product candidates and will not be able to successfully commercialize our products and product candidates. In such event, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all; and
- If our agreement with a third-party manufacturer expires, we may not be able to renegotiate a new agreement with that manufacturer on favorable terms, if at all. If we cannot successfully complete such renegotiation, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all.

Any of these factors could delay clinical trials, regulatory submissions or commercialization of our products for particular diseases, interfere with current sales, entail higher costs and result in our being unable to effectively sell our products.

Our agreements with third-party manufacturers may restrict our ability to establish alternative sources of products in a timely manner or at an acceptable cost, which may cause us to be unable to meet demand for our products and to lose potential revenues.

Our key supply agreements provide that the manufacturer is our exclusive source of supply for the product, except under certain circumstances. For example, BI Austria is currently our exclusive manufacturer for Actimmune. Under our agreement with BI Austria, we cannot seek a secondary source to manufacture Actimmune until BI Austria has indicated to us its inability or unwillingness to meet our requirements. Amgen is currently our exclusive manufacturer of Infergen. In December 2004 we amended our Licensing and Commercialization Agreement with Amgen to allow us to transfer the manufacturing of Infergen from Amgen to a new supplier. Even if we were to enter into an agreement with a new supplier to manufacture Infergen, it could take several years to transfer the Infergen manufacturing process to a secondary source. If we are delayed in establishing a secondary supply source for Actimmune or Infergen, or cannot do so at an acceptable cost, we may suffer a shortage of commercial supply of that product or a higher cost of product, either of which would have a material and adverse effect on our revenues, business and financial prospects.

We rely on third parties to conduct clinical trials for our products and product candidates, and those third parties may not perform satisfactorily.

If our third-party contractors do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in or prevented from obtaining regulatory approvals for our products and product candidates, and may not be able to successfully commercialize our products and product candidates for targeted diseases. We do not have the ability to independently conduct clinical trials for all of our products and product candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to perform this function. Our ability to monitor and audit the performance of these third parties is limited. If these third parties do not perform satisfactorily, our clinical trials may be extended or delayed, resulting in potentially substantial cost increases to us and other adverse impacts on our product development efforts. We may not be able to locate any necessary acceptable replacements or enter into favorable agreements with them, if at all.

Risks Related to the Commercialization of Our Products and Product Candidates

If we are not able to obtain required regulatory approvals to change Infergen's label to provide for daily dosing and to market Infergen in combination with ribavirin for Hepatitis C nonresponders or in combination with other anti-viral drugs, our revenues, business and financial prospects would be adversely affected.

We believe that market acceptance of and demand for Infergen for the treatment of chronic HCV infections may depend upon our ability to change Infergen's label to provide for daily dosing and to market Infergen in combination therapy with ribavirin for Hepatitis C nonresponders or in combination with other anti-viral drugs. Before we may change Infergen's label or market Infergen for use in combination therapy with ribavirin for Hepatitis C nonresponders or in combination with other anti-viral drugs, we will need to obtain FDA approval. To seek and obtain such approval, we will need to supplement Infergen's current FDA license with data that support daily use of Infergen and the combination use of Infergen and ribavirin or another anti-viral drug for increased effectiveness in treating chronic HCV infections. We cannot be certain how long it would take us to submit such data and obtain such an approval from the FDA, if at all. In June 2004, we initiated a Phase III clinical trial designed to evaluate the safety and efficacy of daily Infergen in combination with ribavirin for the treatment of patients chronically infected with HCV who have failed to respond to a previous course of therapy with pegylated interferon alfa-2 plus ribavirin. However, we cannot provide assurance that this trial will be successful. In addition, seeking FDA approval for Infergen combination therapy may, in certain circumstances, involve our complying with FDA patent certification and notice provisions relating to ribavirin that could result in deferral for up to 30 months or, longer in the case of judicial intervention, of FDA approval pending the outcome of ongoing patent infringement litigation. If we are unable to obtain FDA approval of daily dosing of Infergen and for these new uses for Infergen, we will be unable to market Infergen in combination with ribavirin or other anti-viral drugs, and our revenues, business and financial prospects would be adversely affected.

If Amgen is unable or refuses to meet our requirements for the manufacture of Infergen or we cannot manufacture PEG-Alfacon-1 in sufficient quantities or at an acceptable cost in the future to meet anticipated commercial demand, our revenues, business and financial prospects would be adversely affected.

Amgen is currently our exclusive manufacturer of Infergen. In December 2004 we amended our Licensing and Commercialization Agreement with Amgen to allow us to transfer the manufacturing of Infergen from Amgen to a new supplier. Even if we were to enter into an agreement with a new supplier to manufacture Infergen, it could take several years to transfer the Infergen manufacturing process to a secondary source. If Amgen is unable or refuses to meet our requirements for the manufacture of Infergen, we would be unable to meet market demand for Infergen, which would harm our ability to generate revenue. In addition, we have limited control over the cost of goods for Infergen. If we are unable to purchase Infergen at an acceptable cost, it would have a material and adverse effect on our revenues,

business and financial prospects. Although we have an existing manufacturing process for PEG-Alfacon-1 that has been sufficient to meet our needs to date, there are technical challenges to scaling-up that process to meet anticipated commercial demand. These challenges include attempting to maintain the bioactivity of the compound during the pegylation process. There is no assurance that we will successfully complete any required scale-up. If we develop and commercialize PEG-Alfacon-1 and are unable to obtain or manufacture a sufficient supply of PEG-Alfacon-1, our revenues, business and financial prospects would be adversely affected.

Existing patents and patents acquired by others in the future may limit our ability to market our products for the treatment of chronic HCV infections.

Our competitors and their strategic partners have substantial and extensive patent rights related to combination therapy of interferon alpha and ribavirin for the treatment of chronic HCV infections. For example, we are aware of three U.S. patents that relate to the use of interferon alpha and ribavirin to treat chronic HCV infections. These patents expire in 2015, 2016 and 2017, respectively. It is possible that these patents could adversely impact or prevent our efforts to market Infergen and/or PEG-Alfacon-1 in combination therapy with ribavirin. If these patents adversely impact our ability to market Infergen or PEG-Alfacon-1 with ribavirin, it is possible that the commercial prospects for Infergen or PEG-Alfacon-1 could be reduced and our prospects for profitability may be impaired. Further, it is possible that our competitors and their strategic partners may obtain additional patent rights in connection with filed patent applications for combination therapy of interferon alpha and other anti-viral drugs for the treatment of chronic HCV infections. If those patent applications were to issue, we may be unable to market Infergen or PEG-Alfacon-1 with ribavirin or with another anti-viral drug, reducing the commercial prospects for Infergen and PEG-Alfacon-1 and our prospects for profitability.

In addition, we are aware of a U.S. patent that relates to the use of pegylated interferon alpha to treat chronic HCV infections. This patent expires in 2016. It is possible that this patent could adversely impact or prevent us from marketing PEG-Alfacon-1 for the treatment of chronic HCV infections. If this patent impacts our ability to market PEG-Alfacon-1 for the treatment of chronic HCV infections, the commercial prospects for PEG-Alfacon-1 could be reduced. Our competitors and their strategic partners may have patent rights relating to pegylation technology in general and the use of pegylated interferon alpha for the treatment of chronic HCV infections in particular. These patents may adversely impact the commercial prospects for PEG-Alfacon-1.

Although we have licensed from Amgen rights to PEG-Alfacon-1, we may not have, and may not be able to license on commercially reasonable terms, if at all, sufficient rights to all the intellectual property necessary for us to commercialize PEG-Alfacon-1 for the treatment of chronic HCV infections. For example, our competitors and their strategic partners have substantial and extensive patent rights in connection with interferon alpha and its recombinant production.

We are aware of the existence of a patent in the United States that relates to the administration of alpha interferon and gamma interferon to treat HCV patients. We are uncertain what impact, if any, this patent may have on our efforts to commercialize our development program for once daily Infergen in combination with Actimmune with and without ribavirin. It is possible that this patent could adversely impact or prevent us from marketing the combination of Infergen and Actimmune for HCV should our development program prove successful. If we determine that we need a license, we may not be able to secure such a license on commercially reasonable terms, if at all, reducing the commercial prospects for this product combination in the United States.

Because our competitors' pegylated interferon alpha products permit less frequent dosing than non-pegylated products, Infergen, which is not pegylated, is at a competitive disadvantage with respect to frequency of administration, which may impede its ability to gain acceptance with physicians and patients.

Pegylated interferon alpha products may have an advantage over non-pegylated products because they circulate longer in the body, permitting a less frequent dosing schedule and enhancing efficacy in some patients infected with the HCV virus. Because our competitors Schering-Plough Corporation and Roche Laboratories have commenced marketing their respective pegylated interferon alpha products, Infergen, which is a non-pegylated interferon alpha product, may be at a significant disadvantage. Pegylated interferon alpha products have an advantage over non-pegylated products because they circulate longer in the body, permitting a less frequent dosing schedule and enhancing efficacy in some patients infected with HCV. As a result, these competing products may impede Infergen's ability to gain acceptance with physicians and patients and thus our ability to generate revenue. In addition, both of these companies have obtained and it is likely they will continue to obtain significant patent protection relating to their respective products.

If non-interferon-based products prove to be safe and effective in the treatment of chronic HCV infections, our business and financial prospects will be adversely affected.

Specific targeted agents directed against HCV may be effective in reducing the amount of virus in infected chronic HCV patients. If the use of these specific targeted anti-HCV agents proves to be effective in the treatment of chronic HCV infections, then the use of interferon-based therapies, like Infergen for chronic HCV infections may diminish, which would harm our business.

If we are unable to achieve results that are consistent with our assessment of the current and future market potential of Infergen and PEG-Alfacon-1, we may be required to take a charge to the carrying value of our Infergen-related intangible asset that would have a material adverse effect on our financial condition and results of operations.

If the use of interferon-based therapies, including Infergen, for chronic HCV infections were to diminish or not grow as we expect, this could impact the recoverability of the Infergen-related intangible asset, which was $15.2 million as of December 31, 2004. During the quarter ended December 31, 2003, we conducted a detailed assessment of the current and future market potential of Infergen and PEG-Alfacon-1, including, but not limited to, the impact of competing products on the market potential of these interferon-based therapies. This assessment resulted in no reduction of the carrying value of the Infergen-related intangible asset. If we are unable to achieve results consistent with those assumed in our detailed assessment, it may be necessary to perform a future detailed assessment, which could result in a reduction of the carrying value of the Infergen-related intangible asset. This could have a material adverse effect on our financial condition and results of operations during the period in which we recognize a reduction.

We rely on one customer for approximately 53% of our total product sales. If this customer does not continue to sell our products at its current levels, our business will be harmed.

During the fiscal year ended December 31, 2004, Priority Healthcare Corporation accounted for approximately 53% of our total product sales and 47% of our outstanding receivables. If this customer or any other customer that sells a significant portion of our products were to experience financial difficulties, or otherwise became unable or unwilling to sell our products, our business would be harmed. Additionally, any reduction, delay or loss of orders from our key customers could harm our revenues in any period or harm our business generally.

If the specialty pharmacies and distributors that we rely upon to sell our products fail to perform, our business may be adversely affected.

Our success depends on the continued customer support efforts of our network of specialty pharmacies and distributors. A specialty pharmacy is a pharmacy that specializes in the dispensing of injectable or infused medications for complex or chronic conditions, which often require a high level of patient education and ongoing management. The use of specialty pharmacies and distributors involves certain risks, including, but not limited to, risks that these specialty pharmacies and distributors will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using our products or product complaints;
- not effectively sell or support our products;
- reduce their efforts or discontinue to sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Any such failure may result in decreased product sales and lower product revenues, which would harm our business.

Even if regulatory authorities approve our products or product candidates for the treatment of the diseases we are targeting, our products may not be marketed or commercially successful.

Our products and product candidates are expensive, and we anticipate that the annual cost for treatment for each of the diseases for which we are seeking approval will be significant. These costs will vary for different diseases based on the dosage and method of administration. Accordingly, we may decide not to market any of our products or product candidates for an approved disease because we believe that it may not be commercially successful. Market acceptance of and demand for our products and product candidates will depend on many factors, including, but not limited to:

- cost of treatment;
- pricing and availability of alternative products;
- ability to obtain third-party coverage or reimbursement for our products or product candidates to treat a particular disease;
- perceived efficacy relative to other available therapies;
- shifts in the medical community to new treatment paradigms or standards of care;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

If third-party payors do not provide coverage or reimburse patients for our products, our revenues and prospects for profitability will suffer.

Our ability to commercialize our products or product candidates for particular diseases is highly dependent on the extent to which coverage and reimbursement for our products is available from:

- private health insurers, including managed care organizations;

- governmental payors, such as Medicaid, the U.S. Public Health Service Agency or the Veterans' Administration; and
- other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of pharmaceutical products, particularly with respect to products that are prescribed by physicians for off-label use. If governmental and other third-party payors do not provide adequate coverage and reimbursement levels for our products, market acceptance of our products will be reduced, and our sales will suffer. Many third-party payors provide coverage or reimbursement only for FDA approved indications. If any large or many third-party payors decide to deny reimbursement for Actimmune used to treat IPF, sales of Actimmune would decline, and our revenues would suffer.

Often, third-party payors make the decision to reimburse an off-label prescription based on whether that product has a compendium listing. The drug compendia list approved indications that products have received from the FDA. The compendia also evaluate the body of clinical evidence to determine whether an off-label use of products should be listed in the compendia as medically appropriate. A compendium listing of an off-label use is many times a requirement by payors, such as Medicare and private payors, to approve that use. To receive a compendium listing for the use of Actimmune in the treatment of IPF, we would have to complete an application and submit clinical data regarding the use of Actimmune in the treatment of IPF. We will evaluate whether we apply for a compendium listing based upon the publication of certain data in peer review journals whose publication is outside of our control. If we file for a compendium listing and are unable to acquire a compendium listing for Actimmune for the treatment of IPF, additional third-party payors may decide to deny reimbursement for Actimmune for the treatment of IPF, and fewer physicians may prescribe Actimmune for such treatment. If either of these were to occur, sales of Actimmune would decline and our revenues would suffer.

Some third-party payors have denied coverage for Actimmune for the treatment of IPF for a variety of reasons, including the cost of Actimmune, the fact that IPF is not an FDA approved indication for Actimmune or a third-party payor's assessment that a particular patient's case of IPF has advanced to a stage at which treatment with Actimmune would not have a significant effect. We believe that approximately 60-70% of the patients who seek coverage for Actimmune for the treatment of IPF from private third-party payors are able to obtain coverage. While coverage trends have not changed significantly in the last two years, major health plans could further restrict coverage or adopt a policy of no coverage.

Medicare generally does not provide coverage for drugs, like Actimmune, that are administered by injection in the home. However, in connection with the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare has recently discussed the possibility of refusing to provide coverage for products for a specific indication unless the product has been approved by the FDA for that indication. If Medicare were to make a formal decision not to cover the off-label use of products, it may have a negative impact on the willingness of private third-party payors to provide coverage for the off-label use of products such as Actimmune.

The activities of competitive drug companies, or others, may limit our products' revenue potential or render them obsolete.

Our commercial opportunities will be reduced or eliminated if our competitors develop or market products that, compared to our products or product candidates:

- are more effective;
- have fewer or less severe adverse side effects;

- are better tolerated;
- have better patient compliance;
- receive better reimbursement terms;
- are more accepted by physicians;
- are more adaptable to various modes of dosing;
- have better distribution channels;
- are easier to administer; or
- are less expensive.

Even if we are successful in developing effective drugs, our products may not compete effectively with our competitors' current or future products. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do. For more information, see the section entitled "Competition."

Risks Related to Our Intellectual Property Rights

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates.

Our commercial success will depend in part on obtaining and maintaining patent protection on our products and product candidates and successfully defending these patents against third-party challenges. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have a material adverse effect on our business.

Others have filed and in the future may file patent applications covering uses and formulations of interferon gamma-1b, interferon alpha, pegylated versions of these products and other products in our development program. If a third party has been or is in the future issued a patent that blocked our ability to commercialize any of our products, alone or in combination, for any or all of the diseases that we are targeting, we would be prevented from commercializing that product or combination of products for that disease or diseases unless we obtained a license from the patent holder. We may not be able to obtain such a license to a blocking patent on commercially reasonable terms, if at all. If we cannot obtain, maintain and protect the necessary proprietary rights for the development and commercialization of our products or product candidates, our business and financial prospects will be impaired.

If we breach our license agreements, we may lose our ability to develop and sell our products.

We license certain patents and trade secrets relating to Actimmune from Genentech, Inc; relating to Infergen from Amgen; relating to pirfenidone from Marnac and KDL; and relating to oritavancin from Eli Lilly. If we breach any of our agreements with Genentech, Amgen, Marnac and KDL or Eli Lilly, any of these licensors could terminate the respective license, and we would have no further rights to utilize the licensed patents or trade secrets to develop and market the corresponding products, which could adversely affect our revenues and financial prospects.

Since the pirfenidone molecule is in the public domain and the patent we licensed from Marnac is limited to specific methods of use of pirfenidone, we may be subject to competition from third party products with the same active pharmaceutical ingredients as our product candidate.

Composition of matter patent protection for pirfenidone molecule has expired in the United States and elsewhere. Marnac and others have obtained patents in the United States and elsewhere relating to methods of use of pirfenidone for the treatment of certain diseases. We have licensed from Marnac and KDL rights to a U.S. patent related to the use of pirfenidone for the treatment of fibrotic disorders, including the use of pirfenidone for the treatment of IPF. Marnac has retained rights under other U.S. and foreign patents for the use of pirfenidone to treat diseases other than fibrotic disorders. It is possible that Marnac will license these patent rights to third parties to develop, market, sell and distribute pirfenidone for these indications in the United States and elsewhere. It is also possible that a third party may develop pirfenidone for the treatment of certain diseases that are not covered by patents held by Marnac or those we licensed from Marnac. If Marnac or others were to license their method of use patents for non anti-fibrotic indications to a third party, or if a third party were to develop pirfenidone for a use that is not covered by any patents and such third parties successfully developed pirfenidone for non-fibrotic indications, we could face competition from third party products with the same active pharmaceutical ingredient as our product candidate. If a third party were to obtain FDA approval for the use of pirfenidone for an indication before we did, such third party would be first to market and could establish the price for pirfenidone. This could adversely impact our ability to implement our pricing strategy for the product and may limit our ability to maximize the commercial potential of pirfenidone. The presence of a lower priced competitive product with the same active pharmaceutical ingredients as our product could lead to use of the competitive product for our anti-fibrotic indications. This could lead to pricing pressure for pirfenidone, which would adversely affect our ability to generate revenue from the sale of pirfenidone for anti-fibrotic indications.

Over time, we will lose our ability to rely upon the intellectual property we currently own to prevent competing products, which may impair our ability to generate revenues.

We have licensed certain patents relating to interferon gamma-1b, the active ingredient in Actimmune, from Genentech. Certain of the U.S. patents covering DNA vectors and host cells relating to interferon gamma-1b expire or expired in 2005 and 2006 without a material impact on our business. In

addition, a U.S. patent relating to the composition of interferon gamma-1b expires in 2014. Other material U.S. patents relating to interferon gamma-1b expire between 2009 and 2013. When these various patents expire, we will be unable to use these patents to block others from marketing Actimmune in the United States.

We have licensed U.S. and Canadian patent rights relating to Infergen, a type of interferon alpha, from Amgen. Two of Amgen's U.S. patents relating to Infergen's active ingredient, the interferon alfacon-1 molecule, expire in 2004. However, the U.S. Patent and Trademark Office recently issued a Certificate of Extension of Patent Term, officially extending the term of one of these patents by five years, to 2009. After expiration of the extended patent term in 2009, we would rely on a U.S. patent related to the use of interferon alfacon-1 at a dose within the range of 2 million to 30 million units of interferon alfacon-1 per administration for the treatment of chronic HCV infections to block others from marketing interferon alfacon-1 for the treatment of chronic HCV infections at these doses. When this patent expires in 2011, we will not be able to use this patent to block others from marketing Infergen or other forms of interferon alfacon-1 for the treatment of chronic HCV infections in the United States.

We have licensed from Marnac and KDL rights to a U.S. patent related to the use of pirfenidone for the treatment of fibrotic disorders, including the use of pirfenidone for the treatment of IPF. After the U.S. patent expires in 2011, we will not be able to use this patent to block others from marketing pirfenidone for fibrotic disorders, including IPF although we may be able to extend our U.S. exclusivity for IPF if we gain FDA approval for IPF under orphan drug designation. The pirfenidone molecule itself has no composition of matter patent protection in the United States or elsewhere. Therefore, we have no ability to prevent others from commercializing pirfenidone for (i) uses covered by the patents held by Marnac and third parties, or (ii) other uses in the public domain for which there is no patent protection. We are relying on exclusivity granted from orphan drug designation in IPF to protect pirfenidone from competitors in this indication. The exclusivity period begins on NDA approval and ends seven years thereafter. We cannot provide any assurance that we will be able to maintain this orphan drug designation. However, a third party could develop pirfenidone for another non-fibrotic disease that also qualifies for orphan drug designation and could be granted seven years exclusivity in that indication.

We have licensed certain patents throughout the world relating to oritavancin from Eli Lilly. After patents related to the composition of oritavancin expire in 2015, we will not be able to use such patents to block others from marketing oritavancin.

Once our patents expire, we will be subject to competition from third parties who will be able to use the intellectual property covered by these patents, which could impair our ability to generate revenues.

Our competitors and others may have or may obtain rights that may limit or prevent us from developing and commercializing our products and product candidates.

Our competitors and their strategic partners have substantial and extensive patent rights in connection with the use of interferon alpha to treat a variety of diseases. It is possible that our competitors and their strategic partners may obtain additional patent rights in connection with filed patent applications for interferon alpha. We are uncertain of the extent to which the currently issued patents and any additional patents of our competitors that may issue will prevent us from marketing Infergen for the treatment of certain diseases. If these patents adversely impact our ability to market, or prevent us from marketing, Infergen for a range of diseases, the commercial prospects for Infergen will be reduced and our prospects for profitability may be impaired. In addition, our competitors and their strategic partners have substantial and extensive patent rights in connection with the use of pegylated interferon alpha to treat a variety of diseases. Although we have licensed from Amgen rights to PEG-Alfacon-1, we may not have, and may not be able to license on commercially reasonable terms, if at all, sufficient rights to all the intellectual property necessary for us to commercialize PEG-Alfacon-1.

