INTERMUNE

INC

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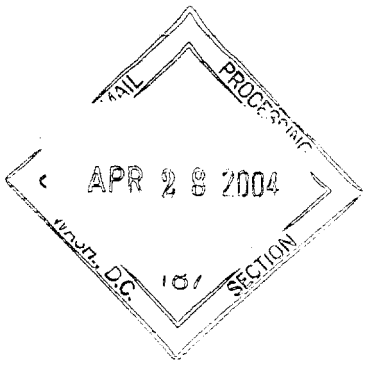
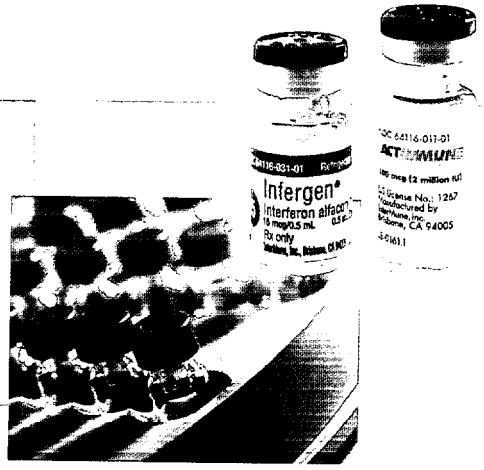




Annual Report 2003

Leveraging Core Expertise with Strategic Partnerships One of our key guiding principles is to leverage our commercial and development organizations through co-promotional and co-development partnerships. We plan to more fully leverage our commercial capabilities by establishing appropriate co-promotion agreements in hepatology and pulmonology. In early 2004 we announced a partnership with Baxter to co-promote Aralast® (alpha1-proteinase inhibitor (human)) for the treatment of hereditary emphysema to pulmonologists in the United States. This is a first step towards optimizing the efficiency of our commercial organization.

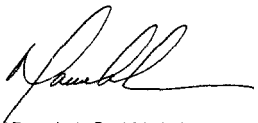
In addition, we have an abundance of development opportunities in the areas of hepatology and pulmonology. We realize that a company of our size must seek partnerships to appropriately advance our wealth of development options. One program where this is especially appropriate is our PEG-Alfacon program. In 2003, we completed a Phase I trial, and the results demonstrated that PEG-Alfacon has an attractive pharmacokinetic, pharmacodynamic and safety profile. We are excited about the potential of PEG-Alfacon to treat patients with chronic HCV. However, we recognize that this development program will be lengthy and very expensive, and that the duration and expense carry significant risk. Accordingly, we are considering alternative development plans and business collaborations that could increase the speed and mitigate the risk and the expense of this program.

Creating Near-Term Value From Non-Core Assets Consistent with our focus on hepatology and pulmonology, InterMune intends to capture near-term value from non-core assets. We are seeking a partner to assume the future development investment in oritavancin, a novel hospital-based glycopeptide antibiotic agent. In addition, we are working to divest Amphotec®, an antifungal agent. While oncology is no longer a core area, we have decided to maintain control of the rights to Actimmune in oncology. Our 847-patient Phase III clinical trial of Actimmune plus standard therapy in ovarian cancer was fully enrolled in April 2004. InterMune will make a decision on the future of this program upon interim analysis of progression-free survival data, anticipated to occur in mid-2005.

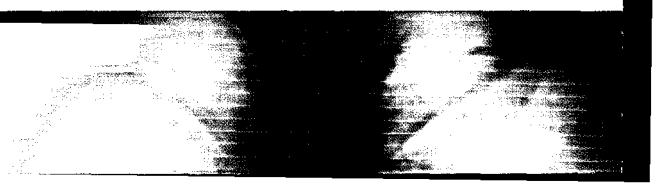
Enhanced Fiscal and Corporate Discipline We have already succeeded in significantly reducing overall research and development expenses while increasing investment in our core hepatology and pulmonology programs. We have narrowed our therapeutic focus from four areas to two and realigned our organization around these areas. We will also pursue strategic partnerships that will help to further decrease our rate of cash burn, increase development speed, mitigate risk and further maximize value for shareholders.

2004 – Charting A New Course This year promises to be a period of progress and advancement for InterMune. We now have a strong foundation on which to build our Company: a new focused vision, a new strategic plan, a new management team, a new organizational structure and a new positive and constructive culture. We intend to leverage our considerable capabilities and expertise to address the important, unmet medical needs of patients with serious life-threatening diseases in the areas of hepatology and pulmonology. InterMune has charted a new course for the future, and we are working to achieve our vision of becoming a leader in the development and commercialization of innovative medicines for hepatology and pulmonology. I look forward to updating you on our progress throughout the year.

Sincerely,



Daniel G. Welch
CEO and President



First-line therapy for naïve HCV patients is treatment with pegylated interferons plus ribavirin. This treatment regimen is only effective in approximately half of the HCV patients treated, while the other half do not respond (nonresponders) or relapse. There are approximately 150,000 nonresponders in the United States, and this number is growing by an estimated 50,000 each year. InterMune's near term clinical programs in hepatology are focused on expanding treatment options for this seriously underserved patient population.

Infergen® (Interferon alfacon-1), which is indicated for the treatment of adults with chronic HCV infections, is currently the only FDA approved interferon with data in its label specifically for retreatment of nonresponder or relapsing patients. InterMune intends to make Infergen an important source of revenue growth and has significantly increased its commercial efforts on Infergen, focusing on the large, rapidly growing and underserved market of HCV nonresponders.

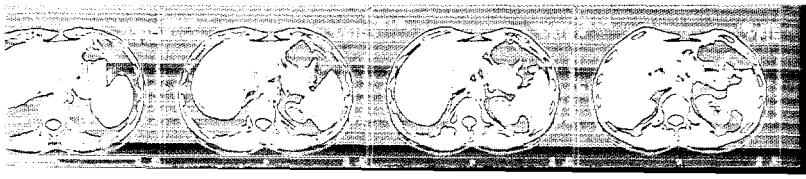
Throughout 2003, promising data were presented demonstrating that Infergen, in combination with ribavirin, may have the potential to address the unmet medical need of HCV nonresponders. Based on these data, InterMune is planning to initiate a Phase III clinical trial of Infergen and ribavirin combination therapy in the nonresponder patient population in the first half of 2004.

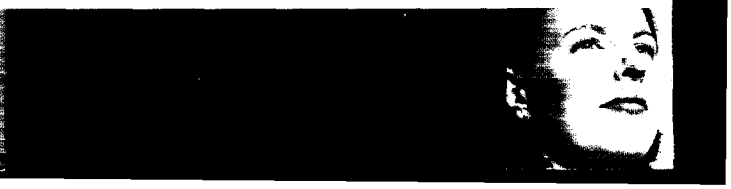
We are also particularly excited by the prospects of combining our two interferon products, Infergen and Actimmune® (Interferon gamma-1b) for the treatment of HCV nonresponders. There is strong scientific rationale for the use of these two compounds in combination. We believe that our pioneering in vitro experiments in models of HCV have demonstrated synergistic effects for a range of doses of Infergen and Actimmune in combination. We have also observed promising results from an independent retrospective clinical analysis evaluating the use of Infergen plus Actimmune for the treatment of HCV nonresponders. We believe that this combination therapy may represent a significant opportunity for InterMune, and the company plans on advancing this clinical program in the first half of 2004 with a Phase II study.

InterMune is also working on small molecule approaches to treating HCV that are rapidly progressing to preclinical development. Along with our partner, Array Biopharma, we have identified and characterized several highly potent protease inhibitor candidates with improved bioavailability over competitive compounds.

Industry Leader in the Development of Innovative Therapies for IPF In the area of pulmonology, InterMune continues to be committed to developing therapies for the treatment of idiopathic pulmonary fibrosis (IPF). IPF is a disease characterized by progressive scarring or fibrosis of the lungs, which ultimately results in death; there is no FDA approved therapy. InterMune is developing Actimmune and pirfenidone, which we believe are the two most promising and clinically advanced compounds for the treatment of this condition. Our pivotal Phase III INSPIRE Trial, which is designed to evaluate the impact of Actimmune on survival time in IPF patients with mild-to-moderate disease, is enrolling patients at sites in North America and Europe. The trial was designed in collaboration with key IPF thought leaders and is based on survival observations from previous randomized controlled trials of Actimmune for the treatment of patients with IPF (including InterMune's 330-patient randomized, double-blind, placebo controlled Phase III clinical trial, GIPF-001).