We are aware of the settlement of a lawsuit involving Infergen filed in 1997 by Biogen, Inc. against Amgen in the U.S. District Court for the District of Massachusetts. The suit alleged that the manufacture of Infergen infringed three Biogen U.S. patents relating to vectors for expressing cloned genes, methods of making vectors and expressing cloned genes, and host cells. All claims in the lawsuit were dismissed with prejudice by order of the court in December 2001 under a confidential settlement agreement entered into between Biogen and Amgen. Although Amgen has informed us that the settlement agreement applies to Infergen, we do not know the terms of the settlement agreement or how the terms of the settlement may affect our ability to commercialize Infergen in the United States. The settlement agreement may have a material adverse effect on our ability to commercialize Infergen in the United States.

The combination of our products with other drugs may have a greater therapeutic effect in treating certain diseases than our products alone. In some cases, third parties hold patents either on the potential companion drugs or on combination therapies that include our products. We may not be able to negotiate licenses or other rights to potential companion drugs on reasonable terms, or at all. If we are not able to negotiate these licenses or other rights, the market for our products may be diminished.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and could adversely affect our ability to develop and commercialize products.

Our commercial success depends in part on our ability and the ability of our collaborators to avoid infringing patents and proprietary rights of third parties. As noted in the immediately preceding risk factor, third parties may accuse us or our collaborators of employing their proprietary technology in our products, or in the materials or processes used to research or develop our products, without authorization. Any legal action against our collaborators or us claiming damages and/or seeking to stop our commercial activities relating to the affected products, materials and processes could, in addition to subjecting us to potential liability for damages, require our collaborators or us to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. We cannot predict whether we, or our collaborators, would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If we are unable to obtain such a license, we, or our collaborators, may be unable to continue to utilize the affected materials or processes or manufacture or market the affected products or we may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if we are able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair our prospects for profitability. Accordingly, we cannot predict whether or to what extent the commercial value of the affected product or products or our prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from our core business.

If the owners of the intellectual property we license fail to maintain the intellectual property, we may lose our rights to develop our products or product candidates.

We generally do not control the patent prosecution of technology that we license from others. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would exercise over technology that we own. For example, if Genentech fails to maintain the intellectual property licensed to us, we may lose our rights to develop and market Actimmune and may be forced to incur substantial additional costs to maintain or protect the intellectual property or to compel Genentech to do so.

If our employees, consultants and vendors do not comply with their confidentiality agreements or our trade secrets otherwise become known, our ability to generate revenue and profits may be impaired.

We rely on trade secrets to protect technology where it is possible that patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements generally provide that all confidential information developed or made known to an individual or company during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees and consultants, our agreements generally provide that all inventions made by the individual while engaged by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors. If our trade secrets become known, we may lose a competitive advantage and our ability to generate revenue may therefore be impaired.

By working with corporate partners, research collaborators and scientific advisors, we are subject to disputes over intellectual property, and our ability to obtain patent protection or protect proprietary information may be impaired.

Under some of our research and development agreements, inventions discovered in certain cases become jointly owned by our corporate partner and us and in other cases become the exclusive property of one of us. It can be difficult to determine who owns a particular invention, and disputes could arise regarding those inventions. These disputes could be costly and could divert management's attention from our business. Our research collaborators and scientific advisors have some rights to publish our data and proprietary information in which we have rights. Such publications may impair our ability to obtain patent protection or protect our proprietary information, which could impair our ability to generate revenues.

Risks Related to Our Financial Results and Other Risks Related to Our Business

If physicians do not prescribe Actimmune or prescribe it less often for the treatment of IPF, our revenues will decline.

Physicians may choose not to prescribe Actimmune or provide fewer patient referrals for Actimmune for the treatment of IPF because:

- Actimmune is not approved by the FDA for the treatment of IPF, and we therefore are unable to market or promote Actimmune for the treatment of IPF;
- in our initial Phase III clinical trial, Actimmune failed to meet the primary and secondary endpoints;
- physicians prefer to enroll their patients in our Phase III clinical trial of Actimmune or another trial for the treatment of IPF;
- Actimmune does not have a compendium listing, often a criterion used by third-party payors to decide whether or not to reimburse off-label prescriptions;
- physicians' patients are unable to receive or lose reimbursement from a third-party reimbursement organization;
- physicians are not confident that Actimmune has a clinically significant treatment effect for IPF;
- a competitor's product shows a clinically significant treatment effect for IPF; or

- physicians believe that the article and editorial in the January 8, 2004 issue of the New England Journal of Medicine were negative concerning Actimmune as a treatment for IPF.

If physicians do not prescribe Actimmune for the treatment of IPF for the above reasons or any other reasons, our revenues will decline. In addition, the patient referral rate may decline. The patient referral rate reflects the number of new patients who are prescribed Actimmune and who call the call center that coordinates with all of our specialty distributors, although these patients may elect not to have those prescriptions filled. During fiscal year 2004, the patient referral rate that we observed was significantly lower than we expected, and our Actimmune revenues declined from $141.4 million at the end of the fiscal year ended December 31, 2003 to $125.0 million at the end of the fiscal year ended December 31, 2004. If this new lower rate of patient referrals continues or declines further, our Actimmune revenue and total revenue may decline further. We do not know if the lower referral rate was due to better physician screening of patients who are likely to pursue treatment with Actimmune before referring them to the call center or lower physician or patient interest. In addition, the patient referral rate may have been adversely affected by the initiation of our second Phase III clinical trial evaluating the efficacy and safety of Actimmune as a treatment for IPF, as physicians may have held some patients who would have been put on Actimmune therapy for screening and potential enrollment in this trial. The patient referral rate also may have been adversely affected by the publication of an article and a related editorial in the January 8, 2004 issue of the New England Journal of Medicine regarding the results of our initial Phase III trial of Actimmune for the treatment of IPF. The article concluded that "(i)n a well-defined population of patients with idiopathic pulmonary fibrosis, (Actimmune) did not affect progression-free survival, pulmonary function, or the quality of life. Owing to the size of and duration of the trial, a clinically significant survival benefit could not be ruled out." The related editorial that appeared in the January 8, 2004 New England Journal of Medicine, among other things, cast doubt on our study's indication of "increased survival among patients who were compliant with interferon gamma-1b treatment" by stating, "(i)t should be emphasized that survival data based on one year of observation in a disease with an unknown date of onset and a life expectancy of two to five years after diagnosis may be very misleading." The editorial concluded by stating, "(s)tudies of other promising agents ... are indicated, since interferon gamma-1b has not proved to be the answer."

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully execute our business plan.

We believe our existing cash, cash equivalents and available-for-sale securities, together with anticipated cash flows from our operations, will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the end of 2006. However, our current plans and assumptions may change, and our capital requirements may increase in future periods. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable to our stockholders or us. If additional funds are not available, we may be forced to delay or terminate clinical trials, curtail operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights or potential markets, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we will not be able to successfully execute our business plan.

If we continue to incur net losses for a period longer than we anticipate, we may be unable to continue our business.

We have lost money since inception, and our accumulated deficit was approximately $455.6 million at December 31, 2004. We expect to incur substantial additional net losses prior to achieving profitability, if ever. The extent of our future net losses and the timing of our profitability are highly uncertain, and we may never achieve profitable operations. We are planning to expand the number of diseases for which our

products may be marketed, and this expansion will require significant expenditures. To date, we have generated revenues primarily through the sale of Actimmune. However, Actimmune sales have decreased in recent periods. Actimmune revenues declined from $141.4 million for the fiscal year ended December 31, 2003 to $125.0 million for the fiscal year ended December 31, 2004, representing a decrease of approximately 12%. We have not generated operating profits to date from our products. If the time required for us to achieve profitability is longer than we anticipate, we may not be able to continue our business.

Failure to accurately forecast our revenues could result in additional charges for excess inventories or non-cancelable purchase obligations.

We base many of our operating decisions on anticipated revenue trends and competitive market conditions, which are difficult to predict. Based on projected revenue trends, we acquired inventories and entered into non-cancelable purchase obligations in order to meet anticipated increases in demand for our products. However, more recent projected revenue trends resulted in us recording charges of $4.7 million for the year ended December 31, 2004 for excess inventories and non-cancelable purchase obligations. If revenue levels experienced in future quarters are substantially below our expectations, especially those revenues from sales of Actimmune and/or Infergen, we could be required to record additional charges for excess inventories and/or non-cancelable purchase obligations. For additional information relating to difficulties we have experienced forecasting revenues, see the risk factor titled, "We may fail to meet our publicly announced revenue and/or expense projections and/or other financial guidance, which would cause our stock to decline in value" below.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

The testing, marketing and sale of medical products entail an inherent risk of product liability. If product liability costs exceed our liability insurance coverage, we may incur substantial liabilities. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. While we believe that our clinical trial and product liability insurance currently provides adequate protection to our business, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

Our use of hazardous materials, chemicals, viruses and radioactive compounds exposes us to potential liabilities.

Our research and development activities involve the controlled use and disposal of hazardous materials, chemicals, infectious disease agents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for significant damages or fines, which may not be covered by or may exceed our insurance coverage.

We face certain litigation risks that could harm our business.

We have had a federal securities class actions lawsuit filed against us alleging that we, our former chief executive and chief financial officers, made certain false and misleading statements in violation of the federal securities laws. In addition, a derivative action was filed in California state court against our directors, our former chief executive and chief financial officers, that is based on the same factual allegations as the purported federal securities class actions and alleges state law claims of breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. We and the other defendants filed a motion to dismiss the federal class action on April 2, 2004, which was

granted in part and denied in part. Plaintiffs filed a second amended complaint on August 23, 2004, and we filed a motion to dismiss the second amended complaint on October 7, 2004. The motion is scheduled to be heard in April 2005. In the state action, the court has sustained the two motions made by us and the other defendants to dismiss two successive complaints filed by the plaintiff. The plaintiff filed his third amended complaint on July 30, 2004. On November 23, 2004 judgment was entered dismissing the state court action with prejudice. On February 1, 2005 plaintiffs filed a notice of appeal. On March 8, 2005, defendants filed in the First District Court of Appeal a motion to dismiss the appeal on the ground that the notice of appeal was not filed timely, and the Court of Appeal therefore did not have jurisdiction. The results of complex legal proceedings, such as these, are difficult to predict. Moreover, the complaints filed against us do not specify the amount of damages that the plaintiffs seek, and we therefore are unable to estimate at this time the possible range of damages that might be incurred should these lawsuits be resolved against us. While we are unable to estimate the potential damages arising from such lawsuits at this time, certain of them assert types of claims that, if resolved against us, could give rise to substantial damages.

Thus, an unfavorable outcome or settlement of either of these stockholder lawsuits could have a material adverse effect on our financial position, liquidity or results of operations. Even if these lawsuits are not resolved against us, the uncertainty and expense associated with unresolved lawsuits could seriously harm our business, financial condition and reputation. Litigation is costly, time-consuming and disruptive to normal business operations. The continued costs of defending these lawsuits could be quite significant. While we maintain directors and officers liability insurance that we believe to be applicable to these claims, certain costs, such as those below a deductible amount, are not covered by our insurance policies, and our insurance carriers could refuse to cover some or all of these claims in whole or in part. The continued defense of these lawsuits also results in continued diversion of our management's time and attention away from business operations, which could harm our business.

On March 19, 2004, plaintiff Ms. Joan Gallagher filed an action against InterMune and other defendants in the United States District Court for the Eastern District of Pennsylvania. Ms. Gallagher alleges that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Ms. Gallagher alleges that she was wrongfully terminated from InterMune in violation of public policy due to her refusal to engage in the alleged off-label marketing. We and the other defendants dispute Ms. Gallagher's claims and are vigorously defending the lawsuit. The defendants filed a motion to dismiss the complaint on May 4, 2004. Ms. Gallagher filed a first amended complaint on May 28, 2004, and the defendants filed a motion to dismiss the first amended complaint on June 10, 2004 on the grounds that Ms. Gallagher has failed to state any claim upon which relief may be granted under Pennsylvania law. The motion is pending. We cannot predict whether the outcome of this litigation will have a material adverse effect on our business.

On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune, including information regarding the promotion and marketing of Actimmune. We are cooperating with the Department of Justice in this inquiry. We cannot predict whether the outcome of this inquiry will have a material adverse effect on our business.

Insurance coverage is increasingly difficult to obtain or maintain.

While we currently maintain clinical trial and product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and warehouse and transit insurance, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required

to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policies may impact our future ability to obtain or maintain insurance coverage at reasonable costs, if at all.

Budget or cash constraints may force us to delay our efforts to develop certain products in favor of developing others, which may prevent us from meeting our stated timetables and commercializing those products as quickly as possible.

Because we are an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, we may choose to delay our research and development efforts for a promising product candidate to allocate those resources to another program, which could cause us to fall behind our initial timetables for development. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all.

Failure to attract, retain and motivate skilled personnel and cultivate key academic collaborations will delay our product development programs and our business development efforts.

We had 326 employees as of December 31, 2004, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop relationships with leading academic scientists. Competition for personnel and academic collaborations is intense. We are highly dependent on our current management and key scientific and technical personnel, including Daniel G. Welch, our Chief Executive Officer and President, as well as the other principal members of our management. None of our employees, including members of our management team, has a long-term employment contract, and any of our employees can leave at any time. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. In addition, we may need to hire additional personnel and develop additional academic collaborations as we continue to expand our research and development activities.

In the last 12 months, we have experienced significant changes in our management team. In this regard, on August 17, 2004, we announced the resignation of Sharon Surrey-Barbari, Chief Financial Officer and Senior Vice President of Finance and Administration, the appointment of Bennet Weintraub as our Interim Chief Financial Officer, the appointment of Thomas Kassberg as Senior Vice President of Business Development and Corporate Strategy, the appointment of Robin Steele as our Senior Vice President, General Counsel and Corporate Secretary and the appointment of Howard Simon as our Senior Vice President of Human Resources and Associate General Counsel. On October 25, 2004, we announced the hiring of Norman L. Halleen as our new Chief Financial Officer and Senior Vice President of Finance and Administration. On November 4, 2004, we announced the appointment of Cynthia Y. Robinson, Ph.D. to the newly created position of Senior Vice President, Therapeutic Area Teams.

The recent turnover in our management team may make it more difficult to attract and retain key personnel. We do not know if we will be able to attract, retain or motivate personnel or cultivate academic collaborations. Our inability to hire, retain or motivate qualified personnel or cultivate academic collaborations would harm our business and hinder the planned expansion of our business.

If we do not continue to successfully implement our plan to improve our internal control over financial reporting and disclosure controls and procedures, investors and current and potential collaborative partners could lose confidence in our financial reporting, which could harm the market price of our common stock and our business.

In connection with management's assessment of our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) as of the end of the period covered by this annual report, we have determined that we have a material weakness in our financial statement close process, primarily related to the accurate presentation of disclosures in the notes to our financial statements in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. This material weakness in our financial statement close process arises from the lack of sufficient finance staff with proficiency to interpret such principles and rules and inadequate review and approval procedures. As a result of the material weakness noted above, our management has concluded that our internal control over financial reporting and disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were not effective as of the end of the period covered by this annual report.

While audit and other procedures can compensate for problems with internal control over financial reporting and disclosure controls and procedures, our ability to provide reliable financial and other information to investors depends upon the effectiveness of our internal control over financial reporting and disclosure controls and procedures. We have implemented and continue to implement remedial measures to improve our internal control over financial reporting and disclosure controls and procedures. However, if we are not successful in improving our internal control over financial reporting and disclosure controls and procedures, investors and current and potential collaborative partners could lose confidence in the reports we file with the SEC, which could harm the market price of our common stock and our business.

For more information, please refer to the discussion below under the heading "Item 9A. Controls and Procedures."

Risks Related to our Common Stock

We may fail to meet our publicly announced revenue and/or expense projections and/or other financial guidance, which would cause our stock to decline in value.

There are a number of reasons why we might fail to meet our revenue and/or expense projections and/or other financial guidance, including, but not limited to, the following:

- if only a subset of or no affected patients respond to therapy with any of our products or product candidates;
- the actual dose or efficacy of the product for a particular condition may be different than currently anticipated;
- negative publicity about the results of our clinical studies may reduce demand for our products and product candidates;
- the treatment regimen may be different in duration than currently anticipated;
- treatment may be sporadic;
- we may not be able to sell a product at the price we expect;
- we may not be able to accurately calculate the number of patients using the product;
- we may not be able to supply enough product to meet demand;

- there may be current and future competitive products that have greater acceptance in the market than our products do;
- we may decide to divest a product;
- our development activities may proceed faster than planned;
- we may decide to change our marketing and educational programs;
- clinical trial participation may reduce product sales; or
- physicians' prescriptions or patient referrals for Actimmune may decline.

If we fail to meet our revenue and/or expense projections and/or other financial guidance for any reason, our stock could decline in value. In this regard, as a result of changing market dynamics for Actimmune, on April 29, 2004 we removed our Actimmune and total revenue guidance for the year ending December 31, 2004 that was provided on January 29, 2004. Our stock price decreased by $3.30, or 18%, to $14.71 by the close of business on April 30, 2004, the day after we removed this guidance. The changes in market dynamics relate to new rates of patient referrals and average duration of therapy for Actimmune. During fiscal year 2004, the patient referral rate that we observed was significantly lower than we expected, and our Actimmune revenues declined from $141.4 million for the fiscal year ended December 31, 2003 to $125.0 million for the fiscal year ended December 31, 2004. However, we observed an increase in the average duration of therapy that was significantly greater than expected. For a description of factors that may have affected our patient referral rate during fiscal year 2004, please see the risk factor titled, "If physicians do not prescribe Actimmune or prescribe it less often for the treatment of IPF, our revenues will decline" above.

Our stock price may be volatile, and an investment in our stock could decline in value.

The trading price of our common stock has been and is likely to continue to be extremely volatile. During the twelve-month period ended December 31, 2004, the closing price of our common stock on the Nasdaq National Market ranged from $9.74 to $16.03. Our stock price could be subject to wide fluctuations in response to a variety of factors, including, but not limited to, the following:

- our failure to meet our publicly announced revenue and/or expense projections and/or other financial guidance;
- adverse results or delays in clinical trials;
- actual or anticipated variations in quarterly operating results;
- announcements of technological innovations;
- our failure to commercialize additional FDA approved products;
- our decision not to initiate a planned clinical trial;
- new products or services offered by us or our competitors;
- changes in financial estimates by securities analysts;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities; or
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ National Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance. Periods of volatility in the market price of a company's securities frequently results in securities class action and shareholder derivative litigation against that company. This type of litigation can result in substantial costs and a diversion of management's attention and resources, as discussed in more detail above. We have recently had several lawsuits filed against us, as discussed under the risk factor titled, "We face certain litigation risks that could harm our business."

If our officers, directors and certain stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their own best interests and not necessarily those of other stockholders.

At December 31, 2004, our directors, executive officers and greater than 5% stockholders and their affiliates beneficially owned approximately 46% of our issued and outstanding common stock. Accordingly, they collectively may have the ability to significantly influence the election of all of our directors and to significantly influence the outcome of corporate actions requiring stockholder approval, such as mergers or a financing in which we sell more than 20% of our voting stock at a discount to market price. They may exercise this ability in a manner that advances their own best interests and not necessarily those of other stockholders. This concentration of ownership could also depress our stock price.

Substantial sales of shares may negatively impact the market price of our common stock.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or conversion of our outstanding convertible notes, including the notes offered under this prospectus, the market price of our common stock may decline. In addition, the existence of our outstanding convertible notes may encourage short selling by market participants. These sales also might make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the then-prevailing market price of our common stock.

We have filed registration statements covering the approximately 9,340,737 shares of common stock that are either issuable upon the exercise of outstanding options or reserved for future issuance pursuant to our stock plans as of December 31, 2004. We have also filed a shelf registration statement covering the resale of our 0.25% convertible senior notes due in 2011 and the 7,858,811 shares of common stock issuable upon conversion of those notes. In addition, some of the holders of common stock that are parties to our amended and restated investor rights agreement are entitled to registration rights with respect to approximately 6,500,000 shares of our common stock as of December 31, 2004.

On October 29, 2004 we entered into an Amended and Restated Standstill Agreement with Warburg Pincus Equity Partners, L.P. and certain of its affiliates ("Warburg Pincus") that permits Warburg Pincus to acquire up to 25% of our outstanding common stock in the open market. Under this agreement, Warburg Pincus may acquire up to 25% of our outstanding common stock and have granted Warburg Pincus certain registration rights with respect to its holdings. In exchange for allowing Warburg Pincus to increase its ownership stake, Warburg Pincus has granted the independent members of our board of directors the right to vote the shares of InterMune common stock owned by Warburg Pincus in excess of 19.9%. In addition, Warburg Pincus has agreed to certain limitations on the manner in which it may dispose of its ownership interest in InterMune. In connection with this transaction, we have also amended our stockholder Rights Plan to allow Warburg Pincus to acquire up to 25% of our outstanding common stock. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P.

We have implemented anti-takeover provisions, which could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to our stockholders, or frustrate or prevent any attempts by our stockholders to replace or remove our current management or Board of Directors.

The existence of our stockholder Rights Plan and provisions of our Amended and Restated Certificate of Incorporation and Bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions:

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third party from acquiring us.

Risks Related to our Outstanding Notes

Our indebtedness and debt service obligations may adversely affect our cash flow.

As of December 31, 2004, our annual debt service obligation on the $170.0 million in aggregate principal amount of our 0.25% convertible senior notes due March 1, 2011 is $0.4 million. We intend to fulfill our current debt service obligations, including repayment of the principal, both from cash generated by our operations and from our existing cash and investments. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our current debt service obligations, including repayment of the principal, we may have to delay or curtail research and development programs.

We may add additional lease lines to finance capital expenditures and may obtain additional long-term debt and lines of credit. If we issue other debt securities in the future, our debt service obligations will increase further.

Our indebtedness could have significant additional negative consequences, including, but not limited to:

- requiring the dedication of a substantial portion of our expected cash flow from operations to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes, including capital expenditures;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

We may not have the ability to raise the funds necessary to finance any required redemptions of our outstanding convertible notes, which might constitute a default by us.

If a designated event, such as the termination of trading of our common stock on the Nasdaq National Market or a specified change of control transaction, occurs prior to maturity, we may be required to redeem all or part of our 0.25% convertible senior notes due 2011. We may not have enough funds to pay the redemption price for all tendered notes. Although the indenture governing the 0.25% convertible senior notes due 2011 allows us in certain circumstances to pay the applicable redemption prices in shares of our common stock, if a designated event were to occur, we may not have sufficient funds to pay the redemption prices for all the notes tendered.