We are also enthusiastic about the promise of pirfenidone, a molecule with broad in vitro biological activity. Results of Phase II trials with pirfenidone in IPF have been encouraging. In March 2004, InterMune obtained Orphan Drug Designation for the use of pirfenidone in IPF. We expect to complete the clinical data analysis, and pre-clinical and manufacturing activities required to begin our IPF registration program in the first half of 2005.





I am very excited to be leading InterMune at this pivotal stage in its evolution.

I assumed leadership last September, because I believed that InterMune had the necessary elements to create a strong and sustainable biopharmaceutical company: a talented and dedicated workforce, a revenue stream and a rich late-stage development pipeline in pulmonology and hepatology.

However, it was also apparent that in order to grow and thrive, we needed to make some philosophical and organizational changes at InterMune. Thus, in the closing months of 2003, we worked diligently to complete a detailed strategic plan and implement changes that we believe have positioned the company for a promising future.

We have established three key goals or operating principles:

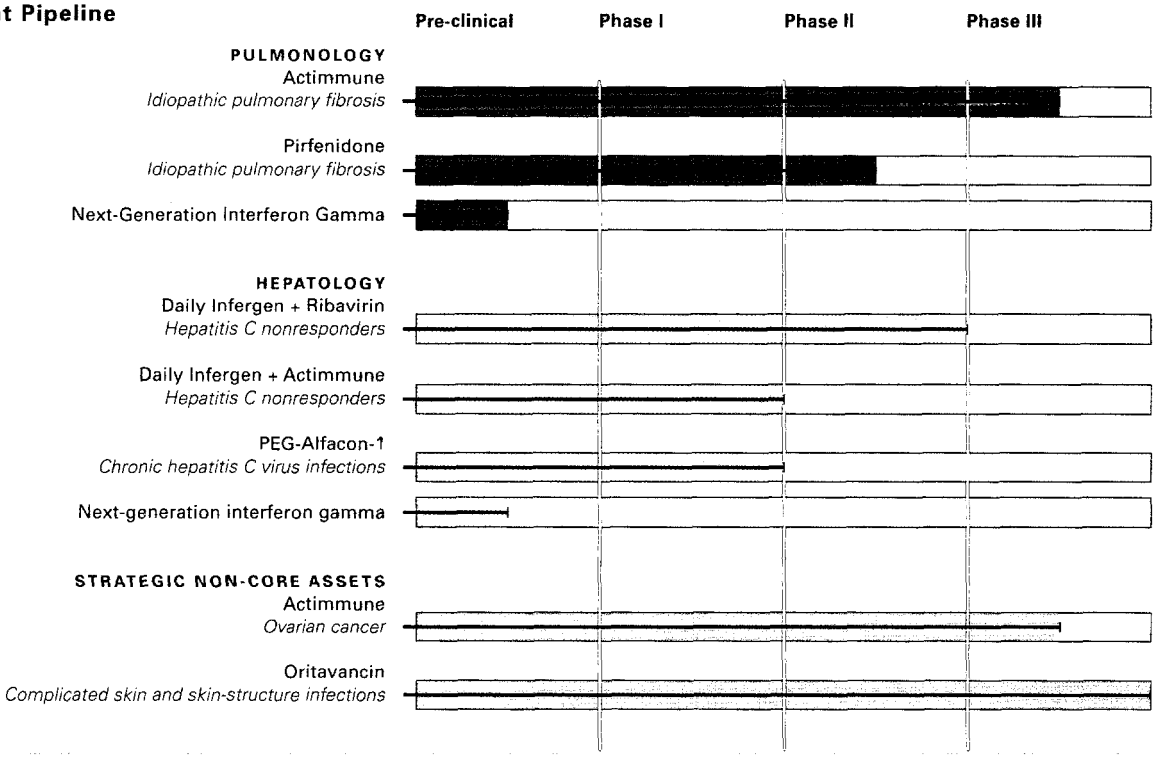
1) Maximize the Value of Our Hepatology Franchise;
2) Maximize the Value of Our Pulmonology Franchise;
3) Achieve Financial Self-Sufficiency in 2006.

In order to achieve these goals we are focused on: advancing our late-stage development programs in hepatology and pulmonology; leveraging core expertise with strategic partnerships; creating near-term value from non-core assets; and enhancing fiscal and corporate discipline. Over the next few paragraphs, I will discuss these efforts with you.

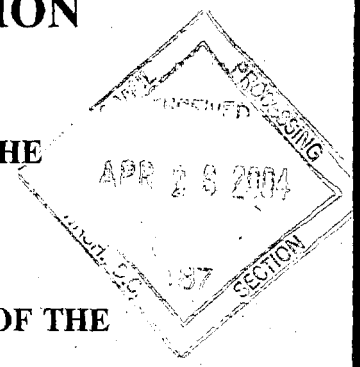
InterMune has successfully charted a new course for the future, and we are working to achieve our vision of becoming a leader in the development and commercialization of innovative medicines for hepatology and pulmonology. I am excited to share the details with you.

One of the Strongest Hepatology Pipelines in the Industry Over the last year, our hepatology portfolio has risen to prominence as a major development opportunity. InterMune is currently conducting clinical research to lead the development of new treatment paradigms for HCV and expand the options for patients suffering from chronic hepatitis C.

Development Pipeline



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549



FORM 10-K

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

For the fiscal year ended December 31, 2003

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)	(I.R.S. Employer Identification No.)

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

(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 Rule 12b-2 of the Act). Yes ☒ No ☐

As of June 30, 2003, 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 $364,827,192. Excludes an aggregate of 9,249,937 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, 2003. 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 29, 2004, the number of outstanding shares of the registrant's Common Stock was 31,878,929 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2004 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, 2003

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PART 1

ITEM 1. BUSINESS

Forward Looking Statements

This Annual Report on Form 10-K 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, such as 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.

We believe it is important to communicate our expectations to our investors. However, there may be events in the future that we are not able to predict accurately or which we do not fully control that could cause actual results to differ materially from those expressed or implied in our forward-looking statements. Because these forward-looking statements involve risks and uncertainties, there are important factors that could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, but not limited to, the following:

- regulatory, supply and competitive factors;
- general economic conditions;
- the uncertain, lengthy and expensive clinical development and regulatory process;
- whether we will be able to obtain, maintain and enforce patent and other intellectual property rights;
- changes in budget constraints;
- reimbursement risks associated with third-party payors;
- patient enrollment and retention in clinical trials;
- changes in industry practices; and
- one-time events.

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 statements. 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. In 2003, we reorganized our business by curtailing investment in non-core areas and focusing our commercial and development efforts in pulmonology and hepatology. We have a stable revenue base provided primarily by our two core marketed products, advanced-stage clinical programs addressing a range of unmet medical needs with attractive potential commercial markets, and several strategic non-core assets that we believe provide us the opportunity to create value. In 2003, our total product revenues increased 38% to $154.1 million for the year ended December 31, 2003, from $112.0 million for the year ended December 31, 2002.

Our two core marketed products are Actimmune® (interferon gamma-1b), approved for the treatment of severe, malignant osteopetrosis and chronic granulomatous disease, or CGD, and Infergen® (consensus interferon alfacon-1), approved for the treatment of chronic hepatitis C virus, or HCV, infections.

We have a late-stage development pipeline in the areas of pulmonology and hepatology. In pulmonology, we are developing two therapies for the treatment of idiopathic pulmonary fibrosis, or IPF. IPF is a fatal disease for which there is no FDA approved therapy. We believe that there are approximately 83,000 patients with IPF in the United States. We are developing what we believe to be the two most promising and clinically advanced compounds for the treatment of IPF—Actimmune and pirfenidone. We initiated a pivotal Phase III clinical trial of Actimmune for the treatment of patients with IPF 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®. We expect to announce our plans regarding a clinical development program for pirfenidone in 2004.

In hepatology, we are focused on expanding treatment options for patients suffering from HCV infections. 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 the current standard of care, pegylated interferon-alpha 2 in combination with ribavirin therapy. These patients are referred to as hepatitis C nonresponders. We believe that there are approximately 150,000 hepatitis C nonresponders in the United States. In investigator-sponsored clinical trials in hepatitis C nonresponders, once-daily treatment with Infergen in combination with ribavirin therapy has shown an approximately three-to-four-times higher sustained virologic response rate, the most commonly used measure of treatment effectiveness, than the rate observed in nonresponders who have been treated with pegylated interferon-alpha 2 in combination with ribavirin therapy. We expect to initiate a Phase III clinical trial of once-daily treatment with Infergen in combination with ribavirin therapy for

hepatitis C nonresponders in the first half of 2004. In addition, we are developing once-daily Infergen in combination with Actimmune for the treatment of hepatitis C nonresponders. We expect to initiate a Phase II clinical trial of this combination in the first half of 2004. We are also evaluating development options and business collaborations for a pegylated form of Infergen, PEG-Alfacon-1, for the treatment of chronic HCV infections. We completed our Phase I clinical trial of PEG-Alfacon-1 for the treatment of chronic HCV infections in 2003.

We also have strategic assets that do not fit within our core focus areas of pulmonology and hepatology. These assets are oritavancin, Amphotec® and Actimmune for the treatment of ovarian cancer. We believe that these non-core assets provide us the opportunity to create value through strategic divestiture and partnering arrangements.

The following chart shows the status of our development programs as of February 29, 2004:

	Pre-clinical	Phase I	Phase II	Phase III
Pulmonology				
Actimmune				
Idiopathic pulmonary fibrosis				X
Pirfenidone				
Idiopathic pulmonary fibrosis			X	
Next-generation interferon gamma	X			
Hepatology				
Daily Infergen + Ribavirin				
Hepatitis C nonresponders				X
Daily Infergen + Actimmune				
Hepatitis C nonresponders			X	
PEG-Alfacon-1				
Chronic hepatitis C virus infections		X		
Next-generation interferon gamma	X			
Strategic Non-Core Assets				
Actimmune				
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 an advanced-stage development pipeline. We also intend to capture value from our strategic non-core assets.

The key elements of our strategy for achieving these objectives include:

Focus our development efforts in the areas of pulmonology and hepatology. InterMune formerly pursued development opportunities in the areas of pulmonology, hepatology, infectious disease and oncology. In order to effectively compete, manage our resources and sustain our business, we have

narrowed our focus to development and commercial efforts in only two of these therapeutic areas—pulmonology and hepatology.

Expand the number of indications for which the FDA approves Actimmune and Infergen as treatment, and obtain FDA approval for our other compounds in pulmonology and hepatology. We plan to develop Actimmune, Infergen and pirfenidone 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. We believe that daily Infergen in combination with ribavirin therapy may have potential to treat hepatitis C nonresponders. We believe that daily Infergen in combination with Actimmune may have potential to treat 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.

Partner or divest strategic non-core assets. Consistent with our focused strategy on pulmonology and hepatology, we intend to capture value from our assets outside these core areas, and are seeking partners for certain of these assets. In particular, we are looking for a partner to assume the future development investment in oritavancin and are in the process of divesting 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 an interim analysis regarding progression-free survival, which we anticipate receiving in the first half of 2005.

Increase sales of marketed products. Actimmune is approved by the FDA for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. We are continuing our marketing efforts in these small, but important, patient populations. In September 2003, we expanded our efforts to support Infergen for the treatment of hepatitis C nonresponders. In particular, we increased our sales force allocation to Infergen, increased our visibility at major medical meetings and sponsored several independent medical education symposia and seminars. We believe that the unmet need for effective treatments for hepatitis C nonresponders provides a significant opportunity for revenue growth.

Establish appropriate co-promotional alliances. One of InterMune's 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 co-promotional arrangements in pulmonology and hepatology. We believe that our commercial expertise and resources for such co-promotional arrangements will make us an attractive potential partner.

Establish appropriate co-development alliances. 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.

Invest in preclinical and applied research. We have a preclinical and applied research group focused on the preclinical development of compounds in pulmonology and hepatology that we believe are 6 to 24 months from human testing. 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 additional formulations to enable us to continue the development of our marketed and late-stage products.

Marketed Products

We have two marketed products—Actimmune and Infergen.

- **Actimmune® (interferon gamma-1b)**

Actimmune is approved by the FDA for the treatment of two rare congenital disorders: chronic granulomatous disease 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 rare disease.

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 rare 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 has similar rights in Europe and the rest of the world, to develop and commercialize Actimmune under the trade name Imukin. See "License and Other Agreements."

- **Infergen® (interferon alfacon-1)**

Infergen was approved by the FDA in 1997 for the treatment of chronic HCV infections in adult patients, 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 non-pegylated interferon alphas.

Chronic HCV infections. Almost four million Americans 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.

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. Attempted drug therapies include corticosteroids and immunosuppressants, 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, 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. We initiated a pivotal Phase III clinical trial of Actimmune for the treatment of IPF (GIPF-007) 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 or 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 more pneumonias were reported in the treated patients than in the placebo group, 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 mild-to-moderate 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 mild-to-moderate 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 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 placebo, and each patient enrolled will be followed for at least 24 months.

- **Pirfenidone for Idiopathic Pulmonary Fibrosis**

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. In May 2003, we concluded a 55-patient, proof-of-concept Phase II clinical trial of pirfenidone in IPF originally initiated by Marnac, Inc. 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 expect to complete the data analysis, preclinical work and manufacturing necessary to design and conduct a pirfenidone registration program for IPF. Once we have completed this work, we will announce our plans regarding the clinical program for pirfenidone. We expect that we will file an amendment to our investigational new drug application, or IND, prior to commencing further clinical trials of pirfenidone.

- **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 protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. See "License and Other Agreements."

HEPATOLOGY

We are also focused on developing therapeutics in the area of hepatology. Our clinical efforts in hepatology are currently focused on expanding treatment options for patients suffering from HCV infections.

Hepatitis C Virus Infections—Nonresponder Patients. When patients who have never been treated with interferons 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 patients show a sustained virologic response (the most commonly used measure of treatment effectiveness). The remaining 50% of patients are known as hepatitis C nonresponders. We believe that the hepatitis C nonresponder patient population currently numbers approximately 150,000 in the United States and is growing rapidly. Retreatment of hepatitis C nonresponders with pegylated interferon-alpha 2 and ribavirin therapy has poor response rates. In the fourth quarter of 2003, we extended our promotion of Infergen into the hepatitis C nonresponder patient population.

- **Daily Infergen in Combination with Ribavirin for Hepatitis C Nonresponders**

In October 2003, data from an investigator-sponsored clinical trial were presented at the 54th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). The trial evaluated once-daily Infergen in combination with ribavirin therapy in 120 hepatitis C nonresponders. The data showed sustained virologic response rates at 72 weeks in the range of 37% to 43%, depending on the dosing regimen. These response rates are three-to-four times those observed when retreating such patients with pegylated interferon-alpha 2 in combination with ribavirin therapy. Due to adverse events, the Infergen dose was reduced in 16 percent of patients and discontinued in 7 percent of patients. The most common cause of adverse events was a reduction in white blood cell and platelet counts. These discontinuation rates and rates of adverse events and serious adverse events are consistent with standard interferon in combination with ribavirin therapy.

Based upon these and other data, we believe that Infergen may have potential in the hepatitis C nonresponder patient population. We expect to initiate a Phase III trial of once-daily Infergen in combination with ribavirin therapy for the treatment of hepatitis C nonresponders. This trial is scheduled to begin in the first half of 2004.

- **Daily Infergen in Combination with Actimmune for Hepatitis C Nonresponders**

In vitro analysis of the combination of daily Infergen and Actimmune 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 December 2003, interim data from an independent retrospective clinical analysis conducted on 32 hepatitis C nonresponder patients were reported. After 12 weeks of therapy with daily Infergen and Actimmune, 38 percent of patients had undetectable levels of virus in their blood. In addition,

65 percent of patients in the retrospective analysis had an early virologic response, defined as having either a 2 log or greater decline in viral load or undetectable levels of virus in the blood.