We have not established a sinking fund for payment of our outstanding notes, nor do we anticipate doing so. In addition, any future credit agreements or other agreements relating to our indebtedness may contain provisions prohibiting redemption of our outstanding notes under certain circumstances, or expressly prohibit our redemption of our outstanding notes upon a designated event or may provide that a designated event constitutes an event of default under that agreement. If a designated event occurs at a time when we are prohibited from purchasing or redeeming our outstanding notes, we could seek the consent of our lenders to redeem our outstanding notes or attempt to refinance this debt. If we do not obtain consent, we would not be permitted to purchase or redeem our outstanding notes. Our failure to redeem tendered notes would constitute an event of default under the indenture for the notes, which might constitute a default under the terms of our other indebtedness.

Executive Officers of the Registrant

The following table provides information regarding our executive officers and key employees as of March 1, 2005:

Name	Age	Title
Daniel G. Welch	47	Chief Executive Officer and President
Marianne Armstrong, Ph.D.	50	Senior Vice President, Regulatory/Medical Affairs and Drug Safety
Lawrence Blatt, Ph.D.	43	Senior Vice President of Preclinical and Applied Research
Williamson Bradford, M.D., Ph.D.	43	Vice President, Clinical Science
Norman L. Halleen	51	Chief Financial Officer, Senior Vice President of Finance and Administration
Roger L. Hawley	52	Executive Vice President of Commercial and Technical Operations
Thomas Kassberg	44	Senior Vice President, Business Development
Steven Porter, M.D., Ph.D.	48	Senior Vice President, Clinical Affairs
Cynthia Y. Robinson Ph.D.	46	Senior Vice President, Therapeutic Area Teams
Howard A. Simon, Esq.	46	Senior Vice President, Human Resources & Associate General Counsel
Robin Steele, Esq.	49	Senior Vice President of Legal Affairs, General Counsel and Secretary

Daniel G. Welch. Mr. Welch has served as our Chief Executive Officer and President and a member of our board of directors since September 2003. From March 2003 to September 2003, Mr. Welch served as a consultant to Warburg Pincus LLC, a global equity investor. From August 2002 to January 2003, Mr. Welch served as chairman and chief executive officer of Triangle Pharmaceuticals, Inc., a pharmaceutical company. From October 2000 to June 2002, Mr. Welch served as president of the pharmaceutical division of Elan Corporation, PLC., a pharmaceutical company. From September 1987 to August 2000, Mr. Welch served in various senior management roles at Sanofi-Synthelabo and its predecessor companies Sanofi and Sterling Winthrop, including vice president of worldwide marketing. From November 1980 to September 1987, Mr. Welch was with American Critical Care, a division of American Hospital Supply. Mr. Welch holds a B.S. from the University of Miami and an MBA from the University of North Carolina.

Marianne Armstrong, Ph.D. Dr. Armstrong has served as our Senior Vice President, Regulatory/Medical Affairs and Drug Safety since January 2004. From April 2002 to January 2004, Dr. Armstrong served as our Senior Vice President of Global Regulatory Operations and Corporate Compliance. From December 1999 to April 2002, Dr. Armstrong served as senior director of clinical development/regulatory affairs at Genentech, Inc, a pharmaceutical company. From July 1998 to November 1999, Dr. Armstrong served as senior director of clinical development at PathoGenesis Corporation, a pharmaceutical company. From May 1995 to July 1998, Dr. Armstrong served as department head of clinical affairs for Amgen Inc., a pharmaceutical company. From January 1981 to April 1995, Dr. Armstrong held management positions in clinical development at Alcon Laboratories, Solvay Pharmaceuticals and Parke-Davis/Warner Lambert, each a pharmaceutical company, and was a regional sales representative at American McGaw, a division of American Hospital Supply. Dr. Armstrong holds a Ph.D. and M.S. from Florida State University.

Lawrence Blatt, Ph.D. Dr. Blatt has served as our Senior Vice President of Preclinical and Applied Research since January 2004. From May 2002 to January 2004, Dr. Blatt served as our Vice President of Biopharmacology Research. From January 1998 to May 2002, Dr. Blatt served as vice president, research, at Ribozyme Pharmaceuticals., a pharmaceutical company. From August 1996 to January 1998, Dr. Blatt served as vice president, product development, at National Genetics Institute. From May 1984 to August 1996, Dr. Blatt was employed at Amgen Inc., a pharmaceutical company, most recently as product development team leader, interferons. Dr. Blatt holds a Ph.D. in Public Health Administration from the University of La Verne.

Williamson Bradford, M.D, Ph.D. Dr. Bradford has served as our Vice President of Clinical Science since January 2004. From July 2001 to January 2004, Dr. Bradford held several positions including most recently Vice President, Clinical Research, responsible for our pulmonary development efforts. From 1999-2001, Dr. Bradford served as Director, Clinical Science at IntraBiotics Pharmaceuticals, Inc., a pharmaceutical company. and from 1998-1999, Dr. Bradford served as Clinical Scientist at Genentech, Inc., a pharmaceutical company. Prior to 1998, Dr. Bradford held various academic and clinical positions including Assistant Professor of Medicine at the University of California, San Francisco (UCSF). Dr. Bradford holds an M.D. from the University of North Carolina at Chapel Hill, School of Medicine, a Ph.D. from the University of California, Berkeley, School of Public Health, and trained in internal medicine and infectious diseases at UCSF. He is board-certified in infectious diseases and serves as an Assistant Clinical Professor of Medicine in the Division of Infectious Diseases at UCSF.

Norman L. Halleen. Norman L. Halleen has served as our Senior Vice President, Finance and Chief Financial Officer since October 2004. Prior to joining InterMune, Mr. Halleen served as Vice President, Finance and Chief Financial Officer of Syrrx, Inc., a privately held drug discovery company, from April 2001 to June 2003. Prior to Syrrx, Mr. Halleen was Vice President, Finance and Chief Financial Officer at Aradigm Corporation, a publicly traded drug delivery company, from January 2000 to April 2001, and previously held the same positions at Collagen Corporation, a publicly traded biomaterials and medical device company, from January 1997 to October 1999. Mr. Halleen has also worked in various

financial consulting and executive positions in Hong Kong and the United States including a ten-year tenure with Syntex Corporation. Mr. Halleen holds a A.B. from Stanford University and an M.B.A. from the Harvard Graduate School of Business.

Roger L. Hawley. Mr. Hawley has served as our Executive Vice President of Commercial Operations since July 2003. From October 2002 to July 2003, Mr. Hawley served as chief commercial officer at Prometheus Laboratories, Inc. From February 2001 to August 2002, Mr. Hawley served as vice president/general manager, sales and marketing at Elan Pharmaceuticals, Inc., a pharmaceutical company. From August 1987 to February 2001, Mr. Hawley held various management positions in corporate finance, sales and marketing and regional sales at GlaxoSmithKline, Inc., a pharmaceutical company. His most recent position at GlaxoSmithKline was Vice President, sales-CNS/GI division. Mr. Hawley holds a B.S. in accounting from Eastern Illinois University.

Thomas Kassberg. Mr. Kassberg has served as our Senior Vice President, Business Development since August 2004. From December 2000 to July 2004, Mr. Kassberg served as founder and Vice President of Business and Corporate Development of Plexxikon, Inc. From 1996 to 1999, Mr. Kassberg worked as Senior Director, Business Development at SUGEN, Inc., and later as Senior Director, Corporate Licensing for Pharmacia, Inc. following the acquisition of SUGEN by Pharmacia in August 1999 until December 2000. Mr. Kassberg began his career at Bristol-Meyers-Squibb Company, a pharmaceutical company, where he served in various commercial functions, including strategic planning, financial analysis, business development and managed care sales. Mr. Kassberg holds a Masters in Management degree from Northwestern University.

Steven Porter, M.D., Ph.D. Dr. Porter has served as our Senior Vice President of Clinical Affairs since January 2004. From July 2001 to January 2004, Dr. Porter served as our Vice President of Clinical Research. From 1999 to June 2001, Dr. Porter was employed at IntraBiotics Pharmaceuticals, Inc., a pharmaceutical company, most recently as Senior Director, Clinical Science and Clinical Affairs. From 1997 to 1999, Dr. Porter served as Senior Director, Clinical Affairs at Shaman Pharmaceuticals, Inc., a pharmaceutical company and from 1996 to 1997, Dr. Porter served as Associate Director, Clinical Research at Bayer Corporation. Dr. Porter received his M.D., and Ph.D. from Vanderbilt University School of Medicine. He completed his residency in internal medicine at the University of California, San Francisco and his fellowship in infectious diseases at the University of California, San Francisco and Stanford University. He is currently an Assistant Clinical Professor of Medicine in the Division of Infectious Diseases at the University of California, San Francisco.

Cynthia Y. Robinson, Ph.D. Dr. Robinson has served as our Senior Vice President, Therapeutic Area Teams since November 2004. From 1996 to 2004, Dr. Robinson held various positions at Elan Pharmaceuticals, Inc., a pharmaceutical company, serving most recently as Vice President, Project Management. From 1989 to 1996, Dr. Robinson was a scientist with Athena Neurosciences, Inc., a pharmaceutical company. From 1980 to 1982, Dr. Robinson was a Product Control Chemist with Texaco, Inc. Dr. Robinson holds a B.S. in Chemistry from the University of Alabama, Tuscaloosa, and a Ph.D. in Organic Chemistry from the University of Alabama, Birmingham.

Howard A. Simon, Esq. Mr. Simon has served as our Senior Vice President, Human Resources & Associate General Counsel since April 2004. Mr. Simon joined us from ABD Insurance and Financial Services, a financial services firm, where he was Senior Vice President, Human Resources & Associate Counsel from June 2003 to March 2004. Prior to ABD, Mr. Simon was the principal in HR & Employment Law Solutions, a consulting firm specializing in the biotechnology industry from February 2002 to June 2003. He served as Vice President, Human Resources at Maxygen, Inc. from 1999 to 2001. He holds an undergraduate degree from UC Berkeley, a law degree from the Boalt Hall School of Law (UC Berkeley), and a Master's Degree from the Graduate Theological Union of Berkeley. Mr. Simon also is a certificated Senior Human Resources Professional.

Robin Steele, Esq. Ms. Steele has served as our Senior Vice President, General Counsel and Corporate Secretary since late May 2004. From 1998 to April 2003, Ms. Steele worked with Elan Pharmaceuticals, Inc., a global pharmaceutical company headquartered in Dublin, Ireland, most recently as Vice President, Commercial and Legal Affairs in San Diego. Prior to joining Elan, Ms. Steele was in private practice and served as outside counsel to a variety of life science and technology based companies in the Bay Area. Ms. Steele holds a B.A. in Biology from University of Colorado, Boulder, a J.D. from Hastings College of the Law, University of California, San Francisco, and a L.L.M. in Taxation from New York University School of Law.

ITEM 2. PROPERTIES

Our facilities currently consist of approximately 55,898 square feet of office space located at our headquarters location at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this building. On January 13, 2005, we entered into an operating lease agreement to sublease an additional 12,988 square feet of office space which consists of 11,444 square feet of usable area and 1,544 square feet of common area located at the second floor of 3240 Bayshore Boulevard, Brisbane, CA 94005. We believe that our facilities are adequate for our current needs, and that suitable additional or substitute space will be available in the future to replace our existing facility, if necessary, or accommodate expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

On June 25, 2003, a purported securities class action entitled Johnson v. Harkonen and InterMune, Inc., No. C 03-2954-MEJ, was filed in the United States District Court for the Northern District of California. Three additional class action complaints entitled Lombardi v. InterMune, Inc., Harkonen and Surrey-Barbari, No. C 03 3068 MJJ (filed on July 1, 2003); Mahoney Jr. v. InterMune Inc., Harkonen and Surrey-Barbari, No. C 03-3273 SI (filed on July 14, 2003); and Adler v. Harkonen and InterMune Inc., No. C 03-3710 MJJ (filed on August 3, 2003), were filed in the same court, each making identical or similar allegations against us, our former chief executive officer and former chief financial officer. On November 6, 2003, the various complaints were consolidated into one case by order of the court, and on November 26, 2003, a lead plaintiff, Lance A. Johnson, was appointed. A consolidated complaint titled In re InterMune Securities Litigation, No. C 03-2954 SI, was filed on January 30, 2004. The consolidated amended complaint named us, and our former chief executive officer and our former chief financial officer, as defendants and alleges that the defendants made certain false and misleading statements in violation of the federal securities laws, specifically Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. The lead plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 7, 2003 through June 11, 2003. We and the other defendants filed a motion to dismiss the complaint on April 2, 2004, which was granted in part and denied in part. Plaintiffs filed a second amended complaint on August 23, 2004, and the defendant filed in a motion to dismiss the second amended complaint on October 7, 2004. The motion is scheduled to be heard in April 2005. We believe that we have meritorious defenses to the allegations contained in the securities class action complaint and intend to defend ourselves vigorously. No trial date has been scheduled.

On July 30, 2003, a stockholder, Michael Adler, purporting to act on our behalf filed a derivative action entitled Adler v. Harkonen, et al., No. CIV 433125, in the California Superior Court for the County of San Mateo against our directors, our former chief executive officer and our former chief financial officer. We were also named as a nominal defendant solely in a derivative capacity. The derivative action is based on the same factual allegations and circumstances as the purported securities class actions and alleges state law claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. The derivative action seeks unspecified damages, injunctive relief and restitution. The court has sustained the two motions made by us and the other defendants on

December 8, 2003 and April 29, 2004 to dismiss two successive complaints filed by the plaintiff on November 3, 2003 and March 25, 2004, respectively. The plaintiff filed his third amended complaint on July 30, 2004 and the defendants filed a motion to dismiss the third amended complaint on September 16, 2004. On November 23, 2004 judgment was entered dismissing the action with prejudice. On February 1, 2005 plaintiffs filed a notice of appeal. On March 8, 2005, defendants filed in the First District Court of Appeal a motion to dismiss the appeal on the ground that the notice of appeal was not filed timely, and the Court of Appeal therefore did not have jurisdiction. No trial date has been set. We believe that we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously.

On March 19, 2004, plaintiff Joan Gallagher filed an action against us and other defendants in the United States District Court for the Eastern District of Pennsylvania. Ms. Gallagher alleges that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Ms. Gallagher alleges that she was wrongfully terminated from InterMune in violation of public policy due to her refusal to engage in the alleged off-label marketing. We and the other defendants dispute Ms. Gallagher's claims and are vigorously defending the lawsuit. The defendants filed a motion to dismiss the complaint on May 4, 2004. Ms. Gallagher filed a first amended complaint on May 28, 2004, and the defendants filed a motion to dismiss the first amended complaint on June 10, 2004 on the grounds that Ms. Gallagher has failed to state any claim upon which relief may be granted under Pennsylvania law. The motion is pending. We believe that we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously.

On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune, including information regarding the promotion and marketing of Actimmune. We are cooperating with the Department of Justice in this inquiry. We cannot predict whether the outcome of this inquiry will have a material adverse effect on our business.

We believe that we have good defenses to the claims asserted in the securities class actions, the derivate action and the wrongful termination suit. These lawsuits may be costly and could prove to be time consuming and disruptive to normal business operations. There can be no assurance that we will prevail or that the cost of defending these lawsuits will be covered by our insurance policies. While it is not possible to predict accurately or to determine the eventual outcome of this litigation, an unfavorable outcome or settlement of this litigation could have a material adverse effect on our financial position, liquidity or results of operations.

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

Not applicable.

PART II

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

Since the initial public offering of our common stock, $0.001 par value, on March 24, 2000, our common stock has traded on the NASDAQ National Market under the symbol "ITMN."

The following table sets forth the high and low closing sales prices of our common stock, as reported on the NASDAQ National Market for the fiscal periods indicated:

Fiscal Year:	High	Low
2004		
First Quarter	$24.55	$17.76
Second Quarter	20.61	13.66
Third Quarter	14.61	9.74
Fourth Quarter	13.59	10.77
2003		
First Quarter	$27.62	$17.00
Second Quarter	27.26	14.99
Third Quarter	21.69	15.81
Fourth Quarter	24.05	17.94

As of March 1, 2005, we had 121 stockholders of record.

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance our operations and do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data that appears below and on the following page has been derived from our audited consolidated financial statements. This historical data should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements contained in this Report, and with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this Report. The selected consolidated statement of operations data for each of the three years ended December 31, 2004, 2003 and 2002, respectively, and the selected consolidated balance sheet data as of December 31, 2004 and 2003, respectively, are derived from and qualified by reference to the audited consolidated financial statements included elsewhere in this Report. The selected consolidated statement of operations data for the years ended December 31, 2001

and 2000, respectively, and the selected consolidated balance sheet data as of December 31, 2002, 2001 and 2000, respectively, are derived from audited financial statements not included in this Report.

	Years ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share data)				
Revenue, net:					
Actimmune	$ 124,980	$ 141,402	$ 105,802	$ 36,320	$ 11,201
Infergen	22,307	9,276	2,931	768	—
Other	3,700	3,460	3,232	2,863	—
Total revenue, net	150,987	154,138	111,965	39,951	11,201
Costs and expenses:					
Cost of goods sold	40,862	36,309	24,161	15,474	4,990
Amortization and impairment of acquired product rights(1)	3,103	8,358	3,593	4,805	1,777
Research and development	81,319	119,858	129,590	52,049	20,821
Selling, general and administrative	76,155	68,451	62,752	35,895	16,152
Acquired research and development and milestone payments(2)	—	12,150	33,750	56,400	—
Total costs and expenses	201,439	245,126	253,846	164,623	43,740
Loss from operations	(50,452)	(90,988)	(141,881)	(124,672)	(32,539)
Interest income	3,490	4,024	7,375	11,253	8,484
Interest and other expense	(12,516)	(10,037)	(9,803)	(4,772)	(191)
Net loss	(59,478)	(97,001)	(144,309)	(118,191)	(24,246)
Preferred stock accretion	—	—	—	—	(269)
Redeemable preferred stock dividend(3)	—	—	—	—	(27,762)
Net loss applicable to common stockholders	$ (59,478)	$ (97,001)	$(144,309)	$(118,191)	$(52,277)
Basic and diluted net loss per share	$ (1.87)	$ (3.06)	$ (4.72)	$ (4.67)	$ (3.05)
Shares used in computing basic and diluted net loss per share	31,760	31,665	30,589	25,322	17,114

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and available-for-sale securities	$ 183,025	$ 216,107	$ 316,411	$ 332,067	$194,520
Working capital	169,884	201,855	285,633	320,345	194,706
Total assets	266,011	288,501	384,881	387,246	201,649
Long-term obligations	170,000	149,500	149,500	149,500	—
Accumulated deficit	(455,646)	(396,168)	(299,167)	(154,858)	(36,667)
Total stockholders' equity	32,791	87,744	182,718	215,059	195,801

(1) The 2003 amortization and impairment of acquired product rights also included a charge of $4.8 million for the impairment of Amphotec product rights recognized during 2003.

(2) These charges represent acquired research and development and milestone payments for projects that were in development, had not reached technical feasibility and had no foreseeable alternative future uses at the time of acquisition or when the milestone became payable. Please see "Results of Operations" and Note 3 of our Financial Statements.

(3) We recorded a deemed dividend of $27.8 million in January 2000, upon the issuance of 4,966,361 shares of Series B redeemable convertible preferred stock. At the dates of issuance, we believed the per share price of $5.59 represented the fair value of the preferred stock and was in excess of the deemed fair value of our common stock. Subsequent to the commencement of our initial public offering process, we re-evaluated the deemed fair value of our common stock and determined it to be $12.60 to $14.40 per share. Accordingly, the aggregate proceeds of $27.8 million were deemed to be the equivalent of a preferred stock dividend.

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

Overview

For additional overview information relating to our business, including our marketed products, co-promotion and product development, please see the discussion in "Item 1. Business—Overview," which is incorporated herein by reference.

Significant License/Acquisition Agreements

We are highly dependent on technology we license or acquire from third parties. All of our currently marketed products are subject to license or acquisition agreements with third parties. The majority of our clinical development pipeline is also based on technology that we have licensed from third parties. Details of these agreements can be found elsewhere in this Report under the headings "License and Other Agreements," "Results of Operations" and Notes 3 and 4 to our Financial Statements.

We will be required to make contingent milestone payments in accordance with all our license and acquisition agreements in the aggregate amount of $225.6 million if all of the milestones defined in each of the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe are reasonable. These estimates are the basis for our judgments about the carrying values of assets and liabilities, which in turn may impact our reported revenue and expenses. We have discussed the development, selection and disclosure of these estimates with the Audit Committee of our board of directors. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimate that are reasonably likely to occur periodically, could materially change the financial statements. We believe that the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition and revenue reserves

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed, and final delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We sell to a limited number of customers, mainly specialty pharmacies and distributors. We

obtain written purchase authorizations from our customers for a specified amount of product at a specified price. Revenue is recognized at delivery when title passes to a credit-worthy customer and reserves are recorded for estimated returns, rebates, chargebacks and cash discounts. We are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date. We have demonstrated the ability to make reasonable and reliable estimates of product returns based on historical experience. Due to the nature of our business model and based on historical experience, these estimates are not highly subjective. We review all sales transactions for potential rebates, chargebacks and discounts each month and monitor product ordering cycles and actual returns, product expiration dates and wholesale inventory levels to estimate potential product return rates. We believe that our reserves are adequate.

Accounting for intangible assets

Our intangible assets are comprised principally of acquired technology rights. We apply judgments to determine the useful lives of our intangible assets and whether such assets are impaired. Factors we consider include the life of the underlying patent, the expected period of benefit from the use of the technology, the existence of competing technology and potential obsolescence.

We review intangible assets with finite lives whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable in accordance with SFAS No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets."* Our asset impairment review assesses the fair value of the assets based on the future cash flow we expect the assets to generate. The assumptions we use in determining cash flows attributable to our intangible assets over their respective estimated useful lives are consistent with the plans and estimates we use to manage our underlying business. In making these estimates, we are required to make judgments as to the future revenue and expenses generated by the asset. The assumptions and estimates we use when determining the fair value of long-lived assets are highly subjective due to the forward-looking nature of these estimates. In some cases we are required to estimate cash flows related to a particular long-lived asset for up to 10 years. Please refer to the statements under the heading "Risk Factors" in this Report to gain a better understanding of the possible reasons why actual results could differ from our estimates.

We recognize an impairment loss when the estimated undiscounted future cash flow we expect to result from the use of the asset plus net proceeds we expect from the disposition of the asset (if any) are less than the carrying value of the asset. When we identify an impairment, we reduce the carrying amount of the asset to its estimated fair value based on a discounted cash flow approach or, when available and appropriate, comparable market values.