We have recently reviewed with the FDA our development plan for this combination in the treatment of hepatitis C nonresponders. We intend to begin the development program of this combination in the first half of 2004 with a Phase II clinical trial to be conducted in the United States.

- **PEG-Alfacon-1 for Chronic Hepatitis C Virus Infections**

To further expand the limited treatments for HCV infections, we are developing 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 September 2003, we completed a Phase I clinical trial to evaluate PEG-Alfacon-1 as a potential treatment for chronic HCV infections.

This 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.

- **Next-Generation Interferon Gamma**

As with our product development programs in the area of pulmonology, we plan to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen in the area of hepatology.

Strategic Non-Core Assets

We currently have strategic assets that do not fit within our core focus areas of pulmonology and hepatology. We believe that these non-core assets provide us the opportunity to create value through strategic divestiture and partnering arrangements.

- **Actimmune for Oncology**

Ovarian cancer. Ovarian cancer is the third most common cancer in women, afflicting approximately 105,000 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 800-patient Phase III clinical trial of Actimmune in combination with carboplatin and paclitaxel for the first-line treatment of ovarian cancer in women who have undergone surgical resection. We anticipate that this clinical trial will complete enrollment during the first half of 2004 and expect data from an interim analysis regarding progression-free survival during the first half of 2005. Although we plan to continue to fund the Phase III clinical trial of Actimmune in ovarian cancer without a partner, we may revisit this decision in the first half of 2005, at which time we expect to see data regarding the rate of progression-free survival from this clinical trial.

- **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, 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 a New Drug Application, or NDA, for oritavancin for the treatment of CSSSIs. We do not intend to market or co-market oritavancin, and are looking for a partner to assume the future development investment in oritavancin. Although we are attempting to complete a value-creating transaction for this asset, we may not be able to complete this transaction in 2004. We expect that our investment in oritavancin will decrease as compared to our investment in 2003.

- **Amphotec® (amphotericin B cholesteryl sulfate complex for injection)**

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 in the process of divesting Amphotec. We are in the early stages of a competitive process to identify a partner that has the ability to maximize the value of this asset.

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 and 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 sales of Actimmune, and make one-time payments to Genentech upon the occurrence of specified milestone events. We must satisfy specified obligations under the agreement with Genentech to maintain our license from Genentech. We are obligated under the agreement to develop and commercialize Actimmune for a number of diseases. 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 an international strategic 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 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. Each party will receive royalties on sales of the product the other party makes in its own territory, on a specified royalty schedule.

Connetics Corporation (Actimmune)

Through an assignment and option agreement with Connetics, we 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 are obligated to pay Connetics a royalty of 4.0% on our net sales of Actimmune for the treatment of scleroderma.

Amgen Inc. (Infergen and PEG-Alfacon-1)

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. 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 our PEG-Alfacon-1 program and for royalties on sales of the resulting product, if any. 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.

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. 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.

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., 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 are funding Maxygen's optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. The agreement terms include up-front license fees, full research funding and development and commercialization milestone payments. In addition, Maxygen will receive royalties on product sales. Our rights to the licensed products under the agreement could revert to Maxygen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

Eli Lilly and Company (oritavancin)

In 2001, we entered into an asset purchase and license agreement with Lilly pursuant to which we acquired worldwide rights to oritavancin. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. In order to partner oritavancin, the agreement requires that we first offer Lilly the opportunity to enter into such a relationship with us, which we have done. 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 Lilly. Any such partner will need to comply with the current and future terms of the agreement. Pursuant to the agreement, we paid Lilly $50.0 million and will be obligated to pay Lilly significant milestone payments and royalties on product sales. In September 2002, 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 Lilly, and we made the actual payment to Lilly during January 2003. In September 2003, we expensed $10.0 million related to a milestone payment due to 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. Our rights to oritavancin could revert to 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 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, Lilly may terminate the agreement and our rights to oritavancin would revert to Lilly. In any event, we may not assign the agreement to a potential acquirer without Lilly's advance, written consent.

ALZA Corporation (Amphotec)

In 2001, we acquired worldwide rights from ALZA 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. 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 have 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. Any such partner will need to comply with the current and future terms of the agreement.

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. 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.

Amgen Inc. (Infergen)

Under our 2001 agreement with Amgen under which we license Infergen, 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.

Abbott Laboratories, Inc. (oritavancin)

In 2001, we entered into an agreement with 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 API from 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 to purchase a minimum amount of oritavancin API during the term of the agreement.

Cardinal Health PTS, Inc. (oritavancin)

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

Ben Venue Laboratories Supply Agreement (Amphotec)

We presently have an agreement with 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.

Patents and Proprietary Rights

We have acquired a 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 expire in 2005 and 2006. 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.

We have acquired a 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 expire 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.

We have acquired a license under certain Lilly patents to develop, make, use and sell oritavancin worldwide for any human disease under our asset purchase and license agreement with 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.

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.

We have acquired a 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.

Competition

Actimmune is the only FDA approved therapy for chronic granulomatous disease 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.

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, such as PEG-Intron and Pegasys, 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. We are also aware that additional therapies, such as Enbrel®, Aranesp® and Neulasta®, are being developed for use in conjunction with interferon alpha products for the treatment of HCV infections.

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®, Tracleer®, Mucomist® and Imuran®.

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 and Distribution

We have clinical specialists dedicated to supporting Infergen for HCV infection and educating the medical community on the early diagnosis of IPF.

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, 2003, the primary specialty pharmacies and distributors for our products were Priority Health Care, Caremark and Merck Medco, who accounted for 59%, 11% 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.

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

	2003	2002	2001
United States	$151,373	$109,537	$37,838
Rest of world	2,765	2,428	2,113
Totals	$154,138	$111,965	$39,951

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 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, or IND, which must become effective before clinical trials may begin;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- FDA approval of a new biologics license application, or a BLA, a new drug application, or 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 conduct of the clinical trial. 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 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 and optimal dosage.
- 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 not uncommon for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous and reliable Phase III clinical trial.

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

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These 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 voluntary 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 and/or a second Phase III pivotal clinical trial. 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. 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, or 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 portions of a BLA or NDA for a product granted priority review 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 and intend to ask for fast track designation for qualified submissions of our other products. We cannot guarantee that the FDA will grant any of our additional requests for fast track designation, that any fast track designation will affect the time of review, or that the FDA will approve the BLA or NDA submitted for any of our product candidates, whether or not fast track designation is granted. 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 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 Actimmune or any of our other 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 market 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. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. Failure to comply with these requirements 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.

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. 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 subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity for seven years, 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. We intend to file for orphan drug designation for those diseases we target that meet the criteria for orphan drug exclusivity. Actimmune has orphan drug exclusivity for severe, malignant osteopetrosis. Actimmune has also been assigned orphan drug designation for the treatment of IPF. Although obtaining FDA 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 $119.9 million, $129.6 million and $52.0 million for the years ended December 31, 2003, 2002 and 2001, 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 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this facility. We believe that this facility has sufficient space to accommodate expansion of our operations until at least the end of the fourth quarter of 2004. We will evaluate additional space in vacant facilities near our building prior to that time.

Employees

As of February 29, 2004, we had 260 full-time employees. Of the full-time employees, 153 were engaged in research and development and 107 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 interim 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. 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 Current Report on Form 8-K that was filed with the SEC on February 11, 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. Although we are developing Actimmune for the treatment of IPF and ovarian cancer, Actimmune will not be marketed for either of these diseases before 2006, if at all. We market Infergen for the treatment of chronic HCV infections, but Infergen revenues may fail to meet our stated earnings guidance for 2004, or to grow significantly in subsequent years. We are developing pirfenidone for the treatment of IPF, but pirfenidone will not be marketed for any diseases before 2011, if at all. We are developing PEG-Alfacon-1, a pegylated form of Infergen, for the treatment of chronic HCV infections, but the development of PEG-Alfacon-1 will be lengthy and very expensive and carries significant risk. PEG-Alfacon-1 will not be marketed for any diseases before 2010, if at all. 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 have decided to divest Amphotec. We are developing oritavancin for the treatment of complicated skin and skin-structure infections and are completing a Phase II clinical trial of oritavancin for the treatment of bacteremia, but we do not intend to market or co-market oritavancin. Accordingly, we are looking for a partner to assume the future investment in oritavancin. We may be unable to conclude either a sale of Amphotec or a partnering transaction for oritavancin in the near term or on favorable terms, if at all.