Clinical trial accruals

We accrue costs for clinical trial activities performed by contract research organizations based upon the estimated amount of work completed on each study. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with contract research organizations and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate activity levels associated with various studies at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual activity level becomes known. All such costs are charged to research and development expenses as incurred. To date, we have not experienced changes in estimates that have led to material research and development expense being recorded in future periods.

Non-cancelable purchase obligations for inventory

Our inventories are stated at the lower of cost or market value and our inventory costs are determined by the first-in first-out method. We enter into non-cancelable purchase obligations to purchase our inventory based upon sales forecasts to enable us to mitigate some of the risk associated with the long lead

times required to manufacture our products. At December 31, 2004, our minimum purchase obligations totaled $209.0 million and are committed through the year 2012. Of these commitments, we have $47.1 and $32.3 million of outstanding fixed purchase order commitments that become due and payable in 2005 and 2006, respectively.

We write off the cost of inventory and reserve for future minimum purchase commitments that we consider to be in excess of forecasted future demand. We define excess inventory as inventory that will expire before it can be sold, based on future sales forecasts. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels. We are also required to make judgments as to the expiration dates of our products, since our products can no longer be used after their respective expiration dates. As part of our excess inventory assessment for all of our products, we also estimate the expiration dates of our products to be manufactured in the future.

Projected revenue trends resulted in us recording charges during 2004 for excess inventories and non-cancelable purchase obligations. If revenue levels experienced in future quarters are substantially below our expectations, especially those revenues from sales of Actimmune and/or Infergen, we could be required to record additional charges for excess inventories and/or non-cancelable purchase obligations. For the year ended December 31, 2004, we recorded a total of $4.7 million to cost of goods for excess inventory, which included a $2.9 million reserve of non-cancelable purchase obligations. Please refer to the statements under the heading "Risk Factors" in this Report to gain a better understanding of the possible reasons why actual results could differ from our estimates.

Results of Operations

Comparison of years ended December 31, 2004 and 2003

The following table presents our consolidated statement of operations for the year ended December 31, 2004, the change in dollars and the percentage change when compared to the year ended December 31, 2003.

	Year ended December 31, 2004	Change from 2003—Increase/(decrease) Amount	%
	(In thousands, except percentages)		
Revenue, net:			
Actimmune	$124,980	$(16,422)	(12)%
Infergen	22,307	13,032	141%
Other	3,700	239	7%
Total revenue, net	150,987	(3,151)	(2)%
Costs and expenses:			
Cost of goods sold (excludes amortization and impairment of acquired product rights)	40,862	4,553	13%
Amortization and impairment of acquired product rights	3,103	(5,255)	(63)%
Research and development	81,319	(38,539)	(32)%
Selling, general and administrative	76,155	7,704	11%
Acquired research and development and milestone payments	—	(12,150)	(100)%
Total costs and expenses	201,439	(43,687)	(18)%
Loss from operations	(50,452)	40,536	45%
Interest income	3,490	(534)	(13)%
Interest expense	(5,065)	4,561	47%
Other expense	(7,451)	(7,041)	(1,717)%
Net loss	$(59,478)	$ 37,523	39%

Revenue

For the year ended December 31, 2004, InterMune recorded total net revenue of $151.0 million, compared to $154.1 million for the same period in 2003, a decrease of 2%. Net sales of Actimmune for 2004 were $125.0 million, compared to $141.4 million for 2003, a decline of 12%. Net sales of Infergen were $22.3 million for the year ended 2004 compared to $9.3 million in the same period of 2003, an increase of 141%. For the years ended December 31, 2004 and 2003, Actimmune accounted for approximately 83% and 92%, respectively, of our total net revenue, and substantially all of these sales were derived from physicians' prescriptions for the off-label use of Actimmune in the treatment of IPF.

Actimmune sales declined during the year ended December 31, 2004 compared to the corresponding period in 2003 due to a decrease in the underlying demand for Actimmune. We believe that the rate of patient referrals by physicians and the average duration of therapy are among the key uncertainties that affect demand for Actimmune and our Actimmune revenue and total product revenue. The patient referral rate reflects the number of new patients who are prescribed Actimmune and who call the call center that coordinates with all of our specialty distributors, although these patients may elect not to have those prescriptions filled. We believe that the following factors are among those that may affect the patient referral rate for Actimmune: physician screening of patients who are likely to pursue treatment with Actimmune; physician or patient interest; the publication of the results of our initial Phase III IPF clinical trial, GIPF-001, in the New England Journal of Medicine and the negative editorial that accompanied the publication; and the extent to which physicians enroll their patients in our Phase III IPF clinical trial, GIPF-007, who would otherwise be put on Actimmune therapy. During the year ended December 31, 2004, the patient referral rate that we observed for Actimmune was significantly lower than for the same period in 2003; however, the average duration of therapy that we observed was greater than expected.

Infergen sales increased during the year ended December 31, 2004 compared to the corresponding period in 2003 due to marketing and sales programs initiated in 2004. Also, Infergen demand in terms of vials dispensed grew 124% in 2004 compared to 2003. We believe the difference between Infergen's annual revenue growth of 141% and the reported annual demand growth of 124% is the result of two factors: price increases during the year, which ranged from 6.5% to 14.2% on various package sizes, and the establishment of several new Infergen distribution agreements with specialty pharmacies. As is customary in the industry, inventory stocking follows new distribution agreements and we believe these agreements resulted in an additional two to three weeks of Infergen inventory worth $1.0 million to $2.0 million in 2004.

Cost of Goods Sold

Cost of goods sold included product manufacturing costs, royalties and distribution costs associated with our revenues and inventory reserves. Cost of goods sold for the year ended December 31, 2004 was $40.9 million, approximately 27% of total net revenue, compared to $36.3 million, or approximately 24% of total net revenue, in the corresponding period of 2003. The increase in cost of goods sold primarily reflects a charge of $4.7 million taken for obsolete inventory and contractual purchase commitments in excess of our present forecasts compared to $1.3 million in 2003 and a shift in the mix of product sales toward a higher proportion of Infergen revenue.

Exchange rate fluctuations on inventory purchases may adversely affect cost of goods sold on Actimmune Inventory purchased from BI Austria. We utilize forward exchange contracts to partially offset the effect of exchange rate fluctuations.

Amortization and Impairment of Acquired Product Rights

We recorded amortization and impairment of acquired product rights for the years ended December 31, 2004 and 2003 of $3.1 million and $8.4 million, respectively. The acquired product rights

related to the acquisition of Amphotec, Infergen and interferon gamma-1b patents. The decrease for the 2004 period versus the same period in 2003 was primarily due to a charge of $4.8 million taken in the third quarter of 2003 for the impairment of Amphotec product rights which reduced the remaining carrying value of the intangible asset being amortized.

Research and Development Expenses

Research and development expenses were $81.3 million and $119.9 million for the years ended December 31, 2004 and 2003, respectively, representing a decrease of $38.6 million or 32%. The decrease in 2004 was largely attributable to the focusing of our R&D investment for clinical trials in the areas of hepatology and pulmonology and discontinuing a number of programs outside of these two core areas, particularly anti-infectives.

The following table lists our current product development programs and the research and development expenses recognized in connection with each program during the indicated periods. The category titled "Programs—Non-specific" is comprised of facilities and personnel costs that are not allocated to a specific development program or discontinued programs. Our management reviews each of these program categories in evaluating our business. For a discussion of the risks and uncertainties associated with developing our products, as well as the risks and uncertainties associated with potential commercialization of our product candidates, see the "Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials," "We do not know whether our planned clinical trials will begin on time, or at all, or will be completed on schedule, or at all," "Preclinical development is a long, expensive and uncertain process, and we may terminate one or more of our current preclinical development programs," "If our clinical trials fail to demonstrate to the FDA and foreign regulatory authorities that any of our products or product candidates are safe and effective for the treatment of particular diseases, the FDA and foreign regulatory authorities may require us to conduct additional clinical trials or may not grant us marketing approval for such products or product candidates for those diseases," "The manufacturing and manufacturing development of our products and product candidates present technological, logistical and regulatory risks, each of which may adversely affect our potential revenues," "Our manufacturing strategy, which relies on third-party manufacturers, exposes us to additional risks as a result of which we may lose potential revenues" and "We rely on third parties to conduct clinical trials for our products and product candidates, and those third parties may not perform satisfactorily" sections, as well as other sections under "Business—Risk Factors" above.

Development Program	2004	2003	2002
		(in thousands)	
Pulmonology	$19,589	$ 12,552	$ 22,937
Hepatology	18,712	15,694	23,837
Oncology	18,307	17,859	12,672
Anti-infectives(1)	2,561	41,300	31,847
Programs—Non-specific	22,150	32,453	38,297
Total	**$81,319**	**$119,858**	**$129,590**

(1) Includes amounts related to oritavancin and Amphotec; a substantial majority of the expenses related to oritavancin.

The largest component of our total operating expenses is our ongoing investments in research and development and, in particular, the clinical development of our product pipeline. The process of conducting the clinical research necessary to obtain FDA approval is costly and time consuming. Current FDA requirements for a new human drug to be marketed in the United States include:

- the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety;

- the filing with the FDA of an IND to conduct human clinical trials for drugs;
- the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and
- the filing by a company and acceptance and approval by the FDA of an NDA or BLA for a drug product to allow commercial distribution of the drug.

In light of the factors mentioned above, we consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Due to these factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs.

Selling, general and administrative expenses

Selling general and administrative expenses were $76.2 million and $68.5 million for the years ended December 31, 2004 and 2003, respectively, representing an increase of $7.7 million. The increased spending for the year ended December 31, 2004 versus the same period in 2003 was primarily associated with the increased investment in the Infergen brand including the creation of a new Infergen sales force of 31 sales representatives in the fourth quarter of 2004 and increased compensation, recruiting and consulting expenses associated with our therapeutic refocus and rebuilding initiatives.

Acquired research and development and milestone payments

There were no charges for acquired research and development and milestone payments in the year ended December 31, 2004. We recorded charges of $12.2 million for acquired research and development and milestone payments for the year ended December 31, 2003. These charges related to milestone expenses recognized as a result of the commencement of a Phase I clinical trial for PEG-Alfacon-1 and the Lilly milestone for oritavancin. We expensed these amounts as acquired research and development and milestone payments as PEG-Alfacon-1 and oritavancin are currently in clinical development, have not reached technical feasibility and have no foreseeable alternative future uses.

Interest income

Interest income decreased to $3.5 million for the year ended December 31, 2004 as compared to $4.0 million for the comparable period ended December 31, 2003. The decrease in interest income in the year ended December 31, 2004 reflects declining investment funds in our cash and short-term investments throughout the year.

Interest expense

Interest expense decreased to $5.1 million compared to $10.0 million for the year ended December 31, 2004. The decrease in interest expense in the year ended December 31, 2004 reflects the repurchase of all of our $149.5 million 5.75% convertible subordinated notes due in mid-2006, and the impact of the lower interest rate on our $170 million 0.25% convertible senior notes.

Other expense

Other expense of $7.4 million for the year ended December 31, 2004 includes a charge of $5.0 million for the repurchase of all $149.5 million of our 5.75% convertible subordinated notes due in July 2006, and the accelerated amortization of $2.1 million of the deferred issuance costs associated with these notes.

Also, included in other expense for the year ended December 31, 2004 is a $0.3 million foreign currency exchange loss on our unhedged foreign currency payables for inventory and clinical material purchases from BI Austria at year-end.

Provision for income taxes

Due to our continuing operating losses and the uncertainty of our recognizing the potential future benefits from these losses, we recorded no provision or benefit for income taxes for the years ended December 31, 2004 and 2003. As of December 31, 2004, we had federal net operating loss carryforwards of approximately $338.3 million. The net operating loss carryforwards will expire at various dates beginning in 2019 through 2024 if not utilized. We also have federal research and development tax credits of approximately $5.2 million that will expire in the years 2018 through 2024. In addition, we had net operating loss carryforwards for state income tax purposes of approximately $120.2 million, that expire in the years 2005 through 2014, and state research and development tax credits of approximately $1.9 million that do not expire. Utilization of the net operating losses may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

Comparison of years ended December 31, 2003 and 2002

The following table presents our consolidated statement of operations for the year ended December 31, 2003, the change in dollars and the percentage change when compared to the year ended December 31, 2002.

	Year ended December 31, 2003	Change from 2002 Increase/(decrease) Amount	%
	(In thousands, except percentages)		
Revenue, net:			
Actimmune	$141,402	$ 35,600	34%
Infergen	9,276	6,345	216%
Other	3,460	228	7%
Total revenue, net	154,138	42,173	38%
Costs and expenses:			
Cost of goods sold (excludes amortization and impairment of acquired product rights)	36,309	12,148	50%
Amortization and impairment of acquired product rights.	8,358	4,765	153%
Research and development	119,858	(9,732)	(8)%
Selling, general and administrative	68,451	5,699	9%
Acquired research and development and milestone payments	12,150	(21,600)	(64)%
Total costs and expenses	245,126	(8,720)	(3)%
Loss from operations	(90,988)	50,893	36%
Interest income	4,024	(3,351)	(45)%
Interest expense	9,626	(41)	—%
Other expense	410	(193)	(89)%
Net loss	$ (97,001)	$ 47,308	33%

Revenue

Total product revenues were $154.1 million and $112.0 million for the years ended December 31, 2003 and 2002, respectively. The growth in product sales for the year ended December 31, 2003 was primarily due to a volume increase in sales of Actimmune of $35.6 million or 34%, and a volume increase in sales of Infergen of $6.3 million or 216%. Our revenues experienced fluctuations during the year due to market and physician acceptance and use of our products, influenced by published reports in medical journals, reimbursement policies of major insurance companies, revised treatment guidelines and the rate of patient enrollment in our INSPIRE trial for Actimmune.

Cost of Goods Sold

Cost of goods sold were $36.3 million and $24.2 million for the years ended December 31, 2003 and 2002, respectively. Cost of goods sold included manufacturing costs, royalties and distribution costs associated with our revenues. The increase in cost of goods sold in 2003 was due primarily to costs associated with increased product sales volumes.

The cost of goods sold, as a percentage of revenues, were 24% and 22% for the years ended December 31, 2003 and 2002, respectively. The increase in cost of goods sold as a percentage of revenue in 2003, when compared to 2002, was primarily due to reserves included in cost of goods sold for 2003 in the amount of $1.3 million for excess Infergen and Amphotec inventory and due to the mix of products sold during 2003.

Amortization and Impairment of Acquired Product Rights

We recorded amortization and impairment of acquired product rights of $8.4 million and $3.6 million for the years ended December 31, 2003 and 2002, respectively. The charges recorded in 2003 and 2002 were comprised of the amortization charges related to the acquisition of Amphotec and Infergen product rights and interferon gamma-1b patents. The 2003 charges also included a charge of $4.8 million for the impairment of Amphotec product rights recognized during 2003. The $4.8 million impairment charge reduced the remaining carrying value of the intangible asset that we recorded in 2001 when we acquired Amphotec. This impairment charge was based on our impairment review of the Amphotec product rights, which took into account that sales levels were lower than expected, and that Amphotec is not aligned with our new strategic focus in pulmonology and hepatology. Consequently, we decided to divest Amphotec and are currently in the early stages of a competitive process to identify a partner that has the ability to maximize the value of the asset.

Research and Development Expenses

Research and development expenses were $119.9 million and $129.6 million for the years ended December 31, 2003 and 2002, respectively, representing a decrease of $9.7 million or 8%. The decrease in 2003, when compared to 2002, was primarily due to lower spending in the areas of pulmonology and hepatology offset in part by increased spending in the areas of oncology and anti-infectives.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $68.5 million and $62.8 million for the years ended December 31, 2003 and 2002, respectively, representing an increase of $5.7 million or 9%. The increased spending in 2003 was primarily due to increased legal, insurance, compensation and recruiting expenses totaling $6.3 million offset in part by lower non-cash compensation charges.

Acquired Research and Development and Milestone Payments

We recorded charges for acquired research and development and milestone payments of $12.2 million and $33.8 million for the years ended December 31, 2003 and 2002, respectively.

In 2003, we recorded charges for acquired research and development and milestone payments of $10.4 million primarily due to a milestone-based liability under our agreement with Eli Lilly for the completion of the Phase III clinical trial of oritavancin for complicated skin and skin structure infections, and a $1.8 million charge related to milestone payments primarily due to our license and commercialization agreement with Amgen as a result of the commencement of a Phase I clinical trial for PEG-Alfacon-1. We expensed both of these charges as acquired research and development and milestone payments as oritavancin and PEG-Alfacon-1 were in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses as of December 31, 2003.

In 2002, we entered into license agreement for pirfenidone with Marnac and KDL. At the time of the product acquisition from Marnac and KDL, pirfenidone was in Phase II clinical development for certain fibrotic diseases of the lung, heart, kidney and liver. Under the terms of the agreement, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and future milestone and royalty payments. We expensed the $18.8 million as acquired research and development and milestone payments as pirfenidone was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses at the time of acquisition.

Also in 2002, we paid Eli Lilly $15.0 million due to its exercise of its option under our asset purchase and license agreement to reduce the agreed percentage of royalty payable by us to Eli Lilly for oritavancin product sales. We expensed the $15.0 million in 2002 as acquired research and development and milestone payments as oritavancin was in clinical development, had not reached technical feasibility and had no foreseeable alternative future use as of December 31, 2002. At December 31, 2002, the $15.0 million was recorded as an accrued liability and was paid in January 2003.

Interest Income

Interest income totaled $4.0 million and $7.4 million for the years ended December 31, 2003 and 2002, respectively. The decrease in interest income in 2003 was primarily due to declining investment yields on our cash and short-term investments resulting from substantially lower market interest rates and a lower average portfolio balance for during the period.

Interest and Other Expense

Interest expense totaled $10.0 million and $9.8 million for the years ended December 31, 2003 and 2002, respectively. Interest expense for each of 2003 and 2002 was primarily due to $8.6 million in interest expense incurred on $149.5 million aggregate principal amount of our 5.75% convertible subordinated notes which mature in July 2006 and $1.0 million in interest expense related to the amortization of the deferred debt issuance cost. As of December 31, 2003, we had $2.6 million of unamortized deferred issuance costs related to these convertible subordinated notes.

Provision for Income Taxes

Due to our continuing operating losses and the uncertainty of our recognizing the potential future benefits from these losses, we recorded no provision or benefit for income taxes for the years ended December 31, 2003 and 2002.

Liquidity and Capital Resources

At December 31, 2004, we had available cash, cash equivalents and available-for-sale securities of $183.0 million. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. federal and state governments and their agencies and high-quality corporate issuers, and, by policy, restrict our exposure by imposing concentration limits and credit worthiness requirements for all corporate issuers. In 2004, we completed the repurchase of $149.5 million of our outstanding 5.75% convertible subordinated notes due July 2006 and issued $170 million of 0.25% convertible senior notes due in March 2011. We paid a total of $157.6 million related to the repurchase, which included $3.2 million for accrued interest on the convertible subordinated notes and a premium of $5.0 million recognized as a loss on the early extinguishment of debt. We also expensed a non-cash charge of approximately $2.1 million for the acceleration of the amortization of the deferred issuance costs associated with the notes.

Operating activities used $43.1 million in cash during the year ended December 31, 2004, primarily due to the loss from operations of $59.5 million and an increase in inventories of $12.9 million. The use of funds was offset by an increase in accounts payable, accrued liabilities and accrued compensation of $11.7 million and a decrease in accounts receivable of $1.2 million. The increase in accounts payable and accrued liabilities was due to the timing of payments of accounts payable at December 31, 2004, including our 2004 inventory purchases from BI Austria. Details concerning the loss from operations can be found above in this report under the heading "Results of Operations."

Investing activities provided $44.8 million in cash during the year ended December 31, 2004, due in part to maturities and sales of short-term investments totaling $185.8 million, offset by $139.6 million of short-term investment purchases and purchases of property and equipment of $1.4 million. Cash provided by investing activities increased by $24.9 million for the 2004 period, compared to the same period in 2003, primarily due to a higher draw-down of the available for sale investment portfolio of $6.1 million, and $18.8 million paid in the 2003 period related to the purchase of acquired product rights, including research and development and milestone payments.

Cash provided by financing activities of $12.0 million for the year ended December 31, 2004 was primarily due to the receipt of net proceeds of $164.2 million related to the issuance of $170.0 million face value 0.25% convertible senior notes due March 2011. These proceeds were offset by the repurchase of $149.5 million in principal amount of our outstanding 5.75% convertible subordinated notes due July 2006. We paid a total of $157.6 million related to the repurchase, which included $3.2 million for accrued interest on the convertible subordinated notes and a premium of $5.0 million recognized as a loss on the early extinguishment of debt. We also expensed a non-cash charge of approximately $2.1 million for the acceleration of the amortization of the deferred issuance costs associated with the notes.

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We have no commercial commitments with related parties, except for ongoing payments in connection with the oritavancin acquisition from Eli Lilly to the SGO Group LLC, in which Nicholas Simon, a former member of our board of directors who resigned in February 2003, was a principal at the time of the acquisition. We paid an execution fee of $1.0 million to SGO Group LLC during 2001 and have accrued $0.4 million that is potentially due to the SGO Group. We have no loans with related parties, except for executive loans to Dr. Marianne Armstrong, our Senior Vice President of Regulatory/Medical Affairs and Drug Safety in the amount of $0.3 million, and Dr. Lawrence Blatt, our Senior Vice President of Preclinical and Applied Research, in the amount of $0.2 million. Both of these loans were in place prior to the enactment of the Sarbanes-Oxley Act in 2002.

We believe that we will continue to require substantial additional funding to complete the research and development activities currently contemplated and to commercialize our product candidates. We

believe our existing cash, cash equivalents and available-for-sale securities, together with anticipated cash flows from our operations, will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the end of 2006. However, this forward-looking statement is based upon the risks identified in this report; our current plans and assumptions, which may change; and our capital requirements, which may increase in future periods. Our future capital requirements will depend on many factors, including, but not limited to:

- the commercial performance of any of our products or product candidates in development that receive commercial approval;
- our ability to partner our development and commercialization programs;;
- the progress of our research and development efforts;
- the scope and results of preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory reviews;
- determinations as to the commercial potential of our product candidates in development;
- the pace of expansion of administrative expenses;
- the status of competitive products and competitive barriers to entry;
- the establishment and maintenance of manufacturing capacity through third-party manufacturing agreements;
- the pace of expansion of our sales and marketing capabilities, in preparation for product launches;
- the establishment of collaborative relationships with other companies;
- the ability to divest oritavancin and Amphotec;
- the payments of annual interest on our long-term debt; and
- whether we must repay the principal in connection with our convertible debt obligations.

As a result, we may require additional funds and may attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources. We have no commitments for such fund raising activities at this time. Additional funding may not be available to finance our operations when needed or, if available, the terms for obtaining such funds may not be favorable or may result in dilution to our stockholders.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities, such as milestone payments, for which we cannot reasonably predict future payments. The following chart represents our contractual obligations as of December 31, 2004, aggregated by type (in millions):

Contractual Obligations	Total	2005	2006-2007	2008-2009	After 2009
Long-term debt obligations(1)	$173.1	$ 0.4	$ 0.9	$ 0.9	$170.9
Operating leases	27.8	4.6	9.0	8.3	5.9
Non-cancelable purchase obligations—Inventory	209.0	47.1	52.3	41.9	67.7
Non-cancelable purchase obligations—Other(2)	8.8	8.8	—	—	—
Research and development funding commitments	2.6	1.0	1.6	—	—
Total contractual cash obligations	$421.3	$61.9	$63.8	$51.1	$244.5

(1) These amounts include interest payments and principal amount of the 0.25% convertible senior notes due 2011.

(2) These amounts consist of clinical and marketing related obligations.

The operating leases for our facilities require letters of credit secured by a restricted cash balance with our bank. The amount of each letter of credit approximates 6-12 months of operating rent payable to the landlord of each facility.

The majority of our non-cancelable purchase obligations for inventory are denominated in foreign currencies, principally the purchase of Actimmune inventory, which is denominated in Euros. We assumed an average foreign currency exchange rate of Euro to U.S. dollars of 1.32 over the length of the agreement.

Recent Accounting Pronouncements

In March 2004, the Financial Accounting Standards Board ("FASB") approved the consensus reached on the Emerging Issues Task Force ("EITF") Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The Issue's objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued a FASB Staff Position ("FSP") EITF 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF 03-1 until further notice. The disclosure requirements of EITF 03-1 are effective with this annual report for fiscal 2004. Once the FASB reaches a final decision on the measurement and recognition provisions, we will evaluate the impact of the adoption of the accounting provisions of EITF 03-1.

In December 2004, the FASB issued Statement No. 123 (revised 2004), "Share-Based Payment," effective beginning after June 15, 2005. FAS 123R supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plan. We will be required to implement FAS 123R no later than the third quarter that begins July 1, 2005. We are currently evaluating option valuation methodologies and assumptions in light of FAS 123R, and therefore cannot estimate the impact of our adoption at this time. These methodologies and assumptions may be different than those we currently employ in applying FAS 123, outlined in "Stock-Based Compensation" above. We expect that the adoption of FAS 123R will have an impact on our consolidated results of operations and financial position.

Material Weakness and Remediation

In connection with management's assessment of its internal control over financial reporting as of December 31, 2004, we have determined that we have a material weakness in our financial statement close process, related to the preparation and review of the annual consolidated financial statements and accompanying footnote disclosures in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. The insufficient controls include a lack of finance staff with the proficiency to interpret such principles and rules, and inadequate review and approval procedures to prepare external financial statements in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. As a result of this material weakness, management made material revisions to the 2004 annual consolidated financial statements, footnote disclosures before they were issued.

In 2004, we began an evaluation of our finance department staffing and as a result have terminated certain employees and hired additional personnel with technical accounting expertise to improve our financial statement close process. We intend to continue to improve our financial statement close process in 2005 including the remediation of the material weakness dicussed above by identifying, recruiting, and training personnel with the appropriate accounting and SEC reporting skills.

Please refer to Item 9A of this Annual Report on Form 10-K for management's assessment of internal control over financial reporting.

Our efforts to enhance our systems of internal control by adding additional qualified personnel and our continuing compliance with Sarbanes-Oxley Section 404 and the related audit of that assessment by our registered public accounting firm has required, and will continue to require, the commitment of significant financial and managerial resources. Our internal control systems are designed to provide reasonable assurance to management and our board of directors that our internal control over financial reporting is adequate, but there can be no guarantee that such controls will be effective.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market rates would have a significant negative impact on the value of our investment portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. federal and state governments and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates we maintain investments of shorter effective maturities.

The table below presents the principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as of December 31, 2004 by effective maturity (in millions, except percentages):

	2005	2006	2007	2008	2009 and beyond	Total	Fair value at December 31, 2004
Assets:							
Available-for-sale securities	$158.3	$9.9	$5.4	—	—	$173.6	$174.0
Average interest rate	2.0%	3.3%	4.6%	—	—	2.2%	—
Liabilities:							
0.25% convertible senior notes due 2011	—	—	—	—	$170.0	$170.0	$144.0
Average interest rate	—	—	—	—	0.25%	0.25%	—

The table below presents the principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as December 31, 2003 by effective maturity (in millions, except percentages):

	2004	2005	2006	2007	2008	Total	Fair value at December 31, 2003
Assets:							
Available-for-sale securities	$165.9	$36.1	$ 2.4	—	—	$204.4	$208.0
Average interest rate	1.6%	1.6%	2.1%	—	—	1.6%	—
Liabilities:							
5.75% convertible subordinated notes due 2006	—	—	$149.5	—	—	$149.5	$148.6
Average interest rate	—	—	5.75%	—	—	5.75%	—

Foreign Currency Market Risk

We have obligations denominated in Euros for the purchase of Actimmune inventory. In 2004, we used foreign currency forward contracts to partially mitigate this exposure. We regularly evaluate the cost-benefit of entering into such arrangements and presently have no foreign currency hedge agreements outstanding.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders
InterMune, Inc.

We have audited management's assessment, included in "Management's Report on Internal Control Over Financial Reporting" in Item 9A of this Form 10-K, that InterMune, Inc. (the "Company") did not maintain effective internal control over financial reporting as of December 31, 2004, because of the effect of the material weakness identified in management's assessment and described below, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). InterMune's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weakness has been identified and included in management's assessment. Management identified a material weakness for insufficient controls related to the preparation and review of the annual consolidated financial statements and accompanying footnote disclosures in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC"). The insufficient controls include a lack of finance staff with the proficiency to interpret such principles and rules, and inadequate review and approval procedures to prepare external financial statements in accordance with GAAP and rules and regulations of the SEC. As a result of this material weakness, management made material revisions to the 2004 annual consolidated financial statements and footnote disclosures before they were issued. This

material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 financial statements, and this report does not affect our report dated March 15, 2005 on those financial statements.

In our opinion, management's assessment that InterMune, Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, InterMune, Inc. has not maintained effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

San Jose, California
March 15, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENTS

The Board of Directors and Stockholders
InterMune, Inc.

We have audited the accompanying consolidated balance sheets of InterMune, Inc. (the "Company") as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of InterMune, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of InterMune's internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2005, expressed an unqualified opinion on management's assessment of internal control over financial reporting and an adverse opinion on the effectiveness of internal control over financial reporting.

/s/ ERNST & YOUNG LLP

San Jose, California
March 15, 2005

INTERMUNE, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,769	$ 42,071
Available-for-sale securities	127,256	174,036
Accounts receivable, net of allowance of $3,403 in 2004 and $2,977 in 2003	12,098	13,270
Inventories, net	32,990	20,062
Prepaid expenses and other current assets	3,478	2,417
Total current assets	231,591	251,856
Property and equipment, net	8,261	9,621
Acquired product rights, net	18,875	21,978
Restricted cash	1,675	1,675
Notes receivable from employees	470	698
Other assets	5,139	2,673
Total assets	$ 266,011	$ 288,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 29,448	$ 20,281
Accrued compensation	7,746	6,357
Other accrued liabilities	24,513	23,363
Total current liabilities	61,707	50,001
Deferred rent	1,513	1,256
Convertible notes	170,000	149,500
Commitments and contingencies (Notes 14 and 18)		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2004 and 2003, respectively	—	—
Common stock, $0.001 par value, 70,000,000 shares authorized; 32,583,226 and 31,845,011 shares issued and outstanding at December 31, 2004 and 2003, respectively	33	32
Additional paid-in capital	492,663	483,697
Deferred stock compensation	(5,845)	(217)
Accumulated other comprehensive income	1,586	400
Accumulated deficit	(455,646)	(396,168)
Total stockholders' equity	32,791	87,744
Total liabilities and stockholders' equity	$ 266,011	$ 288,501

See Accompanying Notes to Consolidated Financial Statements

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	For the year ended December 31,		
	2004	2003	2002
Revenue, net			
Actimmune	$124,980	$141,402	$ 105,802
Infergen	22,307	9,276	2,931
Others	3,700	3,460	3,232
Total revenue, net	150,987	154,138	111,965
Costs and expenses:			
Cost of goods sold	40,862	36,309	24,161
Amortization and impairment of acquired product rights	3,103	8,358	3,593
Research and development	81,319	119,858	129,590
Selling, general and administrative	76,155	68,451	62,752
Acquired research and development and milestone payments	—	12,150	33,750
Total costs and expenses	201,439	245,126	253,846
Loss from operations	(50,452)	(90,988)	(141,881)
Other income (expense):			
Interest income	3,490	4,024	7,375
Interest expense	(5,065)	(9,626)	(9,586)
Other expense	(7,451)	(411)	(217)
Net loss	$ (59,478)	$ (97,001)	$ (144,309)
Basic and diluted net loss per common share	$ (1.87)	$ (3.06)	$ (4.72)
Shares used in computing basic and diluted net loss per common share	31,760	31,665	30,589

See Accompanying Notes to Consolidated Financial Statements

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except per share data)

	Stockholders' Equity							
	Common stock		Additional paid-in capital	Notes receivable from stockholder	Deferred stock compensation	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount						
Balance at December 31, 2001	**28,451**	**$28**	**$373,310**	**$(56)**	**$(3,414)**	**$ 49**	**$ (154,858)**	**$ 215,059**
Net unrealized gain on available-for-sale securities	—	—	—	—	—	908	—	908
Net loss	—	—	—	—	—	—	(144,309)	(144,309)
Comprehensive net loss	—	—	—	—	—	—	—	(143,401)
Exercise of stock options	227	1	2,333	—	—	—	—	2,334
Stock issued under employee stock purchase plan	67	—	1,464	—	—	—	—	1,464
Issuance of common stock in a public offering at $37.00 per share, net of issuance costs of $6,540	3,000	3	104,457	—	—	—	—	104,460
Repurchase of common stock at $0.125 per share	(49)	—	(6)	—	—	—	—	(6)
Reversal of deferred stock compensation due to employees termination	—	—	(1,447)	—	657	—	—	(790)
Payment of note receivable net of accrued interest	—	—	—	18	—	—	—	18
Stock compensation related to the modification of unvested stock options	—	—	965	—	242	—	—	1,207
Stock compensation related to options granted to consultants for services	—	—	805	—	—	—	—	805
Amortization of deferred stock compensation	—	—	—	—	1,568	—	—	1,568
Balance at December 31, 2002	**31,696**	**$32**	**$481,881**	**$(38)**	**$ (947)**	**$ 957**	**$ (299,167)**	**$ 182,718**
Net unrealized gain/(loss) on available-for-sale securities	—	—	—	—	—	(557)	—	(557)
Net loss	—	—	—	—	—	—	(97,001)	(97,001)
Comprehensive net loss	—	—	—	—	—	—	—	(97,558)
Exercise of stock options	74	—	413	—	—	—	—	413
Stock issued under employee stock purchase plan	74	—	1,272	—	—	—	—	1,272
Repurchase of common stock at $0.125 per share	(7)	—	(1)	—	—	—	—	(1)
Reversal of deferred stock compensation due to employees termination	—	—	(550)	—	161	—	—	(389)
Payment of note receivable net of accrued interest	—	—	—	38	—	—	—	38

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

(In thousands, except per share data)

	Stockholders' Equity							
	Common stock		Additional paid-in capital	Notes receivable from stockholder	Deferred stock compensation	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount						
Stock compensation related to the modification of unvested stock options	—	—	442	—	—	—	—	442
Stock compensation related to options granted to consultants for services	—	—	83	—	—	—	—	83
Stock compensation related to the grant of restricted shares	8	—	157	—	—	—	—	157
Amortization of deferred stock compensation					569			569
Balance at December 31, 2003	**31,845**	**$32**	**$483,697**	**$ —**	**$ (217)**	**$ 400**	**$ (396,168)**	**$ 87,744**
Net unrealized gain (loss) on available-for-sale securities	—	—	—	—	—	(638)	—	(638)
Net unrealized/realized gain on foreign exchange contract	—	—	—	—	—	1,824	—	1,824
Net loss	—	—	—	—	—	—	(59,478)	(59,478)
Comprehensive net loss	—	—	—	—	—	—	—	(58,292)
Exercise of stock options	109	—	879	—	—	—	—	879
Stock issued under employee stock purchase plan	97	—	1,161	—	—	—	—	1,161
Stock compensation related to the modification of unvested stock options	—	—	110	—	—	—	—	110
Stock compensation related to options granted to consultants for services	—	—	45	—	—	—	—	45
Issuance of restricted stock to employees	532	1	8,129	—	(8,067)	—	—	63
Reversal of deferred stock compensation due to employee terminations	—	—	(1,358)	—	1,193	—	—	(165)
Amortization of deferred stock compensation	—	—	—	—	1,246	—	—	1,246
Balance at December 31, 2004	**32,583**	**$33**	**$492,663**	**$ —**	**$(5,845)**	**$1,586**	**$ (455,646)**	**$ 32,791**

See Accompanying Notes to Consolidated Financial Statements

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	For the year ended December 31,		
	2004	2003	2002
Cash flows used for operating activities:			
Net loss	$ (59,478)	$ (97,001)	$(144,309)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization of deferred compensation, net of reversals	1,081	180	1,020
Non-cash stock compensation	217	682	1,770
Acquired research and development and milestone payments	—	12,150	33,750
Amortization	4,264	4,622	4,619
Depreciation	2,700	2,680	1,964
Deferred rent	257	379	496
Impairment of intangible asset	—	4,761	—
Gain on foreign currency hedge	1,096	—	—
Loss on early extinguishment of debt	7,072	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	1,172	(1,135)	(6,780)
Inventories, net	(12,928)	(13,458)	(2,682)
Prepaid expenses	(332)	(148)	(962)
Restricted cash	—	—	—
Other assets	32	222	(746)
Accounts payable and accrued compensation	10,556	4,042	11,041
Other accrued liabilities	1,150	773	3,439
Net cash used for operating activities	(43,141)	(81,251)	(97,380)
Cash flows from investing activities:			
Purchase of property and equipment	(1,340)	(1,468)	(5,204)
Purchase of acquired product rights, including research and development and milestone payments	—	(18,750)	(22,250)
Purchases of available-for-sale securities	(139,617)	(256,156)	(223,869)
Maturities of available-for-sale securities	124,287	113,528	163,873
Sales of available-for-sale securities	61,471	182,763	55,328
Net cash provided by (used for) investing activities	44,801	19,917	(32,122)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	2,040	1,684	108,252
Proceeds from convertible senior notes, net	164,221	—	—
Repurchase of convertible subordinated notes	(154,451)	—	—
Repayment of notes receivable from stockholder	228	38	18
Net cash provided by financing activities	12,038	1,722	108,270
Net increase (decrease) in cash and cash equivalents	13,698	(59,612)	(21,232)
Cash and cash equivalents at beginning of period	42,071	101,683	122,915
Cash and cash equivalents at end of period	$ 55,769	$ 42,071	$ 101,683
Supplemental disclosure of cash flow information:			
Interest paid	$ 3,903	$ 8,596	$ 8,836
Schedule of non-cash transactions:			
Payable for acquired product rights and milestone payments	—	10,400	2,000
Payable for royalty rate buy down	—	—	15,000

See Accompanying Notes to Consolidated Financial Statements

1. ORGANIZATION

Overview

InterMune, Inc. ("InterMune," "we," "our," or "us") is an independent biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonary and hepatology. Our revenue base provided primarily from sales of our three marketed products, Actimmune, Infergen and Amphotec. We also have a number of advanced stage clinical programs addressing a range of unmet medical needs with attractive potential commercial markets as well as two non-core assets that we are seeking to divest in 2005.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of consolidation

The consolidated financial statements include the accounts of InterMune and its wholly owned subsidiaries, InterMune Canada Inc., and InterMune Ltd. All inter-company accounts and transactions have been eliminated. To date, the operations of InterMune Canada Inc. and InterMune Ltd. have been immaterial.

Use of estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

We evaluate our estimates and assumptions on an ongoing basis, including those related to reserves for doubtful accounts, returns, charge backs, cash discounts and rebates; excess inventories; inventory purchase commitments; and accrued clinical and preclinical expenses and allowed manufacturing development costs. We base our estimates on historical experience and on various other specific assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Cash, cash equivalents and available-for-sale securities

Cash and cash equivalents consist of highly liquid investments with original maturities, when purchased, of less than three months. We classify all debt securities as available for sale. Cash equivalents and available-for-sale securities are carried at fair value, with unrealized gains and losses, reported as other comprehensive income, a separate component of stockholders' equity. We have estimated the fair value amounts by using available market information. The cost of securities sold is based on the specific identification method.

Fair value of other financial instruments

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at historical cost, which we believe approximates fair value because of the short-term maturity

of these instruments. The fair value of our convertible senior debt was $144.0 million at December 31, 2004, which we determined using available market information.

Non-cancelable purchase obligations for inventory

Because of the long lead times required to manufacture our products, we enter into non-cancelable obligations to purchase our inventory. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels. We are also required to make judgments as to the expiration dates of our products, since our products can no longer be used after their respective expiration dates. In an effort to best manage the procurement and distribution of levels of Actimmune in 2004 we successfully completed the necessary testing to extend the expiration period of Actimmune from 30 months to a total of 36 months. As part of our excess inventory assessment for all of our products, we also consider the expiration dates of our products to be manufactured in the future under non-cancelable purchase obligations. During 2004, we recognized a charge of $2.9 million for Actimmune purchase commitments in excess of forecasted demand.

Significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of our inventories may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on our financial condition and results of operations during the period in which we recognize an inventory reserve. During the years ended December 31, 2004 and 2003, we charged $4.7 million and $1.3 million to cost of goods sold for excess inventory and contractual purchase commitments for inventory in excess of forecasted needs.

Concentration of risks

Cash equivalents and investments are financial instruments that potentially subject us to concentration of risk to the extent recorded on the balance sheet. We have established guidelines for investing excess cash relative to diversification and maturities that we believe maintain safety and liquidity. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. federal and state governments and their agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To reduce the exposure due to adverse shifts in interest rates we maintain investments with short effective maturities.

Our revenues and trade receivables are concentrated with a few customers. We perform credit evaluations on our customers' financial condition and limit the amount of credit extended. However, we generally do not require collateral on accounts receivable. Concentrations of credit risk, with respect to accounts receivable, exist to the extent of amounts presented in the financial statements. Three customers represented 47%, 14% and 12%, respectively, of total accounts receivable at December 31, 2004, and three customers represented 59%, 10% and 10%, respectively, of total accounts receivable at December 31, 2003. No other customer represented more than 10% of accounts receivable at December 31, 2004 or December 31, 2003.

Revenues from customers representing 10% or more of total sales during the years ended December 31, 2004, 2003 and 2002 were as follows:

Customer	2004	2003	2002
Priority Healthcare	53%	59%	57%
Caremark	12%	11%	10%
Merck Medco	10%	10%	11%

Foreign Currency and Derivative Instruments

From time to time, we use derivatives to manage our market exposure to fluctuations in foreign currencies. We record all derivatives on the balance sheet at fair value. For derivative instruments that are designated and qualify as a fair value hedge (i.e., hedging the exposure to changes in the fair value of an asset or a liability or an identified portion thereof that is attributable to a particular risk), the gain or loss on the derivative instrument, as well as the offsetting loss or gain on the hedged item attributable to the hedged risk, is recognized in current earnings during the period of the change in fair values. For derivative instruments that are designated and qualify as a cash flow hedge (i.e., hedging the exposure to variability in expected future cash flows that is attributable to a particular risk), the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. The gain or loss on the derivative instruments in excess of the cumulative change in the present value of future cash flows of the hedged transaction, if any, is recognized in current earnings during the period of change. We do not use derivative instruments for speculative purposes.

We purchase commercial and clinical products from BI Austria in a foreign currency. This exposes us to foreign currency exchange rate risk. To protect against currency exchange risks on forecasted foreign currency cash payments for the purchases of Actimmune from BI Austria over the next year, we have instituted a foreign currency cash flow hedging program. We hedge portions of our forecasted foreign currency cash payments with forward contracts. When the dollar strengthens significantly against the foreign currencies, the decline in the value of future foreign currency expenses is offset by losses, in the value of the option or forward contracts designated as hedges. Conversely, when the dollar weakens, the increase in the value of future foreign currency expenses is offset by gains in the value of the forward contracts. In accordance with FAS 133, hedges related to anticipated transactions are designated and documented at the hedge's inception as cash flow hedges and evaluated for hedge effectiveness at least quarterly.

At December 31, 2004, net gains on derivative instruments expected to be reclassified from accumulated other comprehensive income to earnings ratably with sales of Actimmune were $1.8 million of which $1.1 million were realized gains and $0.7 million were unrealized gains. The fair value of the derivative instrument is recorded in "Prepaid expenses and other current assets" on the balance sheet.

Inventories

Inventories consist principally of raw materials and finished-good products and are stated at the lower of cost or market value. Cost is determined by the first-in, first-out (FIFO) method.

Property and equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the assets.

Acquired product rights

Initial payments for the acquisition of products that, at the time of acquisition, are already marketed or are approved by the FDA for marketing are capitalized and amortized ratably over the estimated life of the products, typically ten years. At the time of acquisition, the product life is estimated based upon the term of the agreement, the patent life of the product and our assessment of future sales and profitability of the product. We assess this estimate regularly during the amortization period and adjust the asset value or useful life when appropriate. Initial payments for the acquisition of products that, at the time of acquisition, are under development or are not approved by the FDA for marketing, have not reached

technical feasibility and have no foreseeable alternative uses are expensed as research and development costs. Acquired product rights consist of payments made for the acquisition of rights to Amphotec and Infergen (see Note 3). Accumulated amortization of these intangible assets was $17.2 million and $14.1 million at December 31, 2004 and 2003, respectively. Amortization expense for acquired product rights for each of the next five years is as follows: 2005 - $3.1 million; 2006 - $3.1 million; 2007 - $3.1 million; 2008 - $3.1 million; 2009 - $2.8 million; thereafter - $3.7 million.

Impairment of long-lived assets

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we will measure the amount of such impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset.