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 recently reported that our exploratory Phase II clinical trial evaluating Actimmune for the potential treatment of advanced liver fibrosis caused by hepatitis C virus 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 also terminating our Phase II clinical trial of Actimmune for the treatment of non-Hodgkin's lymphoma, as it is not aligned with our current strategic focus.

We are conducting a Phase III clinical trial of Actimmune as a treatment for IPF. 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 harm our business and result in a precipitous decline in our stock price.

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:

- a country's regulatory authority does not approve a clinical trial protocol;
- 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. 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. Accordingly, we may elect to terminate our programs for and, in certain cases, our licenses to, such product candidates or programs.

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

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 clearance 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 idiopathic pulmonary fibrosis, we are aware that physicians are prescribing Actimmune for the treatment of idiopathic pulmonary fibrosis. 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 for the treatment of chronic hepatitis C infections, even though the FDA has not approved this combination for the treatment of chronic hepatitis C infections. The FDA does not regulate the behavior of physicians in

their choice of treatments. The FDA does, 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 market Actimmune for the treatment of idiopathic pulmonary fibrosis, or Infergen in combination with ribavirin therapy for the treatment of chronic hepatitis C infections. The FDA and other governmental authorities actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. We engage in medical education activities that are subject to scrutiny under these regulations. Failure to comply with these regulations can result in regulatory enforcement action by the FDA or other governmental authorities, any of which would have an adverse effect on our revenues, business and financial prospects.

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 ongoing 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. 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. 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.

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 recently reported results from our confirmatory pivotal Phase III clinical trial of oritavancin for the treatment of complicated skin and skin-structure infections. However, in two additional small clinical pharmacology trials, we observed adverse events 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 an NDA for oritavancin. Because of this additional clinical trial, we will incur additional development costs and we will be significantly delayed in, or indefinitely prevented from, receiving approval for oritavancin for the treatment of complicated skin and skin-structure infections.

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, 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 which 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, such as oritavancin, PEG-Alfacon-1 or pirfenidone, 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. 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, are subject to scrutiny under these laws. For example, we are one of what we believe to be a number of companies that have received letters from the Office of the Florida Attorney General 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). 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 decline in our stock price. 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:

- before we can obtain approval of any of our products or product candidates for the treatment of a particular disease, we must demonstrate to the FDA's and other governmental authorities' satisfaction that the drug manufactured for the clinical trials is comparable to the drug manufactured for commercial use;
- 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.

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 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.

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 be 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 these manufacturers' facilities and processes prior to our use or sale of products they manufacture 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 are transferring the manufacturing of oritavancin from 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 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 Lilly's oritavancin product, our ability to commercialize or partner oritavancin would be slowed or halted, which would significantly harm our business;

- 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;
- 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, 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, 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. Under our agreement with Amgen for Infergen, Amgen is our exclusive manufacturer of Infergen. Even if we believe that Amgen will be unable to meet our requirements for the manufacture of Infergen, we cannot transfer the Infergen manufacturing process to a secondary source unless Amgen has materially breached its manufacturing obligations. 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 high 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 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

There are significant regulatory, supply, intellectual property and competitive barriers to entry that may prevent us from successfully marketing or developing Infergen or PEG-Alfacon-1 for the chronic HCV infections market.

We have extended our efforts regarding Infergen in the United States for the treatment of chronic HCV infections. However, we believe that there are significant regulatory, supply, intellectual property and competitive barriers to Infergen's penetration of the chronic HCV infections market, including the following:

Regulatory. We believe that market acceptance of and demand for Infergen for the treatment of chronic HCV infections may depend upon our ability to market Infergen in combination therapy with ribavirin or other anti-viral drugs. Before we may market Infergen for use in combination therapy with ribavirin or any other anti-viral drug, we will need to obtain FDA approval for such combination. To seek and obtain such approval, we will need to supplement Infergen's current FDA license with data that support 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. 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, in the case of judicial intervention, longer, of FDA approval pending the outcome of ongoing patent infringement litigation.

Supply. Amgen is our exclusive manufacturer of Infergen. 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. 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. There is no assurance that we will successfully complete any required scale-up.

Intellectual Property. Our competitors and their strategic partners have substantial and extensive patent rights in connection with 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. We believe that these patents may prevent us from marketing Infergen in combination therapy with ribavirin for certain patients. If, because of these patents, we are unable to market Infergen or PEG-Alfacon-1 with ribavirin or with another anti-viral drug, the commercial prospects for Infergen or PEG-Alfacon-1 are likely to be reduced and our prospects for profitability may be impaired. Further, we believe 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 with ribavirin or with another anti-viral drug, reducing the commercial prospects for Infergen 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. We believe that this patent may prevent us

from marketing PEG-Alfacon-1 for the treatment of chronic HCV infections. If because of this patent we are unable to market PEG-Alfacon-1 for the treatment of chronic HCV infections, the commercial prospects for PEG-Alfacon-1 are likely to be reduced. Also, we believe that our competitors and their strategic partners have substantial and extensive patent rights relating to pegylation technology in general and the use of pegylated interferon alpha for the treatment of chronic HCV infections in particular. Further, several third parties have substantial and extensive patent rights in connection with the use of pegylation to modify biologically active compounds generally.

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. Specifically, we are aware of two U.S. patents that relate to interferon alpha polypeptides, DNAs encoding the same, host cells transformed with such DNA and processes for the production of interferon alpha polypeptides from such DNAs and host cells. These patents expire in 2019 and 2020, respectively. We believe that these patents may prevent us from marketing PEG-Alfacon-1, which would have a material adverse effect on our business.

Competition. 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 and Roche have commenced marketing their respective pegylated interferon alpha products, Infergen has a significant disadvantage in the market with respect to the frequency of administration. In addition, both of these companies have obtained and will likely continue to obtain significant patent protection relating to their respective products.

Further, 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 for chronic HCV infections may diminish, which would harm our business.

Valuation. If the use of interferon-based therapies for chronic HCV infections were to diminish, this could impact the recoverability of the Infergen-related intangible asset. 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 distributors and specialty pharmacies for approximately 88% of our total product sales. If those parties do not perform satisfactorily, our business will be harmed.

During the year ended December 31, 2003, approximately 88% of our total product sales were through distributors and specialty pharmacies. As a result, our success depends on the continued customer support efforts of our network of distributors and specialty pharmacies. In addition, during this period, one specialty pharmacy accounted for approximately 59% of our outstanding receivables and 59% of our total product sales. If this or any other specialty pharmacy or distributor that sells 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 significant distributors and specialty pharmacies could harm our revenues.

The use of distributors and specialty pharmacies involves certain risks, including, but not limited to, risks that distributors and specialty pharmacies 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.

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 Public Health Service 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, such third-party payors make the decision to reimburse an off-label product based on a compendium listing. Actimmune has no such listing. If it does not receive such a compendium listing, additional third-party payors, including Medicaid, may decide to deny reimbursement for Actimmune used to treat 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.

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 fully integrated pharmaceutical companies and biotechnology companies that currently market competitive drugs or have drug and target discovery programs directed to the same therapeutic areas as we focus on, as well as universities and public and private research institutions. Many of the organizations competing with us 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.

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 were issued a patent that blocked our ability to commercialize any of our products for any or all of the diseases that we are targeting, we would be prevented from commercializing that product 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.

We license certain patents and trade secrets relating to Actimmune from Genentech, Inc; relating to Infergen from Amgen Inc.; relating to pirfenidone from Marnac, Inc. and KDL GmbH; and relating to oritavancin from Eli Lilly and Company. If we breach any of our agreements with Genentech, Amgen, Marnac and KDL or 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.

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 in 2005 and 2006. 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.

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.

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. Further, we believe 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 because of these patents we are unable to market 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.

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. In addition, we are aware of two international patent application publications relating to manufacturing processes for pirfenidone. If either or both of these patent applications were to result in a granted patent or patents, and if any such granted patent or patents were to be interpreted to cover the manufacturing process for pirfenidone, we believe that such patent or patents may enable the patent holder to block our ability to commercialize pirfenidone unless we obtained a license under such patent or patents. We cannot predict whether we would be able to obtain such a license under commercially reasonable terms, if at all. If we were not able to obtain such a license under the patent or patents on commercially reasonable terms, or at all, it would have a material adverse effect on our ability to commercialize any pirfenidone product.

We have licensed certain patents throughout the world relating to oritavancin from 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. In addition, we are aware of two U.S. patents, and corresponding European, Australian, Korean, Canadian and Japanese patents, that relate to a molecule that is produced during the manufacture of oritavancin. A derivative of this molecule is retained in the final oritavancin product. If any of these patents were interpreted to cover the oritavancin manufacturing process, any molecules formed during the manufacturing process, or the final oritavancin product itself, we believe that such patent or patents could enable the patent holder to block our ability to commercialize oritavancin unless we obtained a license under such patent or patents. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. If we were not able to obtain such a license under the patents on commercially reasonable terms, or at all, it would have a material adverse effect on our ability to commercialize oritavancin.

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.

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.

We rely on trade secrets to protect technology where we believe 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 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. 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.

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.

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. Third parties may accuse us or our collaborators of employing their proprietary technology in our products, or in the processes used to 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 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 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 processes or manufacture or market the affected products. 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.

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 prescribe it less often for the treatment of IPF because:

- Actimmune is not approved by the FDA 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 one of our competitors' trials for the treatment of IPF;
- Actimmune does not have a compendium listing;
- 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;
- physicians believe that the article and editorial in the January 8, 2004 NEJM were negative concerning Actimmune as a treatment for IPF; or
- We are unable to market or promote Actimmune for the treatment of IPF.

If physicians do not prescribe Actimmune for the treatment of IPF for the above reasons or any other reasons, our revenues will decline.

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 2004. 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 $396.2 million at December 31, 2003. 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, since we do not expect to seek FDA approval for the use of Actimmune for the treatment of IPF for at least four more years, Actimmune revenues may not continue to increase or may decrease. We have not generated significant 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 during the quarters ended September 30, 2003 and December 31, 2003 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.

If we are unable to divest Amphotec, we may need to record another impairment charge for Amphotec, which would have a material adverse effect on our financial condition and results of operations.

The recoverability of the carrying value of the Amphotec-related intangible asset that we acquired in 2001 is based on its ability to generate a profit from sales. During the quarter ended September 30, 2003, we recorded a charge of $4.8 million for the impairment of Amphotec product rights. This impairment charge reduced the remaining carrying value of the intangible asset recorded in 2001 when we acquired the product. This reduction was based on our detailed assessment of the current and future market potential of Amphotec, which took into account that sales levels have been lower than we expected and that Amphotec is not aligned with our new strategic focus in pulmonology and hepatology. If we are unable to divest the product or to achieve results consistent with those assumed in our assessment, it may be necessary to further reduce the remaining carrying value of the Amphotec intangible asset. This would have a material adverse effect on our financial condition and results of operations during any period in which we recognize any such reduction.

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. 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.

Insurance coverage is increasingly difficult to obtain or maintain.

While we currently have insurance for our business, directors and officers, and property and products, 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.

We face certain litigation risks that could harm our business.

We have had numerous lawsuits filed against us asserting various claims, including several securities class actions and a shareholder derivative lawsuit. The results of complex legal proceedings, such as these, are difficult to predict. Moreover, many of the complaints filed against us do not specify the amount of damages that the plaintiffs seek, and we therefore are unable to estimate 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, 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 one or more of these 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 can be costly, time-consuming and disruptive to normal business operations. The costs of defending these lawsuits could be quite significant, and certain costs, such as those below a deductible amount, are not covered by our insurance policies. The defense of these lawsuits could also result in continued diversion of our management's time and attention away from business operations, which could harm our business.

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 260 employees as of February 29, 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. 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. 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.

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

Our annual debt service obligations on both of our outstanding notes are approximately $9.0 million per year in interest payments. We intend to purchase or redeem, before and/or during the third quarter of this year, all of our outstanding 5.75% convertible subordinated notes due 2006 with the proceeds of the recent issuance of our 0.25% convertible senior notes due 2011. However, we may determine not to purchase or redeem all of our 5.75% convertible subordinated notes due 2006. Should any such purchase or redemption occur, we would record a charge for any unamortized debt issuance costs and for any premium paid in connection with such purchase or redemption. 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.

If we do not purchase or redeem our outstanding 5.75% convertible subordinated notes or receive stockholder approval to increase our authorized shares of common stock, we may not be able to deliver shares of common stock upon conversion of our outstanding 0.25% convertible senior notes due 2011, which would affect our reported net income or loss.

We currently have 51,000,000 authorized shares of common stock. As of March 10, 2004, we had:

- 31,879,554 shares of common stock issued and outstanding;
- 2,526,042 shares of common stock reserved for issuance upon conversion of our 5.75% convertible subordinated notes;
- 5,394,867 shares of common stock reserved for issuance upon exercise of outstanding options; and
- 3,203,979 shares of common stock reserved for future option grants and future purchases in accordance with our employee stock purchase plan.

Excluding outstanding and reserved shares, we have 7,995,558 authorized shares of common stock available for issuance upon conversion of our 0.25% convertible senior notes due 2011, which is fewer than the total number of shares issuable upon conversion of these notes. If we redeem our 5.75% convertible subordinated notes or receive stockholder approval to increase our authorized shares of common stock, we will have sufficient shares available for issuance upon conversion of our 0.25% convertible senior notes due 2011. We have the option under our 0.25% convertible senior notes due 2011 to deliver cash in lieu of shares and will effectively be required to exercise this option if we do not have sufficient shares available for issuance. As an accounting matter, during any period in which we do not have sufficient authorized but unissued shares of common stock, without giving effect to reserved shares, we are required to account for the conversion feature of our 0.25% convertible senior notes due 2011 as a derivative. During any period in which we are required to use derivative accounting, any increases and decreases in the fair value of the conversion feature will result in a non-cash charge or credit, respectively, which will affect our reported net income or loss.

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.

We may be required to redeem all or part of our outstanding convertible notes upon the occurrence of certain events designated in the indentures governing these notes. Although the

indentures governing these notes allow 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 these 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 these notes under certain circumstances, or expressly prohibit our redemption of these 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 these notes, we could seek the consent of our lenders to redeem these notes or attempt to refinance this debt. If we do not obtain consent, we would not be permitted to purchase or redeem these notes. Our failure to redeem tendered notes would constitute an event of default under the respective indentures, which might constitute a default under the terms of our other indebtedness.

Risks Related to our Common Stock

We may fail to meet our publicly announced revenue and/or expense projections and/or other financial guidances, 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 guidances, 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;
- 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; or
- we may decide to expand our marketing and educational programs.

If we fail to meet our revenue and/or expense projections and/or other financial guidances for any reason, our stock would decline in value.

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. 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 guidances;
- 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.

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, 2003, our directors, executive officers and greater than 5% stockholders and their affiliates beneficially owned approximately 40% 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. They may exercise this ability in a manner that advances their own best interests and not necessarily those of other stockholders.

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, 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 a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans, and plan to file a shelf registration statement covering the resale of our 0.25% convertible senior notes due 2011 and the common stock issuable upon conversion of these 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.

We have implemented anti-takeover provisions, which could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to our stockholders.

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. 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.

Executive Officers of the Registrant

The following table provides information regarding our executive officers and key employees as of February 29, 2004:

Name	Age	Title
Daniel G. Welch	46	Chief Executive Officer and President
Roger L. Hawley	51	Executive Vice President of Commercial Operations
Stephen N. Rosenfield	54	Executive Vice President of Legal Affairs, General Counsel and Secretary
Marianne Armstrong, Ph.D.	49	Senior Vice President, Regulatory/Medical Affairs and Drug Safety
Sharon Surrey-Barbari	49	Chief Financial Officer, Senior Vice President of Finance and Administration
Lawrence Blatt, Ph.D.	42	Senior Vice President of Preclinical and Applied Research
Peter Van Vlasselaer, Ph.D.	45	Senior Vice President of Technical Operations

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. From August 2002 to January 2003, Mr. Welch served as chairman and chief executive officer of Triangle Pharmaceuticals, Inc. From

October 2000 to June 2002, Mr. Welch served as president of the pharmaceutical division of Elan Corporation, PLC. 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 an MBA from the University of North Carolina.