Revenue recognition and revenue reserves

We recognize revenue generally upon delivery when title passes to a credit-worthy customer, and record reserves for estimated returns, rebates, chargebacks and cash discounts against accounts receivable. We are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date. We believe that we are able to make reasonable and reliable estimates of product returns, rebates, chargebacks and cash discounts based on historical experience. We review all sales transactions for potential rebates, chargebacks and discounts each month and believe that our reserves are adequate. We include shipping and handling costs in cost of goods sold.

We recognize Aralast co-promotion revenue upon receipt of the co-promotion funds from Baxter. The co-promotion revenue calculation is dependent upon national sales data which lags one quarter for reporting purposes, therefore estimates are not used. Co-promotion revenue is based on a percentage of Baxter's sales of Aralast to pulmonologists.

Research and development expenses

Research and development ("R&D") expenses include salaries, contractor and consultant fees, external clinical trial expenses performed by contract research organizations, in-licensing fees and facility and administrative expense allocations. In addition, we fund R&D at research institutions under agreements that are generally cancelable at our option. Research costs typically consist of applied and basic research and preclinical and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis and the transfer and scale-up of manufacturing at our contract manufacturers. Clinical development costs include the costs of Phase I, II and III clinical trials. These costs, along with the manufacturing scale-up costs, are a significant component of research and development expenses.

We accrue costs for clinical trial activities performed by contract research organizations based upon the estimated amount of work completed on each study. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities using available information; however, if we underestimate activity levels associated with various studies at a given point in time, we could record significant R&D expenses in future periods when the actual activity level becomes known. We charge all such costs to R&D expenses.

Advertising costs

We expense advertising costs as incurred. Advertising costs were $479,000, $146,000 and $93,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Income taxes

In accordance with SFAS No. 109, *"Accounting for Income Taxes,"* we determine a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. We provide a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

Comprehensive income (loss)

SFAS No. 130, *"Reporting Comprehensive Income,"* requires components of other comprehensive income, including unrealized gains or losses on our available-for-sale securities, to be included in total comprehensive income (loss). Total comprehensive loss for each of the periods presented is disclosed in Note 9 below. Also, other comprehensive income includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in other comprehensive income changes in the fair value of our available-for-sale investments and derivatives designated as effective cash flow hedges.

Net loss per share

We compute basic net loss per share by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. We deduct shares subject to repurchase by us from the outstanding shares to arrive at the weighted average shares outstanding. We compute diluted net loss per share by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. We exclude potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and common shares issuable on conversion of our convertible notes, from diluted net loss per share because of their anti-dilutive effect.

The securities excluded were as follows (in thousands):

	Year ended December 31,		
	2004	2003	2002
Options	4,945	5,728	4,491
Shares issuable upon conversion of convertible notes	7,859	3,893	3,893

The calculation of basic and diluted net loss per share is as follows (in thousands, except per share data):

	Year ended December 31,		
	2004	2003	2002
Net loss	$(59,478)	$(97,001)	$(144,309)
Basic and diluted net loss per common share:			
Weighted-average shares of common stock outstanding	32,089	31,761	30,976
Less: weighted-average shares subject to repurchase	(329)	(96)	(387)
Weighted-average shares used in computing basic and diluted net loss per common share	31,760	31,665	30,589
Basic and diluted net loss per common share	$ (1.87)	$ (3.06)	$ (4.72)

Stock-Based Compensation

We follow APB Opinion No. 25, "*Accounting for Stock Issued to Employees*," ("APB 25") in accounting for stock-based incentives. In October 1995, the FASB issued SFAS No. 123, "*Accounting for Stock Based Compensation,*" ("SFAS 123") and in December 2002, the FASB issued SFAS No. 148, "*Accounting for Stock-Based Compensation—Transition and Disclosure.*" Although these pronouncements allow us to continue to follow the APB 25 guidelines for the measuring and recording of employee stock-based compensation expense, we are required to disclose the effect on net loss and net loss per share as if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation.

When the exercise price of the employee or director stock options is less than the deemed fair value of the underlying stock on the grant date, we record deferred compensation for the difference. We amortize deferred compensation using the graded vesting method over the vesting period of the general award, generally four years. For restricted stock grants, we record the fair value on the date of grant as deferred compensation, which is amortized as the underlying shares vest. We record options or stock awards issued to non-employees at their fair value as determined in accordance with SFAS 123, which we recognize over the related service period and periodically re-measure as the underlying options vest.

The following tables provide such disclosure (in thousands, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net loss, as reported	$(59,478)	$ (97,001)	($144,309)
Add: Stock-based employee compensation expense, included in reported net loss	1,081	180	2,790
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(9,549)	(24,999)	(30,611)
Pro forma net loss	$(67,946)	$(121,820)	$ (172,130)
Net loss per share:			
Basic and diluted—as reported	$ (1.87)	$ (3.06)	$ (4.72)
Basic and diluted—pro forma	$ (2.14)	$ (3.85)	$ (5.63)

The pro forma impact of applying SFAS 123 for the year ended December 31, 2004, 2003 and 2002, respectively, does not necessarily represent the pro forma impact in future quarters or years.

We estimate the fair value of each option grant on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year Ended December 31,		
	2004	2003	2002
Expected stock price volatility	74%	80%	85%
Risk-free interest rate	3.6%	3.3%	2.3%
Expected life (in years)	6.0	4.9	3.4
Expected dividend yield	—	—	—

The weighted average fair value per share of options granted was $9.21 in 2004, $12.59 in 2003 and $18.99 in 2002.

We estimate the fair value of the employees' stock purchase rights using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year Ended December 31,		
	2004	2003	2002
Expected stock price volatility	80%	83%	78%
Risk-free interest rate	2.5%	2.3%	1.7%
Expected life (in years)	2.0	2.0	2.0
Expected dividend yield	—	—	—

The weighted-average fair value for shares issued under the employee stock purchase plan for the years ended December 31, 2004, 2003 and 2002 was $12.76, $16.63, and $18.44, respectively.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. This model also requires the input of highly subjective assumptions including the expected stock price volatility.

Recent accounting pronouncements

In March 2004, the FASB approved the consensus reached on the Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The Issue's objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued a FASB Staff Position (FSP) EITF 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF 03-1 until further notice. The disclosure requirements of EITF 03-1 are effective with this annual report for fiscal 2004. (See Note 5.) Once the FASB reaches a final decision on the measurement and recognition provisions, we will evaluate the impact of the adoption of the accounting provisions of EITF 03-1.

In December 2004, the FASB issued Statement No. 123 (revised 2004), "Share-Based Payment," effective beginning after June 15, 2005. FAS 123R supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plan. We will be required to implement FAS 123R no later than the third quarter that begins July 1, 2005. We are currently evaluating option valuation methodologies and assumptions in light of FAS 123R, and therefore cannot estimate the impact of our adoption at this time. These methodologies and assumptions may be different than those we currently employ in applying FAS 123, outlined in "Stock-Based Compensation" above. We expect that the adoption of FAS 123R will have an impact on our consolidated results of operations.

3. ACQUIRED PRODUCT RIGHTS

Marnac, Inc./KDL GmbH (pirfenidone)

In 2002, we licensed from Marnac and its co-licensor, KDL, their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and future milestone and royalty payments. We expensed the $18.8 million as acquired research and development and milestone payments in the first quarter of 2002 since pirfenidone was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses. Future milestone payments will be based on the progress of clinical development of pirfenidone. We had made no royalty or milestone payments under this agreement through December 31, 2004. Assuming that all of the milestones under this agreement are

achieved, we will be required to make milestone payments of $14.5 million. Our rights to the licensed products under the agreement could revert to Marnac if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. The agreement will expire upon the later of the expiration of the primary patent licensed under the agreement; or on a disease-by-disease and country-by-country basis (as determined by reference to the indications for which pirfenidone is approved in such country) on the later of (i) the expiration of market exclusivity in such country (if any) resulting from the grant of orphan drug designation to pirfenidone for the treatment of a human fibrotic disease; and (ii) the expiration of the last valid and enforceable claim in a issued licensed patent claiming the use of pirfenidone to treat such disease in such country. Following expiration of the agreement, we will retain a fully paid-up, royalty-free, perpetual, irrevocable, sublicenseable license to the patents, know-how, and other intellectual property rights licensed under the Agreement. We may terminate the agreement after giving the requisite notice to Marnac. In the event Marnac or KDL terminate the agreement, we have the right to seek specific performance of the agreement.

Amgen Inc. (Infergen, PEG-Alfacon-1 and interferon gamma)

In 2001, we entered into a licensing and commercialization agreement with Amgen through which we obtained an exclusive license in the United States and Canada to Infergen and the rights to an early stage program to develop a pegylated form of Infergen (PEG-Alfacon-1). Infergen is currently approved in both the United States and Canada to treat chronic HCV infections. Under the agreement, we have the exclusive right to market Infergen and clinically develop it for other indications in the United States and Canada. In December 2004, we amended our Licensing and Commercialization Agreement with Amgen to remove certain non-competition restrictions on Amgen with respect to alpha interferons in exchange for a specified reduction in the royalties payable by us to Amgen on Infergen sales should Amgen engage in certain competitive activities as well as Amgen's consent to transfer the manufacturing of Infergen to a new supplier. We initially paid Amgen total consideration of $29.0 million for up-front license and other fees and milestones with respect to our license, and are obligated to pay royalties on sales of Infergen. Based upon independent appraisal, the $5.4 million fair value of the in-process research and development program for PEG-Alfacon-1 was expensed as acquired research and development and milestone payments because at the time of acquisition the PEG-Alfacon-1 program was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses. The remainder of the purchase price of approximately $23.6 million was allocated to developed technology and recorded as an intangible asset, which is being amortized over ten years. We evaluate this intangible asset, like our other intangible assets, for impairment on a regular basis. In March 2003, we commenced a Phase I clinical trial for PEG-Alfacon-1, which required us to make a $1.5 million milestone payment to Amgen pursuant to the terms of the agreement. We may be required to make additional milestone payments to Amgen based on the progress of our PEG-Alfacon-1 clinical development program, and we will be obligated to pay royalties on sales of the resulting product, if any. Assuming that all of the reasonably possible milestones under this agreement are achieved, we will be required to make additional milestone payments of $51.5 million under this agreement. The agreement with Amgen will expire on the date that the last of the Amgen patents licensed under the agreement expires, at which point the exclusive licenses granted to us relating to Infergen and PEG-Alfacon-1 will become fully paid and irrevocable. Prior to such expiration, either party can terminate the agreement for the uncured material breach of the other party, and our rights to Infergen and PEG-Alfacon-1 could revert to Amgen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. In addition, we can at any time discontinue our development and commercialization efforts under the agreement, terminate the agreement, and return to Amgen all rights to Infergen and PEG-Alfacon-1.

In 2002, we acquired certain pending patent applications relating to interferon gamma from Amgen in exchange for $3.5 million, of which $1.5 million was paid in June 2002, and the remaining $2.0 million was paid in January 2003. We are amortizing these product rights to operations over the expected useful product life of Actimmune.

Shearwater Corporation (PEG-Alfacon-1)

In June, 2002 we entered into a development, license and manufacturing agreement with Shearwater, a wholly owned subsidiary of Nektar Therapeutics, to access Shearwater's pegylation technology in order to develop a pegylated version of Infergen. Under the terms of the agreement, we received a co-exclusive license with Maxygen from Shearwater in exchange for an up-front payment of $500,000 and future milestone and royalty payments. We had paid $250,000 in milestone payments, but no royalty payments, under this agreement in the aggregate through December 31, 2004. Assuming that all the milestone payments under this agreement are achieved, we will be required to make additional milestone payments of $8.3 million.

In countries in which patents covering one of our products using Shearwater's pegylation technology have issued or will issue, our royalty obligations will generally expire upon the expiration of all such patents. In other countries, our royalty obligations will continue for a specified period following the first commercial sale of a product using Shearwater's pegylation technology in such country. Our agreement with Shearwater will expire upon the expiration of all royalty obligations under the agreement. We can terminate the agreement (i) if marketing authorization for any of our products using Shearwater's pegylation technology is withdrawn or suspended by regulatory authorities; (ii) if safety or certain other issues associated with the product render further development or marketing unjustified; (iii) if we are unable to market the product due to valid patent infringement claims of third parties; or (iv) if competing products render the marketing of the product not commercially feasible. Prior to the expiration of the agreement, either party can terminate the agreement for the uncured material breach of the other party, and our rights to Shearwater's pegylation technology could revert to Shearwater if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

Eli Lilly & Company (oritavancin)

In 2001, we entered into an asset purchase and license agreement with Eli Lilly pursuant to which we acquired worldwide rights to oritavancin. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. We are obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for oritavancin in accordance with our proposed development plan and to commercialize oritavancin in accordance with our proposed commercialization plan. In order to partner oritavancin, the agreement requires that we first offer Eli Lilly the opportunity to enter into such a relationship with us, which we have done. Eli Lilly has declined the opportunity to partner with us, and the agreement prohibits us from entering into an agreement with a third party on more favorable terms than those we offered to Eli Lilly. Pursuant to the agreement, we paid Eli Lilly $50.0 million and will be obligated to pay Eli Lilly significant milestone payments and royalties on product sales. We expensed the $50.0 million during 2001 since oritavancin was in clinical development, had not reached technical feasibility and had no foreseeable alternative uses. We had made no royalty or milestone payments under this agreement through December 31, 2004. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $95.0 million. In September 2002, Eli Lilly exercised its option under the agreement to reduce the agreed percentage of royalties on product sales. The exercise of this option required us to pay $15.0 million to Eli Lilly, and we made the actual payment to Eli Lilly during January 2003. In September 2003, we expensed $10.0 million related to a milestone payment due to Eli Lilly for the completion of the Phase III clinical trials for

oritavancin. This amount was recorded as a milestone-based liability at December 31, 2003 as a result of an understanding between Eli Lilly and ourselves.

Our agreement with Eli Lilly will expire on a country-by-country basis upon the expiration of all royalty obligations in each country covered by the agreement, at which point we will possess a fully paid, perpetual, irrevocable, and sublicensable exclusive license to oritavancin. In countries where patents licensed under the agreement have issued or will issue, our royalty obligations will in most cases expire upon the expiration of all such patents. In other countries, our royalty obligations will in most cases continue for a specified period following the first commercial sale of an oritavancin product in such country. Prior to expiration of the agreement, either party can terminate the agreement for the insolvency of the other party or for an uncured material breach by the other party. Our rights to oritavancin could revert to Eli Lilly if we do not meet our diligence obligations under the agreement or otherwise commit a material breach of the agreement. Additionally, if we are acquired by a company with a certain type of competing program and Eli Lilly has notified us prior to the acquisition that it believes in good faith that its economic interests in oritavancin under the agreement will be harmed in light of the acquisition, Eli Lilly may terminate the agreement and our rights to oritavancin would revert to Eli Lilly. In any event, we may not assign the agreement to a potential acquirer without Eli Lilly's advance, written consent. We are attempting to divest oritavancin and are currently in the process of identifying a buyer for this asset.

ALZA Corporation (Amphotec)

In 2001, we acquired worldwide rights from ALZA, (now a subsidiary of Johnson & Johnson) to Amphotec (sold under the trade name Amphocil in certain countries outside the United States). The transaction terms included an up-front product acquisition fee of $9.0 million which was capitalized as acquired product rights, milestone payments based upon sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune and royalties payable upon net sales of Amphotec. Assuming that all of the milestones under this agreement that we continue to believe are relevant are achieved, we will be required to make milestone payments of $1.0 million. Under the agreement, we obtained access to certain existing distributorships for Amphotec and assumed ALZA's obligations under agreements with its existing Amphotec distributors and service providers. We have diligence obligations under the agreement to set up additional distributorships for Amphotec or establish a sales force and begin to promote Amphotec in specified countries at specified times. Our rights to Amphotec could revert to ALZA if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. The product acquisition fee has been capitalized as acquired product rights and will be amortized over its estimated useful life of ten years. We are also subject to certain royalty obligations to the University of California under this agreement. During September 2003, we reduced the remaining carrying value of the intangible asset recorded in 2001 when we acquired Amphotec by recording an impairment charge of $4.8 million. This impairment charge was based on our impairment review of the Amphotec product rights, which took into account that sales levels were lower than expected and that Amphotec is not aligned with our new strategic focus in pulmonology and hepatology. Consequently, we are attempting to divest Amphotec and are in the process of identifying a buyer for this asset. Any such buyer will need to comply with the current and future terms of the agreement with ALZA.

Genentech, Inc. License Agreement (Actimmune)

In 1998, we obtained a license under Genentech's patents relating to Actimmune. The license from Genentech terminates on the later of May 5, 2018 or the date that the last of the patents licensed under the agreement expires. Our licensed Actimmune rights include exclusive and non-exclusive licenses. The exclusive licenses include the right to develop and commercialize Actimmune in the United States and Canada for the treatment and prevention of all human diseases and conditions, including infectious

diseases, pulmonary fibrosis and cancer, but excluding arthritis and cardiac and cardiovascular diseases and conditions. The non-exclusive licenses include the right to make or have made Actimmune for clinical and commercial purposes within our field of use in the United States and Canada. In Japan, we have the exclusive license rights to commercialize Actimmune for the treatment and prevention of all infectious diseases caused by fungal, bacterial or viral agents, including in patients with CGD or osteopetrosis. We also have the opportunity, under specified conditions, to obtain further rights to Actimmune in Japan and other countries. In addition, we received an exclusive sublicense under certain of Genentech's patents outside the United States, Canada and Japan under the BI International agreement discussed below. Under the Genentech license, we pay Genentech royalties on the revenue from sales of Actimmune and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the filing for FDA approval to market Actimmune for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune for the treatment of particular categories of diseases and the achievement of certain annual revenue targets for Actimmune. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $3.2 million. We must satisfy specified diligence obligations under the agreement with Genentech to maintain our license from Genentech. In particular, we are obligated under the agreement to develop and commercialize Actimmune for a number of diseases. In addition, the agreement specifies deadlines for achieving a number of milestones related to clinical development of Actimmune for such diseases, and we are obligated to use our best efforts to meet these deadlines, to the extent reasonably allowed by our financial resources. Our rights to Actimmune under this agreement could revert to Genentech if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

Connetics Corporation (Actimmune)

Through an assignment and option agreement with Connetics, we paid Connetics $5.7 million to acquire rights to Actimmune and are obligated to pay to Connetics a royalty of 0.25% of our net United States sales for Actimmune until our net United States sales cumulatively surpass $1.0 billion. Above $1.0 billion, we are obligated to pay a royalty of 0.5% of our net United States sales of Actimmune. Through a separate purchase agreement, we paid Connetics $0.4 million to acquire rights related to scleroderma and are obligated to pay Connetics a royalty of 4.0% on our net revenue from sales of Actimmune for the treatment of scleroderma. There are no milestone payments pursuant to this agreement.

4. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS

Array BioPharma Inc. (small molecule therapeutics)

In 2002, we entered into a drug discovery collaboration agreement to create small molecule therapeutics targeting hepatitis with Array. We will fund drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and will be responsible for all development and commercialization. Array will be entitled to receive milestone payments based on the selection and progress of clinical drug candidates, as well as royalties on net sales of products derived from the collaborative efforts. The original term of this agreement expired in September 2004 and was extended to June 30, 2005, subject to certain conditions. In addition, in December 2004, the agreement was amended to provide a mechanism for us to purchase certain intellectual property rights arising from the collaboration. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of $9.1 million. Total research and development expenses related to this agreement were $5.7 million, $2.1 million, and $0.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. Included in the $5.7 million is a one-time non-refundable fee of $2.5 million paid in connection with securing the right to purchase Array's ownership interest in certain collaboration patents.

Maxygen Holdings Ltd. (next-generation interferon gamma)

We have a license and collaboration agreement with Maxygen to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune. We plan to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. We have funded Maxygen's optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. Our diligence obligations include a minimum level of clinical development expenditures for an initial period of time, as well as the general obligation to use commercially reasonable efforts to clinically develop, seek regulatory approval for and commercialize a product in specified major market countries. The agreement terms include up-front license fees and full research funding, as well as development and commercialization milestone payments, which are payable based on the progress of our clinical development program for next-generation interferon gamma products and the achievement of certain sales targets with respect to such products. In addition, Maxygen will receive royalties on product sales. We paid Maxygen a total of $106,000, $228,000, and $5.1 million for the years ended December 31, 2004, 2003 and 2002, respectively. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of $43.0 million.

In countries in which patents covering next-generation interferon gamma products have issued or will issue to either us or Maxygen, our royalty obligations will generally expire upon the expiration of all such patents. In other countries, our royalty obligations will continue for a specified period following the first commercial sale of a next-generation interferon gamma product in such country. Our agreement with Maxygen will expire upon the expiration of all royalty obligations under the agreement. Prior to expiration of the agreement, either party can terminate the agreement for the insolvency of the other party, and in the event of a material breach of the agreement by a party, the other party has the right to pursue a remedy through arbitration. If we commit a material breach of the agreement, the remedy selected by the arbitrator may include termination of the licenses granted to us by Maxygen under the agreement. In addition, if we do not meet certain diligence obligations, Maxygen may have the right to terminate the agreement, as well as to obtain royalty-bearing licenses from us that would allow it to continue the development and commercialization of next-generation interferon gamma products.

Boehringer Ingelheim International GmbH (Imukin)

In 2001, we formed a collaboration with BI International to clinically develop and seek regulatory approval for interferon gamma-1b, the active ingredient in Actimmune, in certain diseases, and to commercialize a liquid formulation of interferon gamma-1b under one or more of BI International's trade names, including Imukin, in Europe and other major markets of the world (other than the United States, Canada and Japan). Under the agreement, the parties will seek to develop and obtain regulatory approval for the use of Imukin in the treatment of a variety of diseases, including IPF, ovarian cancer, CGD and osteopetrosis. The agreement provides that we will fund and manage clinical and regulatory development of interferon gamma-1b for these diseases in the countries covered by the agreement. BI International will pay us royalties on sales of the product when it meets a specified minimum sales level. BI International has an option to exclusively promote Imukin in all of the major market countries covered by the agreement, and we may opt to promote the product in those countries and for those new diseases for which BI International does not do so. If we opt to promote the product in those countries or for those new diseases for which BI International does not, we will pay royalties to BI International on sales of the product in those countries and/or for those new diseases. We had neither paid nor received any royalties under this agreement through December 31, 2004, and there are no milestone payments under this agreement. The agreement will expire, on a country-by-country basis, upon expiration of the parties' royalty obligations in each country covered by the agreement. Such royalty obligations generally expire fifteen years after

regulatory approval of Imukin for certain specified indications in the relevant country. If no such regulatory approvals are granted in a particular country, the royalty obligations in such country will expire in 2016. Prior to such expiration, either party can terminate the agreement for the uncured material breach of the other party or for the insolvency of the other party. In addition, we have the right to terminate the agreement with respect to certain countries at any time subsequent to regulatory approval for IPF.