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. From August 1987 to February 2001, Mr. Hawley held various management positions in corporate finance, sales and marketing and regional sales at GlaxoSmithKline, Inc. 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.

Stephen N. Rosenfield. Mr. Rosenfield has served as our Executive Vice President of Legal Affairs, General Counsel and Secretary since March 2003. From March 2000 to March 2003, Mr. Rosenfield served as our Senior Vice President of Legal Affairs, General Counsel and Secretary. From February 1996 to February 2000, Mr. Rosenfield was an associate at Cooley Godward LLP. From September 1992 to January 1996, Mr. Rosenfield was an associate at Coblentz Cahen McCabe & Breyer LLP. Mr. Rosenfield holds a J.D. from Northeastern University School of Law.

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. From July 1998 to November 1999, Dr. Armstrong served as senior director of clinical development at PathoGenesis Corporation. From May 1995 through July 1998, Dr. Armstrong served as department head of clinical affairs for Amgen Inc. Previously, Dr. Armstrong held management positions in clinical development at Alcon Laboratories, Solvay Pharmaceuticals and Parke-Davis/Warner Lambert, and was a regional sales representative at American McGaw. 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. 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., most recently as product development team leader, interferons. Dr. Blatt holds a Ph.D. in Public Health Administration from the University of La Verne.

Sharon Surrey-Barbari. Ms. Surrey-Barbari has served as our Chief Financial Officer and Senior Vice President of Finance and Administration since September 2002. From January 1998 to June 2002, Ms. Surrey-Barbari served at Gilead Sciences, Inc., most recently as vice president and chief financial officer. From January 1996 to January 1998, Ms. Surrey-Barbari served as vice president, strategic planning at Foote, Cone & Belding Healthcare. From 1972 to 1995, Ms. Surrey-Barbari was employed by Syntex Corporation/Roche Pharmaceuticals in Palo Alto, Calif., where she held various management positions in corporate finance, financial planning, marketing and commercial planning. Ms. Surrey-Barbari's most recent position at Syntex was director of commercial planning. Ms. Surrey-Barbari holds a B.S. in accounting from San Jose State University.

Peter Van Vlasselaer, Ph.D. Dr. Van Vlasselaer has served as our Senior Vice President of Technical Operations since November 1999. From July 1993 to November 1999, Dr. Van Vlasselaer served as vice president of development at Dendreon Corporation. Dr. Van Vlasselaer holds a Ph.D. from the University of Leuven in Belgium and was an immunology fellow at Stanford University.

ITEM 2. PROPERTIES

Our facilities currently consist of 55,898 square feet of office space located at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this building. We believe that this facility has sufficient space to accommodate expansion of our operations until at least the end of the fourth quarter of 2004. We will evaluate additional space in vacant facilities near our building prior to that time.

ITEM 3. LEGAL PROCEEDINGS

On June 25, 2003, a purported securities class action was filed in the United States District Court for the Northern District of California. The complaint named us and our former Chief Executive 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 Securities Exchange Act of 1934, and Rule 10b-5. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 6, 2003 through June 11, 2003. Additional class action complaints have since been filed in the same court, each making identical or similar allegations against us, our former Chief Executive Officer and our current Chief Financial Officer. We believe that we have meritorious defenses to the allegations contained in the securities class action complaints and intend to defend ourselves vigorously. We expect that these complaints will eventually be consolidated into a single action. No trial date has been scheduled.

On July 30, 2003, a stockholder purporting to act on our behalf filed a derivative action in the California Superior Court for the County of San Mateo against our directors, our former Chief Executive Officer and our current 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. We believe that we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously. No trial date has been scheduled.

We believe that the factual allegations and circumstances underlying the purported securities class actions and the derivative action are without merit. The litigation 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 InterMune's initial public offering of its Common Stock, $0.001 par value ("Common Stock"), on March 24, 2000, InterMune's Common Stock has been traded on the NASDAQ National Market under the symbol "ITMN."

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

Fiscal Year:	High	Low
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
2002		
First Quarter	$48.61	$28.65
Second Quarter	32.11	21.10
Third Quarter	32.82	16.80
Fourth Quarter	37.62	25.51

As of February 29, 2004, there were 149 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, 2003, 2002 and 2001, respectively, and the selected consolidated balance sheet data as of December 31, 2003 and 2002, 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, 2000 and 1999, respectively, and the selected consolidated balance

sheet data as of December 31, 2001, 2000 and 1999, respectively, are derived from audited financial statements not included in this Report.

	Years ended December 31,				
	2003	2002	2001	2000	1999
	(In thousands, except per share data)				
Statement of Operations Data:					
Product sales:					
Actimmune	$141,402	$ 105,802	$ 36,320	$ 11,201	$ 556
Other	12,736	6,163	3,631	—	—
Total product sales, net	154,138	111,965	39,951	11,201	556
Costs and expenses:					
Cost of goods sold	36,309	24,161	15,474	4,990	240
Amortization and impairment of acquired product rights(1)	8,358	3,593	4,805	1,777	—
Research and development	119,858	129,590	52,049	20,821	2,969
Selling, general and administrative	68,451	62,752	35,895	16,152	2,656
Acquired research and development and milestone payments(2)	12,150	33,750	56,400	—	1,094
Total costs and expenses	245,126	253,846	164,623	43,740	6,959
Loss from operations	(90,988)	(141,881)	(124,672)	(32,539)	(6,403)
Interest income	4,024	7,375	11,253	8,484	240
Interest and other expense	(10,037)	(9,803)	(4,772)	(191)	(186)
Net loss	(97,001)	(144,309)	(118,191)	(24,246)	(6,349)
Preferred stock accretion	—	—	—	(269)	(657)
Redeemable preferred stock dividend(3)	—	—	—	(27,762)	—
Net loss applicable to common stockholders	$(97,001)	$(144,309)	$(118,191)	$(52,277)	$(7,006)
Basic and diluted net loss per share	$ (3.06)	$ (4.72)	$ (4.67)	$ (3.05)	$ (9.12)
Shares used in computing basic and diluted net loss per share	31,665	30,589	25,322	17,114	768

	As of December 31,				
	2003	2002	2001	2000	1999
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and available-for-sale securities	$ 216,107	$ 316,411	$ 332,067	$194,520	$ 4,214
Working capital	201,855	285,633	320,345	194,706	1,222
Total assets	288,501	384,881	387,246	201,649	5,855
Long-term obligations	149,500	149,500	149,500	—	1,624
Redeemable convertible preferred stock	—	—	—	—	7,417
Accumulated deficit	(396,168)	(299,167)	(154,858)	(36,667)	(12,421)
Total stockholders' equity (deficit)	87,744	182,718	215,059	195,801	(7,541)

(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

InterMune is an independent biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology. In 2003, we reorganized our business by curtailing investment in non-core areas and focusing our commercial and development efforts in pulmonology and hepatology. We have a stable revenue base provided primarily by our two core marketed products, advanced-stage clinical programs addressing a range of unmet medical needs with attractive potential commercial markets and several strategic non-core assets that we believe provide us the opportunity to create value. In 2003, our total product revenues increased 38% to $154.1 million for the year ended December 31, 2003, from $112.0 million for the year ended December 31, 2002. Substantially all of our revenues are generated from Actimmune sales.

Marketed Products

Our two core marketed products are Actimmune (interferon gamma-1b), approved for the treatment of severe, malignant osteopetrosis and chronic granulomatous disease, and Infergen (consensus interferon alfacon-1), approved for the treatment of chronic hepatitis C virus, or HCV, infections.

Product Development

Drug development in the United States is a process that includes several steps defined by the U.S. Food and Drug Administration, or FDA. The process begins with the filing of an Investigational New Drug Application, or 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: Phase I, II and III. In our experience, clinical development accounts for an average of 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 not uncommon for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous and reliable Phase III clinical trials.