Funding Commitments

Our non-cancelable funding commitments under the above sponsored research, license and collaboration agreements total $2.6 million as of December 31, 2004 of which $1.0 million and $1.6 million are due during the years ending December 31, 2005 and 2006.

5. AVAILABLE-FOR-SALE INVESTMENTS

The following is a summary of our available-for-sale investments as of December 31, 2004 and 2003 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2004				
Obligations of U.S. federal and state governments	$ 63,399	$ 3	$(129)	$ 63,272
Corporate debt securities	99,076	9	(119)	98,967
Other debt securities	11,810	—	(2)	11,808
Total	$174,285	$12	$(250)	$174,047

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Reported as:				
Cash equivalents	$ 46,788	$ 3	$ —	$ 46,791
Available-for-sale securities	127,497	9	(250)	127,256
Total	$174,285	$12	$(250)	$174,047

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2003				
Obligations of U.S. federal and state governments	$ 67,950	$271	$ (8)	$ 68,213
Corporate debt securities	127,295	165	(30)	127,430
Other debt securities	12,358	2	—	12,360
Total	$207,603	$438	$(38)	$208,003

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Reported as:				
Cash equivalents	$ 33,965	$ 2	$ —	$ 33,967
Available-for-sale securities	173,638	436	(38)	174,036
Total	$207,603	$438	$(38)	$208,003

The realized gains and losses for the years 2004 and 2003 were not material. Realized gains and losses were calculated based on the specific identification method.

The following is a summary of the amortized cost and estimated fair value of available-for-sale debt securities at December 31, by contractual maturity (in thousands):

	2004		2003	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Mature in less than one year	$131,522	$131,326	$132,113	$132,438
Mature in one to three years	19,925	19,890	43,645	43,713
Mature in over three years	22,838	22,831	31,845	31,852
Total	$174,285	$174,047	$207,603	$208,003

6. INVENTORIES

Inventories consist of the following at December 31 (in thousands):

	2004	2003
Raw materials	$ 550	$ 552
Finished goods	32,440	19,510
Total	$32,990	$20,062

For the years ended December 31, 2004, 2003 and 2002 we recognized a total of $4.7 million, $1.3 million and $0, respectively in cost of goods for excess inventory and non-cancelable purchase commitments in excess of forecasted demand.

7. PROPERTY AND EQUIPMENT

Property and equipment and related accumulated depreciation and amortization is as follows at December 31 (in thousands):

	2004	2003
Computer and laboratory equipment	$ 4,802	$ 3,654
Office furniture and fixtures	3,407	3,335
Leasehold improvements	7,982	7,862
	16,191	14,851
Less accumulated depreciation and amortization	(7,930)	(5,230)
Total	$ 8,261	$ 9,621

8. OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following at December 31 (in thousands):

	2004	2003
Accrued clinical trial costs	$ 5,901	$ 4,882
Accrued interest	142	3,940
Payable to Eli Lilly	10,000	10,000
Royalties payable	4,421	4,254
Accrued sales and marketing	2,134	—
Other accrued liabilities	1,915	287
Total other accrued liabilities	$24,513	$23,363

9. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). We include in other comprehensive income (loss) changes in the fair value of derivatives designated as effective foreign currency cash flow hedges and unrealized gains and losses on our available-for-sale securities. The activity in other comprehensive income (loss) are as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Net loss	$(59,478)	$(97,001)	$(144,309)
Change in unrealized gain/(loss) on available-for-sale securities	(638)	(557)	908
Change in realized and unrealized gain on foreign currency hedge	1,824	—	—
Comprehensive loss	$(58,292)	$(97,558)	$(143,401)

Accumulated other comprehensive income consists of the following at (in thousands):

	December 31,		
	2004	2003	2002
Net unrealized gain/(loss) on available-for-sale securities	$ (238)	$400	$957
Change in unrealized gain on foreign currency hedge	1,824	—	—
Accumulated other comprehensive income	$1,586	$400	$957

10. CONVERTIBLE SUBORDINATED NOTES

In 2004, we completed the repurchase of $149.5 million of our outstanding 5.75% convertible subordinated notes due July 2006 and issued $170 million 0.25% convertible senior notes due in March 2011. We paid a total of $157.6 million related to the repurchase, which included $3.2 million for accrued interest on the convertible subordinated notes and a premium of $5.0 million recognized as a loss on the early extinguishment of debt. We also expensed a non-cash charge of approximately $2.1 million for the acceleration of the amortization of the deferred issuance costs associated with the notes.

11. CONVERTIBLE SENIOR NOTES

In February 2004, we issued 0.25% convertible senior notes due March 1, 2011 in an aggregate principal amount of $170.0 million (the "Senior Notes"). The Senior Notes are convertible into our common stock at the option of the holder at a conversion price of approximately $21.63 per share, subject to adjustment in certain circumstances. Interest on the Senior Notes is payable semiannually in arrears on March 1 and September 1 of each year. The Senior Notes are unsecured and rank on parity with all of our other existing and future senior unsecured debt and prior to all subordinated indebtedness. In addition, the Senior Notes are effectively subordinated to any existing and future secured debt to the extent of the value of the collateral securing such debt. As of December 31, 2004, we had no secured debt and no senior obligations. Offering expenses of $5.8 million related to the sale of the Senior Notes have been included in other assets and are being amortized to interest expense over the life of the Senior Notes, which is seven years from the date of issuance.

12. STOCKHOLDERS' EQUITY

Restricted Stock Awards

During the year ended December 31, 2004, and 2003, respectively, we granted to employees restricted stock awards for 525,600 shares and 25,000 shares of our common stock with a weighted-average fair value

of $15.35 per share and $20.15 per share, respectively, that vest annually over a four-year period, thirty percent in each of the first three years and ten percent in the final year, through September 2008. Restricted stock awards are shares of common stock which are forfeited if the employee leaves the company prior to vesting. As a result of these awards, during the years ended December 31, 2004 and 2003, we recognized $1.1 million and $0.2 million in compensation expense, respectively. We reversed approximately $1.1 million of deferred compensation in 2004 due to employee terminations. As the restricted shares vest through 2008, we will continue to recognize stock based compensation expenses related to the grants of these restricted awards. These stock awards offer employees the opportunity to earn shares of our stock over time, rather than options that give the employee the right to purchase stock at a set price. If all of the remaining restricted stock awards that were granted in 2004 vest, we would recognize approximately $5.8 million in compensation expense over the four-year period. However, no compensation expense will be recognized for stock awards that do not vest.

Stock Compensation Plans

In 1999, we adopted the 1999 Equity Incentive Plan ("1999 Plan"). The 1999 Plan provided for the granting of options to purchase common stock and the issuance of shares of common stock, subject to repurchase rights, to directors, employees and consultants. Certain options were immediately exercisable, at the discretion of our board of directors. Shares issued pursuant to the exercise of an unvested option are subject to the right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. In 2000, we terminated all remaining unissued shares under the 1999 Plan amounting to 121,584 shares. We repurchased early exercised and unvested shares from certain terminated employees in the amounts of 0 shares in 2004, 7,217 shares at a purchase price of $0.125 per share in 2003, and 49,501 shares at a purchase price of $0.125 per share in 2002. Under the 1999 Plan, 51,550 shares have been granted to employees that are subject to repurchase as of December 31, 2004.

In 2000, our board of directors adopted the 2000 Equity Incentive Plan ("2000 Plan") and the 2000 Non-Employee Directors' Stock Option Plan ("Directors' Plan"). In 2000, a total of 2 million shares of common stock were initially reserved for issuance under the 2000 Plan and 180,000 shares under the Directors' Plan. In 2004, an additional 1 million shares of common stock were reserved for issuance under the 2000 Plan, and a total of 550,000 shares were reserved for issuance under the Director's Plan. The 2000 Plan and the Directors' Plan provide for the granting of options to purchase common stock and the issuance of shares of common stock, subject to repurchase rights, to directors, employees and consultants. Shares issued pursuant to the exercise of an unvested option are subject to our right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. Options not immediately exercisable generally vest over four years. Options granted under the plans have a maximum term of 10 years.

The stock option and related activity under all of our stock option plans is summarized as follows:

	Outstanding Options		
	Shares available for grant	Number of shares	Weighted average exercise price per share
Balance at December 31, 2001	606,106	2,988,088	$29.79
Authorized	3,741,287	—	—
Shares terminated under 1999 plan and not available for future grants	(138,219)	—	—
Granted	(2,561,300)	2,561,300	$33.81
Cancelled	831,358	(831,358)	$32.73
Exercised	—	(227,326)	$10.27
Repurchased	49,501	—	$0.125
Balance at December 31, 2002	2,528,733	4,490,704	$32.46
Authorized	180,000	—	—
Shares terminated under 1999 plan and not available for future grants	(67,132)	—	—
Granted	(2,476,423)	2,476,423	$19.78
Restricted shares granted	(25,000)	—	—
Cancelled	1,164,290	(1,164,290)	$31.86
Exercised	—	(74,845)	$ 5.51
Repurchased	7,217	—	$0.125
Balance at December 31, 2003	1,311,685	5,727,992	$27.52
Authorized	1,550,000	—	—
Shares terminated under 1999 plan and not available for future grants	(13,667)	—	—
Granted	(1,603,077)	1,603,077	$13.79
Restricted shares granted	(525,600)	—	
Cancelled	2,276,414	(2,276,414)	$29.02
Restricted shares cancelled	74,620	—	$15.55
Exercised	—	(109,203)	$ 8.04
Balance at December 31, 2004	3,070,375	4,945,452	$22.81

The following table summarizes information about options outstanding at December 31, 2004:

	Options outstanding			Options exercisable	
Range of exercise prices	Number of shares	Weighted average remaining contractual life	Weighted average exercise price	Number of shares	Weighted average exercise price
$4.50 - $16.96	1,419,002	9.29	$12.11	197,506	$13.16
$17.13 - $25.00	2,295,692	8.32	$20.76	1,109,366	$21.42
$25.26 - $41.25	592,554	7.03	$33.97	465,725	$34.48
$42.50 - $53.00	638,204	6.75	$43.57	543,802	$43.61
	4,945,452	8.24	$22.81	2,316,399	$28.55

Employee Stock Purchase Plan

To provide employees with an opportunity to purchase our common stock through payroll deductions, our board of directors adopted the 2000 Employee Stock Purchase Plan (the "ESPP"). Under the ESPP, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the date of eligibility for enrollment or the date of purchase, whichever is less. Purchases are

limited to the lesser of 15% of each employee's eligible annual compensation or $25,000. Through the end of December 2004, we issued a total of 267,832 shares under this plan, and 1,324,910 shares remain available for future issuance.

Stock Compensation

In connection with the grant of certain stock options to employees for the years ended December 31, 2000 and 1999, we recorded deferred stock compensation of approximately $8.6 million and $5.6 million, respectively. These amounts represent the difference between the deemed fair value of the common stock and the option exercise price at the date of grant. We recorded amortization of deferred stock compensation related to these options of approximately $0.1 million, $0.6 million, and $1.8 million, for the years ended December 31, 2004, 2003 and 2002, respectively. We reversed approximately $0.1 million and $0.4 million for the years ended December 31, 2004 and 2003, respectively, of amortized deferred stock-based compensation recorded in prior years due to the termination of certain employees. The amortization expense relates to options awarded to employees in all operating expense categories. The amortization of deferred stock compensation has been separately allocated to these categories in the financial statements.

Stockholder Rights Agreement

In July 2001, our board of directors approved the adoption of a stockholder Rights Agreement, which provided for the distribution of one preferred share purchase right (a "Right") for each outstanding share of our common stock. The dividend was paid on August 3, 2001 to the stockholders of record on that date. Each Right entitles the registered holder to purchase one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share (the "Preferred Shares"), at a price of $390.00 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. The Rights will be exercisable upon the earlier of: (i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of the outstanding common shares (an "Acquiring Person"), or (ii) ten business days (or such later date as may be determined by action of the board of directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person. In October 2004, the Rights Agreement was amended to allow Warburg Pincus Equity Partners, L.P. and certain of its affiliates ("Warburg Pincus") to acquire ownership of up to 25% of our issued and outstanding common stock in open market purchases without becoming an Acquiring Person. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P.

In the event that any person, entity or group of affiliated or associated persons become an Acquiring Person, each holder of a Right will have the right to receive, upon exercise, the number of common shares having a market value of two times the exercise price of the Right. In the event that we are acquired in a merger or other business combination transaction or 50% or more of our consolidated assets or earning power are sold to an Acquiring Person, its associates or affiliates or certain other persons in which such persons have an interest, each holder of a Right will have the right to receive, upon the exercise at the then-current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right. At any time after an Acquiring Person becomes an Acquiring Person and prior to the acquisition by such Acquiring Person of 50% or more of the outstanding common shares, our board of directors may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one common share, or one one-hundredth of a Preferred Share, per Right (or, at our election, we may issue cash, debt, stock or a combination thereof in exchange for the Rights), subject to adjustment. The Rights will expire on August 3, 2011, unless we redeem or exchange them.

Reserved Shares

At December 31, 2004, common stock subject to future issuance is as follows:

Common stock issuable upon conversion of convertible senior debt	7,858,811
Outstanding common stock options	4,945,452
Common stock available for grant under stock option plans	3,070,375
Common stock available for grant under the 2000 Employee Stock Purchase Plan	1,324,910
Total	17,199,548

13. INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amount used for income tax purposes. Significant components of our deferred tax assets as follows at December 31 (in thousands):

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 122,000	$ 95,000
Research and development credits	6,000	8,000
Capitalized research and development costs	46,000	50,000
Other, net	12,000	5,000
Total deferred tax assets	186,000	158,000
Valuation allowance	(186,000)	(158,000)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $28.0 million, $43.0 million, and $59.9 million during the years ended December 31, 2004, 2003 and 2002, respectively.

Deferred tax assets related to carryforwards at December 31, 2004 include approximately $4.9 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders equity.

As of December 31, 2004, we had net operating loss carryforwards for federal income tax purposes of approximately $338.3 million, which expire in the years 2019 through 2024, and federal research and development credits of approximately $5.2 million, which expire in the years 2018 through 2024. In addition, we have net operating loss carryforwards for state income tax purposes of approximately $120.2 million, which expire in the years 2005 through 2014 and state research and development tax credits of approximately $1.9 million, which do not expire.

Utilization of our net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.

14. COMMITMENTS AND CONTINGENCIES

Leases

We have a non-cancelable lease for facilities, which expires in 2011. Total rent expense was approximately $3.7 million for each of the years ended December 31, 2004, 2003 and 2002, respectively. In addition, we have entered into auto leases for our field sales force that extend up to five years.

In 2001, we subleased a former facility and recognized rental income of $118,000, $126,000, and $175,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The lease expired December 2004.

The following is a schedule by year of future minimum lease payments of all leases at December 31, 2004 (in thousands):

Year	Operating Leases
2005	$ 4,560
2006	4,620
2007	4,365
2008	4,142
2009	4,148
Thereafter	5,950
	$27,785

The operating leases for our facilities require letters of credit secured by a restricted cash balance with our bank. The amounts of each letter of credit approximates 6-12 months of operating rent payable to the landlord of each facility and are effective until we reach profitability. At December 31, 2004 and 2003, restricted cash under these letters of credit amounted to $1.7 million.

Purchase Commitments

We have purchase commitments with BI Austria and Amgen for the manufacture and supply of Actimmune and Infergen, respectively. At December 31, 2004, our minimum purchase obligations totaled $209.0 million and are committed through the year 2012. Of these commitments, we have $47.1 million and $32.3 million of outstanding fixed purchase order commitments that become due and payable in 2005 and 2006, respectively. Our contractual obligation to BI Austria is denominated in Euros.

Contingent Payments

We will be required to make contingent milestone payments in accordance with our license, commercialization and collaboration agreements in the aggregate amount of $225.6 million if all of the milestones per the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

15. SALES BY GEOGRAPHIC REGION

We have determined that, in accordance with SFAS No. 131, we operate in one segment, because operating results are reported only on an aggregate basis to our chief operating decision makers. We currently market Actimmune in the United States for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis; Infergen in the United States and Canada for chronic HCV infections; and Amphotec worldwide for invasive aspergillosis.

Our net revenues by product for the years ended December 31, are as follows (in thousands):

	2004	2003	2002
Actimmune	$124,980	$141,402	$105,802
Infergen	22,307	9,276	2,931
Amphotec	2,765	3,460	3,232
Co-promotion revenue	935	—	—
Totals	$150,987	$154,138	$111,965

Our net revenue by region for the years ended December 31, are as follows (in thousands):

	2004	2003	2002
United States	$148,594	$151,373	$109,537
Rest of world	2,393	2,765	2,428
Totals	$150,987	$154,138	$111,965

16. RELATED PARTY TRANSACTIONS

On October 29, 2004 we entered into an Amended and Restated Standstill Agreement with Warburg Pincus Equity Partners, L.P. and certain of its affiliates ("Warburg Pincus") that permits Warburg Pincus to acquire up to 25% of our outstanding common stock in the open market. Under this agreement, Warburg Pincus may acquire up to 25% of our outstanding common stock and have granted Warburg Pincus certain registration rights with respect to its holdings. In exchange for allowing Warburg Pincus to increase its ownership stake, Warburg Pincus has granted the independent members of our board of directors the right to vote the shares of InterMune common stock owned by Warburg Pincus in excess of 19.9%. In addition, Warburg Pincus has agreed to certain limitations on the manner in which it may dispose of its ownership interest in InterMune. In connection with this transaction, we have also amended our stockholder Rights Plan to allow Warburg Pincus to acquire up to 25% of our outstanding common stock in open market purchases. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P.

17. EMPLOYEE SAVINGS PLAN

On May 1, 1999, we adopted a 401(k) defined contribution plan that covers all full time employees, as defined, who fulfill certain length-of-service requirements. Employees may contribute up to the maximum limit imposed by federal tax law. As of December 31, 2004, we made no matching contributions under the 401(k) defined contribution plan.

18. LEGAL PROCEEDINGS

On June 25, 2003, a purported securities class action entitled Johnson v. Harkonen and InterMune, Inc., No. C 03-2954-MEJ, was filed in the United States District Court for the Northern District of California. Three additional class action complaints entitled Lombardi v. InterMune, Inc., Harkonen and Surrey-Barbari, No. C 03 3068 MJJ (filed on July 1, 2003); Mahoney Jr. v. InterMune Inc.,

Harkonen and Surrey-Barbari, No. C 03-3273 SI (filed on July 14, 2003); and Adler v. Harkonen and InterMune Inc., No. C 03-3710 MJJ (filed on August 3, 2003), were filed in the same court, each making identical or similar allegations against us, our former chief executive officer and former chief financial officer. On November 6, 2003, the various complaints were consolidated into one case by order of the court, and on November 26, 2003, a lead plaintiff, Lance A. Johnson, was appointed. A consolidated complaint titled In re InterMune Securities Litigation, No. C 03-2954 SI, was filed on January 30, 2004. The consolidated amended complaint named us, and our former chief executive officer and our former chief financial officer, as defendants and alleges that the defendants made certain false and misleading statements in violation of the federal securities laws, specifically Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. The lead plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 7, 2003 through June 11, 2003. We and the other defendants filed a motion to dismiss the complaint on April 2, 2004, which was granted in part and denied in part. Plaintiffs filed a second amended complaint on August 23, 2004, and the defendant filed in a motion to dismiss the second amended complaint on October 7, 2004. The motion is scheduled to be heard in April 2005. We believe that we have meritorious defenses to the allegations contained in the securities class action complaint and intend to defend ourselves vigorously. No trial date has been scheduled.

On July 30, 2003, a stockholder, Michael Adler, purporting to act on our behalf filed a derivative action entitled Adler v. Harkonen, et al., No. CIV 433125, in the California Superior Court for the County of San Mateo against our directors, our former chief executive officer and our former chief financial officer. We were also named as a nominal defendant solely in a derivative capacity. The derivative action is based on the same factual allegations and circumstances as the purported securities class actions and alleges state law claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. The derivative action seeks unspecified damages, injunctive relief and restitution. The court has sustained the two motions made by us and the other defendants on December 8, 2003 and April 29, 2004 to dismiss two successive complaints filed by the plaintiff on November 3, 2003 and March 25, 2004, respectively. The plaintiff filed his third amended complaint on July 30, 2004 and the defendants filed a motion to dismiss the third amended complaint on September 16, 2004. On November 23, 2004 judgment was entered dismissing the action with prejudice. On February 1, 2005 plaintiffs filed a notice of appeal. On March 8, 2005, defendants filed in the First District Court of Appeal a motion to dismiss the appeal on the ground that the notice of appeal was not filed timely, and the Court of Appeal therefore did not have jurisdiction. No trial date has been set. We believe that we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously.

On March 19, 2004, plaintiff Joan Gallagher filed an action against us and other defendants in the United States District Court for the Eastern District of Pennsylvania. Ms. Gallagher alleges that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Ms. Gallagher alleges that she was wrongfully terminated from InterMune in violation of public policy due to her refusal to engage in the alleged off-label marketing. We and the other defendants dispute Ms. Gallagher's claims and are vigorously defending the lawsuit. The defendants filed a motion to dismiss the complaint on May 4, 2004. Ms. Gallagher filed a first amended complaint on May 28, 2004, and the defendants filed a motion to dismiss the first amended complaint on June 10, 2004 on the grounds that Ms. Gallagher has failed to state any claim upon which relief may be granted under Pennsylvania law. The motion is pending. We believe that we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously.

On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune, including information regarding the promotion and marketing of Actimmune. We are cooperating with the Department of Justice in this inquiry. We cannot predict whether the outcome of this inquiry will have a material adverse effect on our business.

We believe that we have good defenses to the claims asserted in the securities class actions, the derivate action and the wrongful termination suit. These lawsuits may be costly and could prove to be time consuming and disruptive to normal business operations. There can be no assurance that we will prevail or that the cost of defending these lawsuits will be covered by our insurance policies. While it is not possible to predict accurately or to determine the eventual outcome of this litigation, an unfavorable outcome or settlement of this litigation could have a material adverse effect on our financial position, liquidity or results of operations.

19. GUARANTEES AND INDEMNIFICATIONS

In November 2002, the FASB issued Interpretation No. 45, *"Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others"* ("FIN 45"). FIN 45 requires that upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligations it assumes under that guarantee.

As permitted under Delaware law and in accordance with our Bylaws, we indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. We terminate the indemnification agreements with our officers and directors upon the termination of their employment, but the termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, our director and officer insurance policy limits our exposure and may enable us to recover a portion of any future amounts paid. Accordingly, we believe the fair value of these indemnification agreements is minimal. Therefore, we have not recorded any liabilities for these agreements as of December 31, 2004.

20. SUBSEQUENT EVENTS

On January 13, 2005, we entered into an operating lease agreement to sublease an additional 12,988 square feet of office space at our headquarters location. As a subtenant we will use the premises for general office and administrative purposes only. The sublease term is for 36 months at a total monthly base rent of $32,470.

21. QUARTERLY FINANCIAL DATA (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(In thousands, except per share amounts)				
2004					
Revenue, net					
Actimmune	$ 32,921	$ 31,349	$ 30,063	$ 30,647	$ 124,980
Infergen	3,999	3,929	6,223	8,156	22,307
Others	1,208	616	1,218	658	3,700
Total revenue, net	38,128	35,894	37,504	39,461	150,987
Cost of goods sold	9,688	8,843	12,270	10,061	40,862
Amortization and impairment of acquired product rights	777	776	774	776	3,103
Loss from operations	(7,290)	(12,110)	(8,948)	(22,104)	(50,452)
Net loss	(11,711)	(13,067)	(12,860)	(21,840)	(59,478)
Basic and diluted net loss per common share	$ (0.37)	$ (0.41)	$ (0.40)	$ (0.69)	$ (1.87)
2003					
Revenue, net					
Actimmune	$ 37,924	$ 33,073	$ 35,049	$ 35,356	$ 141,402
Infergen	1,650	1,909	2,468	3,249	9,276
Others	832	757	669	1,202	3,460
Total revenue, net	40,406	35,739	38,186	39,807	154,138
Cost of goods sold	9,787	7,925	9,427	9,170	36,309
Amortization and impairment of acquired product rights	940	940	5,701	777	8,358
Loss from operations	(17,632)	(18,960)	(33,012)	(21,384)	(90,988)
Net loss	(18,934)	(20,316)	(34,498)	(23,253)	(97,001)
Basic and diluted net loss per common share	$ (0.60)	$ (0.64)	$ (1.09)	$ (0.73)	$ (3.06)
2002					
Revenue, net					
Actimmune	$ 17,714	$ 22,596	$ 28,530	$ 36,962	$ 105,802
Infergen	127	310	1,033	1,461	2,931
Others	911	752	674	895	3,232
Total revenue, net	18,752	23,658	30,237	39,318	111,965
Cost of goods sold	5,403	4,742	6,095	7,921	24,161
Amortization and impairment of acquired product rights	815	815	1,024	939	3,593
Loss from operations	(44,372)	(29,667)	(42,996)	(24,846)	(141,881)
Net loss	(45,128)	(30,097)	(43,480)	(25,604)	(144,309)
Basic and diluted net loss per common share	$ (1.58)	$ (0.97)	$ (1.39)	$ (0.81)	$ (4.72)

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures. Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as a result of the material weakness in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective as of the end of the period covered by this annual report.

Management's Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control system was designed to provide reasonable assurance to management and our board of directors regarding the reliability of financial reporting and preparation of published financial statements in accordance with generally accepted accounting principles.

A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A significant deficiency is a control deficiency, or combination of control deficiencies, that adversely affects the company's ability to initiate, authorize, record, process, or report external financial data reliably in accordance with generally accepted accounting principles such that there is a more than a remote likelihood that a misstatement of the company's annual or interim financial statements that is more than inconsequential will not be prevented or detected. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we have assessed the effectiveness of our internal control over financial reporting as of December 31, 2004, and as a result of this assessment, we have concluded that we have a material weakness in our financial statement close process. Management identified a material weakness for insufficient controls related to the preparation and review of the annual consolidated financial statements and accompanying footnote disclosures in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. The insufficient controls include a lack of finance staff with the proficiency to interpret such principles and rules, and inadequate review and approval procedures to prepare external financial statements in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. As a result of this material weakness, management made material revisions to the 2004 annual consolidated financial statements and footnote disclosures before they were issued.

In making our assessment of internal control over financial reporting, we used the criteria issued in the report Internal Control-Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission. Because of the material weakness described above, our management has concluded that our internal control over financial reporting was not effective as of December 31, 2004 based on these criteria.

Our independent registered public accounting firm has issued an attestation report on management's assessment of our internal control over financial reporting which is included elsewhere herein.

Changes in Internal Control over Financial Reporting. During the fourth quarter of 2004 we employed a new CFO and a new Controller, and contracted two outside consultants to add support to the

financial reporting process and the year-end close. At that time we also began an evaluation of our finance staffing and organization, which resulted in the termination of certain employees and a reallocation of accounting responsibilities within the finance department. In January 2005 we hired three additional personnel with the required technical accounting expertise to improve our financial statement close process. We intend to continue to improve our financial statement close process in 2005 including the remediation of the identified material weakness discussed above by hiring and training personnel with the appropriate accounting and SEC reporting skills required.

Limitations on the Effectiveness of Controls. Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant expect to file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for our Annual Meeting of Stockholders to be held at 9:45 a.m. on May 26, 2005 (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Identification of Directors and Executive Officers

The information required by this Item with respect to Executive Officers may be found under the caption, "Executive Officers of the Registrant" at the end of Item 1 of this Annual Report on Form 10-K. The information required by this Item with respect to Directors, including information with respect to our audit committee financial expert and the identification of our audit committee, is incorporated herein by reference from the information under the caption "Proposal 1—Election of Directors" contained in the Proxy Statement.

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by this Item with respect to compliance with Section 16(a) of the Exchange Act is incorporated herein by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

Code of Business Conduct and Ethics

The information required by this Item with respect to our code of ethics is incorporated herein by reference from the section captioned "Proposal 1—Election of Directors—Code of Business Ethics and Conduct" contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the information under the sections entitled "Executive Compensation" and "Compensation Committee Interlocks and Insider Participation" contained in the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated herein by reference to the information under the caption "Executive Compensation—Certain Relationships and Related Transactions" contained in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Proposal 2—Ratification of Selection of Independent Auditors."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) ***Financial Statements***

See Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K.

(2) ***Financial Statement Schedules***

The following financial statement schedule is filed as part of this Annual Report on Form 10-K. All other financial statement schedules have been omitted because they are either not applicable or the required information has been included in the consolidated financial statements or the notes thereto.

Schedule II

InterMune, Inc.
Valuation and Qualifying Accounts and Reserves
Years ended December 31, 2004, 2003 and 2002

Description	Balance at beginning of year	Charged to revenue or expense	Utilizations	Balance at end of year
		(In thousands)		
Allowance for doubtful accounts, product returns, chargebacks, and rebates:				
Year Ended December 31, 2004	$2,977	$12,465	$ (12,039)	$3,403
Year Ended December 31, 2003	3,415	12,495	(12,933)	2,977
Year Ended December 31, 2002	949	10,811	(8,345)	3,415
Reserves of excess inventory and non-cancelable purchase obligations:				
Year Ended December 31, 2004	$ 921	$ 4,723	$ (996)	$4,648
Year Ended December 31, 2003	—	1,292	(371)	921
Year Ended December 31, 2002	—	—	—	—

(3) *Exhibits*

NUMBER		DESCRIPTION OF DOCUMENT
3.1		Certificate of Incorporation of Registrant.(1)
3.2		Certificate of Ownership and Merger, dated April 26, 2001.(10)
3.3		Bylaws of Registrant.(1)
3.4		Certificate of Amendment of Certificate of Incorporation of Registrant.(16)
3.5		Certificate of Amendment of Amended and Restated Certificate of Incorporation of Registrant.(24)
3.6		Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock.(8)
4.1		Specimen Common Stock Certificate.(1)
4.6		Indenture, dated as of February 17, 2004, between Registrant and The Bank of New York.(20)
4.7		Registration Rights Agreement, dated as of February 17, 2004, among Registrant, Morgan Stanley & Co. Incorporated, Banc of America Securities LLC, Credit Suisse First Boston LLC, Harris Nesbitt Corp. and RBC Capital Markets Corporation.(20)
10.1	+	Form of Indemnity Agreement.(1)
10.2	+	1999 Equity Incentive Plan and related documents.(1)
10.3	+	Stock option grant notice, stock option agreement and notice of exercise for 2000 Equity Incentive Plan.(2)
10.4	+	2000 Employee Stock Purchase Plan and related documents.(1)
10.5	+	Annual stock option grant notice and initial stock option grant notice for 2000 Non-Employee Directors' Stock Option Plan.(14)
10.6		Amended and Restated Investor Rights Agreement, dated January 7, 2000, between Registrant and certain holders of the common stock.(1)
10.7		Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(8)
10.19	*	Data Transfer, Clinical Trial, and Market Supply Agreement, dated January 27, 1999, between the Registrant and Boehringer Ingleheim.(1)
10.20	+	Form of Change of Control Provisions for Officers.(3)
10.24		Assignment and Option Agreement, dated June 23, 2000, between Registrant and Connetics Corporation.(4)
10.25		Consent to Assignment Agreement, dated June 23, 2000, between Registrant, Connetics Corporation and Genentech, Inc.(4)
10.27		Notice re: Return of Rights to Gamma Interferon for Treatment of Infectious Diseases in Japan, dated July 25, 2000, between Registrant and Genentech, Inc.(4)
10.29		Form of Common Stock Purchase Agreement, dated August 11, 2000, between the Company and Investors.(5)
10.31		Lease Agreement, dated December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.32		First Amendment to Brisbane Technology Park Lease, effective as of December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.34		Product Acquisition Agreement, dated January 2, 2001, between Registrant and ALZA Corporation.(7)
10.35		Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(7)
10.38		Amendment No. 5, dated January 25, 2001, to License Agreement, dated May 5, 1998, between Registrant and Genentech, Inc.(7)
10.39	*	License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen, Inc.(9)

NUMBER		DESCRIPTION OF DOCUMENT
10.40		Letter Amendment, dated August 1, 2001, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(10)
10.41	*	Agreement for Consulting Services, dated August 1, 2001, between Registrant and The SGO Group LLC.(10)
10.42	*	Asset Purchase and License Agreement, dated September 19, 2001, between Registrant and Eli Lilly and Company.(10)
10.43	*	Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(11)
10.45	+	2000 Equity Incentive Plan, as amended as of June 19, 2002.(12)
10.46	+	2000 Non-Employee Directors' Stock Option Plan, amended as of May 29, 2003.(16)
10.47	+	Employment Offer Letter, dated April 5, 2002, between Registrant and Marianne Armstrong, Ph.D.(13)
10.48	+	Bonus Plan Memorandum, dated April 18, 2002, from Registrant to Marianne Armstrong, Ph.D.(13)
10.49	+	Secured Promissory Note, dated May 1, 2002, between Registrant and Marianne Armstrong, Ph.D.(13)
10.50	*	Amendment No. 1, dated April 26, 2002, to the Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(13)
10.51	*	Amendment No. 1, dated April 25, 2002, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc.(13)
10.52	*	First Amendment, dated June 19, 2002, to the Data Transfer, Clinical Trial and Market Supply Agreement, dated January 27, 2000, between Registrant and Boehringer Ingelheim International GmbH.(13)
10.53		Letter Amendment, dated May 28, 2002, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(13)
10.54		Letter Amendment, dated July 1, 2002, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(13)
10.57	*	Amendment No. 4, dated January 28, 2003, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(15)
10.58	+	Employment Offer Letter, dated April 30, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(16)
10.59	+	Bonus Plan Memorandum, dated May 22, 2002, from Registrant to Lawrence M. Blatt, Ph.D.(16)
10.60	+	Promissory Note, dated May 22, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(16)
10.62	+	Employment Offer Letter, dated July 2, 2003, between Registrant and Roger L. Hawley.(16)
10.64	*	Amendment No. 2 to Data Transfer, Clinical Trial and Market Supply Agreement, dated January 27, 2000, between Registrant and Boehringer Ingelheim Austria, GmbH.(18)
10.65	+	Employment Offer Letter, dated September 24, 2003, between Registrant and Daniel G. Welch.(17)
10.68	*	License Agreement, dated March 29, 2002, among Registrant, Marnac, Inc., KDL, Inc., KDL GmbH, Dr. Solomon Margolin and Dr. Shitotomo Yamauchi.(21)
10.69	+	Stock Bonus Award Agreement, dated November 5, 2003, between Registrant and William R. Ringo, Jr.(19)

NUMBER		DESCRIPTION OF DOCUMENT
10.74		Aralast Promotion Agreement, dated as of March 26, 2004, by and between Registrant and Baxter Healthcare Corporation.(23)
10.75		Consulting Agreement by and between Registrant and Peter Van Vlasselaer dated April 2, 2004.(22)
10.76	+	Separation and Consulting Agreement, dated as of May 7, 2004, between the Registrant and Stephen N. Rosenfield.(25)
10.77	+	Employment Offer Letter Agreement, dated October 19, 2004, between Registrant and Norman L. Halleen.(26)
10.79		Amended and Restated Standstill Agreement, dated October 29, 2004, among Registrant, Warburg Pincus & Co. and certain affiliates of Warburg Pincus & Co.(27)
10.80		Registration Rights Agreement, dated October 29, 2004, among Registrant, Warburg Pincus & Co. and certain affiliates of Warburg Pincus & Co.(27)
10.81		Amendment, dated October 29, 2004 to Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(27)
10.82	+	Employment Offer Letter Agreement, dated October 29, 2004 and effective as of November 1, 2004, between Registrant and Cynthia Robinson.(27)
10.83	+	Employment Offer Letter Agreement, dated June 13, 2001, between Registrant and Williamson Bradford, M.D., Ph.D.
10.84	+	Employment Offer Letter Agreement, dated May 14, 2004, between Registrant and Thomas Kassberg.
10.85	+	Employment Offer Letter Agreement, dated June 1, 2001, between Registrant and Steven Porter, M.D., Ph.D.
10.86		Employment Offer Letter Agreement, dated August 9, 2004, between Registrant and Robin Steele.
10.87	+	Salary Information for Executive Officers.
10.88	+	Compensation Arrangements with Non-Employee Directors.
10.89	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 18, 2004, between Registrant and Marianne Armstrong, Ph.D.
10.90	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 18, 2004, between Registrant and Lawrence M. Blatt, Ph.D.
10.91	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 27, 2004, between Registrant and Williamson Bradford, M.D., Ph.D.
10.92	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 26, 2004, between Registrant and Roger L. Hawley.
10.93	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 10, 2004, between Registrant and Thomas Kassberg
10.94	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 26, 2004, between Registrant and Steven Porter, M.D., Ph.D.
10.95	+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 27, 2004, between Registrant and Howard A. Simon, Esq.
10.96	**	Amendment No. 2, dated December 31, 2004, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc.
10.97	**	Amendment No. 3, dated December 31, 2004, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc.
21.1		List of Subsidiaries.
23.1		Consent of Independent Registered Public Accounting Firm.
24.1		Power of Attorney (included on the signature pages hereto).
31.1		Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2		Certification required by Rule 13a-14(a) or Rule 15d-14(a).

NUMBER		DESCRIPTION OF DOCUMENT
32.1	†	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

\+ Management contract or compensation plan or arrangement.

† This certification accompanies the Periodic Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

(1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 2, 2000 (No. 333-96029), as amended by Amendment No. 1 filed with the Commission on February 18, 2000, as amended by Amendment No. 2 filed with the Commission on March 6, 2000, as amended by Amendment No. 3 filed with the Commission on March 22, 2000, as amended by Amendment No. 4 filed with the Commission on March 23, 2000 and as amended by Amendment No. 5 filed with the Commission on March 23, 2000.

(2) Incorporated by reference to pages 16 through 26 of Exhibit 10.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 18, 2000 (No. 333-45460).

(3) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.

(4) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(5) Filed as an exhibit to the Registrant's Current Report on Form 8-K on August 23, 2000.

(6) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.

(7) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

(8) Filed as an exhibit to the Registrant's Current Report on Form 8-K on July 18, 2001.

(9) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(10) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(11) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.

(12) Filed as an exhibit to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on July 12, 2002 (No. 333-92276).

(13) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2002.

(14) Incorporated by reference to pages following page 10 of Exhibit 10.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 18, 2000 (No. 333-45460).

(15) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2003.

(16) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2003.

(17) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2003.

(18) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended September 30, 2003.

(19) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

(20) Filed as an exhibit to the Registrant's amended Annual Report on Form 10-K/A (Amendment No. 1) for the year ended December 31, 2003.

(21) Filed as an exhibit to the Registrant's amended Annual Report on Form 10-K/A (Amendment No. 2) for the year ended December 31, 2003.

(22) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2004.

(23) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended March 31, 2004.

(24) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2004.

(25) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended June 30, 2004.

(26) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2004.

(27) Filed as an exhibit to the Registrant's Current Report on Form 8-K on November 4, 2004.

(c) Exhibits

See Item 15(a) above.

(d) Financial Statement Schedules

See Item 15(a) above.

SIGNATURES

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

INTERMUNE, INC.

By: /s/ NORMAN L. HALLEEN
Norman L. Halleen
Senior Vice President of Finance Administration and Chief Financial Officer

Dated: March 16, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Norman L. Halleen and Daniel G. Welch, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other 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 therewith, 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, and any of them or his 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, the following persons on behalf of the registrant and in the capacities and on the dates indicated have signed this Report below:

Signatures	Title	Date
/s/ WILLIAM R. RINGO, JR. William R. Ringo, Jr.	Chairman of the Board of Directors	March 16, 2005
/s/ DANIEL G. WELCH Daniel G. Welch	President and Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2005
/s/ NORMAN L. HALLEEN Norman L. Halleen	Senior Vice President of Finance Administration and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2005
/s/ WILLIAM A. HALTER William A. Halter	Director	March 16, 2005
/s/ JAMES I. HEALY James I. Healy	Director	March 16, 2005
/s/ THOMAS R. HODGSON Thomas R. Hodgson	Director	March 16, 2005
/s/ JONATHAN S. LEFF Jonathan S. Leff	Director	March 16, 2005
/s/ MICHAEL L. SMITH Michael L. Smith	Director	March 16, 2005

EXECUTIVE MANAGEMENT

Daniel G. Welch
President and Chief Executive Officer

Roger L. Hawley
Executive Vice President of
Commercial and Technical
Operations

Marianne T. Armstrong, Ph.D.
Senior Vice President of Regulatory,
Medical Affairs and Drug Safety

Norman L. Halleen
Senior Vice President of Finance
and Chief Financial Officer

Lawrence M. Blatt, Ph.D.
Senior Vice President of Preclinical
and Applied Research

Thomas R. Kassberg
Senior Vice President of Business
Development and Corporate Strategy

Steven B. Porter, M.D., Ph.D.
Senior Vice President
of Clinical Affairs

Howard A. Simon, Esq., SPHR
Senior Vice President of
Human Resources and
Associate General Counsel

Robin J. Steele, Esq.
Senior Vice President, General Counsel
and Corporate Secretary

Cynthia Y. Robinson, Ph.D.
Senior Vice President of
Therapeutic Area Teams

Williamson Z. Bradford, M.D., Ph.D.
Vice President of Clinical Science

BOARD OF DIRECTORS

William R. Ringo
Chairman of the Board
President and Chief Executive Officer
Abgenix, Inc.

Daniel G. Welch
President and Chief Executive Officer
InterMune, Inc.

William A. Halter
Former Acting Commissioner
and Deputy Commissioner
Social Security Administration of the
United States of America

BOARD OF DIRECTORS (CONT'D)

James I. Healy, M.D., Ph.D.
Managing Director and Vice President
Sofinnova Ventures

Thomas R. Hodgson
Former President
and Chief Operating Officer
Abbott Laboratories

Jonathan S. Leff
Partner
Warburg Pincus LLC

Michael L. Smith
Retired Executive Vice President
and Chief Financial Officer
Wellpoint, Inc.

ANNUAL MEETING

The annual stockholders meeting will be held on May 26, 2005 at 9:00 a.m. at InterMune, Inc., 3280 Bayshore Boulevard, Brisbane, CA

LEGAL COUNSEL

Cooley Godward LLP
Palo Alto, CA

CORPORATE SECRETARY

Robin J. Steele, Esq.
Senior Vice President, General Counsel
and Corporate Secretary

INDEPENDENT AUDITORS

Ernst & Young LLP
Palo Alto, CA

TRANSFER AGENT

Mellon Investor Services LLC
235 Montgomery Street, 23rd Floor
San Francisco, CA 94104
(800) 356-2017

STOCK LISTING

Symbol: ITMN
Stock Exchange: NASDAQ

CORPORATE HEADQUARTERS

3280 Bayshore Boulevard
Brisbane, CA 94005
(415) 466-2200
(415) 466-2300

WEBSITES

www.intermune.com
www.infergen.com
www.actimmune.com
www.inspiretrial.com
www.directtrial.com

INVESTOR SERVICES

Investor Relations
InterMune, Inc.
3280 Bayshore Boulevard
Brisbane, CA 94005
Phone: (415) 466-2200
www.intermune.com
ir@intermune.com

Stockholder Information Since our initial public offering of common stock, $0.001 par value, on March 24, 2000, our common stock has been traded on the NASDAQ National Market under the symbol ITMN. As of February 28, 2005, there were 121 stockholders of record. No cash dividends have been paid to date by us, and we do not anticipate the payment of dividends in the foreseeable future.

Forward-Looking Statements/Risk Factors
Except for the historical information contained herein, this letter contains certain forward-looking statements that involve risks and uncertainties, including without limitation, the statements indicating that InterMune: (i) has several development programs with potential to address unmet medical needs in hepatology and pulmonology; (ii) believes that once-daily doses of Infergen in combination with ribavirin may provide a cure for HCV nonresponders; (iii) believes that Infergen in combination with Actimmune may have a synergistic effect; (iv) believes that HCV protease inhibitors may inhibit replication of the HCV virus and could provide an important component of first-line treatment of HCV patients; (v) expects to move forward with a Phase III development program for pirfenidone in IPF; (vi) expects a year of strong growth in Infergen sales and meaningful progress in its late-stage clinical development programs; and (vii) expects to complete enrollment of any particular clinical trial and to report data relating to any such trial by a specified date. Factors that could cause actual results or outcomes to differ materially from those expressed in any forward-looking statement include, but are not limited to, those discussed in our Form 10-K filed with the SEC on March 16, 2005 and enclosed herewith (our "Form 10-K"), including the factors discussed in detail under the heading "Risk Factors" in Item 1 of our Form 10-K. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date of this letter to reflect the occurrence of unanticipated events.

INTERMUNE®

Corporate Headquarters

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