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, or NDA, a Biologic License Application, or BLA, or an NDA or BLA supplement, the FDA may grant marketing approval (i.e., a license), request additional information or refuse to file 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 and hepatology.

- *Pulmonology*

In pulmonology, we are developing two therapies for the treatment of idiopathic pulmonary fibrosis, or IPF. IPF is a fatal disease for which there is no FDA approved therapy. We believe that there are approximately 83,000 patients with IPF in the United States. We are developing what we

believe to be the two most promising and most clinically advanced compounds for the treatment of IPF—Actimmune and pirfenidone. We initiated a pivotal Phase III clinical trial of Actimmune for the treatment of patients with IPF 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. We expect to announce our plans regarding a clinical development program for pirfenidone in 2004.

• *Hepatology*

In hepatology, we are focused on expanding treatment options for patients suffering from HCV infections. 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 the current standard of care, pegylated interferon-alpha 2 in combination with ribavirin therapy. These patients are referred to as hepatitis C nonresponders. We believe that there are approximately 150,000 hepatitis C nonresponders in the United States, and that this patient population is growing rapidly. We expect to initiate a Phase III trial of once-daily treatment with Infergen in combination with ribavirin therapy for hepatitis C nonresponders in the first half of 2004. In addition, we are developing once-daily Infergen in combination with Actimmune for the treatment of hepatitis C nonresponders. We expect to initiate a Phase II trial of this combination in the first half of 2004. We are also evaluating development options and business collaborations for a pegylated form of Infergen, PEG-Alfacon-1, for the treatment of chronic HCV infections. We completed our Phase I trial of PEG-Alfacon-1 for the treatment of chronic HCV infections in 2003.

Non-Core Strategic Assets

We also have strategic assets that do not fit within our core focus areas of pulmonology and hepatology. These assets are oritavancin, Amphotec and Actimmune for the treatment of ovarian cancer. We believe that these non-core assets provide us the opportunity to create value through strategic divestiture and partnering arrangements.

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 Note 3 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 $200.2 million if all of the milestones defined in each of the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

Operating History

We have sustained significant losses since inception and, as of December 31, 2003, we had an accumulated deficit of $396.2 million. We expect to incur losses through at least the end of 2005 or beyond. The extent of our future losses from operations is heavily impacted by revenues from the sale of Actimmune and our expectations regarding future Actimmune revenues may be negatively impacted by many factors, including continued market and physician acceptance and use of Actimmune, reimbursement policies of major insurance companies, the results of our INSPIRE trial for Actimmune, and the other factors described under the heading "Risk Factors" and elsewhere in this Report. Our

loss from operations was $91.0 million for the year ended December 31, 2003 and $141.9 million for the same period in 2002, a decrease of 36%. These losses resulted from costs incurred in the development and commercialization of our products and product candidates and the acquisition of new technology. Our expenses have consisted primarily of those incurred for research and development, sales and marketing and general and administrative costs associated with our operations.

We have a limited history of operations, which makes accurate prediction of future operating results difficult or impossible. We expect that our quarterly and annual results of operations may fluctuate for the foreseeable future due to a number of factors, including, but not limited to, those described under the heading "Risk Factors" in this Report.

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 accounting principles generally accepted in the United States. 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 and consider delivery to have occurred at the time of shipment. Revenue is recognized at shipment 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, 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 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.

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, 2003 we had twelve and twenty-four month fixed purchase orders of $40.7 million and minimum purchase obligations through 2012 that total $167.0 million.

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. In an effort to help manage our inventory levels of Actimmune, we are conducting an ongoing study to determine whether its expiration period may be lengthened. 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.

Recently, projected revenue trends resulted in us recording charges during 2003 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. 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, 2003 and 2002**

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

	Year ended December 31, 2003	Change from 2002—Increase/(decrease) Amount	%
	(In thousands)		
Statement of Operations Data:			
Product sales:			
Actimmune	$141,402	$ 35,600	34%
Other	12,736	6,573	107%
Total product sales, net	154,138	42,173	38%
Costs and expenses:			
Cost of goods sold	36,309	12,148	50%
Amortization and impairment of acquired product rights	8,358	4,765	133%
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 and other expense	(10,037)	234	2%
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 may experience fluctuations due to market and physician acceptance and use of our products, influenced by published reports in medical journals, acceptance in compendia listing, 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 expense 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. We expect an increase in Actimmune's cost of goods sold as a percentage of revenue because we acquire Actimmune in accordance with a supply agreement denominated in Euros, and we experienced unfavorable currency exchange rates during 2003, which led to higher product costs that we believe will be recognized as cost of goods sold during 2004.

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 have 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 7%. The decrease in 2003, when compared to 2002, was primarily due to lower spending on the interferon gamma-1b and pre-clinical development programs of $18.4 million offset in part by increased spending on the oritavancin and pirfendione development programs of $9.7 million. The research and development expenses were lower than expected as a result of delays in the initiation of our Phase III trial of Actimmune in IPF and the Phase II trial for PEG-Alfacon-1 in chronic HCV infections and due to reduced spending on research and development projects that are not aligned with our current strategic focus. We expect that for the 2004 fiscal year, research and development expenses will be lower than in 2003 due to decreased spending on our research and development projects that are not aligned with our current strategic focus in pulmonology and hepatology.

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. The selling, general and administrative expenses for 2003 were lower than forecasted as a result of careful monitoring of discretionary spending and decreased spending on programs not aligned with our current strategic focus. We expect selling, general and administrative expenses for 2004 will be higher than in 2003 primarily due to increased spending on marketing and educational programs.

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 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 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 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. We expect to redeem these notes before and/or during the third quarter of 2004, which would cause us to recognize the remaining unamortized deferred issuance costs as interest expense.

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. As of December 31, 2003, we had federal net operating loss carryforwards of approximately $275.5 million. The net operating loss carryforwards will expire at various dates beginning in 2018 through 2023 if not utilized. We also have federal research and development tax credits of approximately $4.5 million that will expire in the years 2018 through 2023. In addition, we had net operating loss carryforwards for state income tax purposes of approximately $30.1 million, that expire in the years 2008 through 2013, and state research and development tax credits of approximately $1.5 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, 2002 and 2001**

The following table presents our consolidated operations for the year ended December 31, 2002, the change, in thousand dollars and as a percentage when compared to the year ended December 31, 2001.

	Year ended December 31, 2002	Change from 2001 Increase/(decrease) Amount	%
	(In thousands)		
Statement of Operations Data:			
Product sales:			
Actimmune	$ 105,802	$69,482	191%
Other	6,163	2,532	70%
Total product sales, net	111,965	72,014	180%
Costs and expenses:			
Cost of goods sold	24,161	8,687	56%
Amortization and impairment of acquired product rights	3,593	(1,212)	(25)%
Research and development	129,590	77,541	149%
Selling, general and administrative	62,752	26,857	75%
Acquired research and development and milestone payments	33,750	(22,650)	(40)%
Total costs and expenses	253,846	89,223	54%
Loss from operations	(141,881)	17,209	14%
Interest income	7,375	(3,878)	(34)%
Interest and other expense	(9,803)	5,031	105%
Net loss	$(144,309)	$26,118	22%

Revenue. Total product revenues were $112.0 million and $40.0 million for the years ended December 31, 2002 and 2001, respectively. The growth in product sales for the year ended December 31, 2002 was primarily due to a volume increase in sales of Actimmune of $69.5 million or 191%. The product sales in 2002 included sales from Actimmune, Amphotec and Infergen for the entire period.

Product revenues in 2001 included all sales of Actimmune in the United States, worldwide sales of Amphotec for the period from January 5, 2001 (the date we acquired the marketing rights to Amphotec) and sales of Infergen in the United States for the period from June 15, 2001 (the date we acquired the marketing rights to Infergen).

Cost of goods sold. Cost of goods sold were $24.2 million and $15.5 million for the years ended December 31, 2002 and 2001, respectively. Cost of goods sold included manufacturing costs, royalties and distribution costs associated with our revenues. The increase in cost of goods sold in 2002 was due entirely to costs associated with increased product sales volumes.

Cost of goods sold, as a percentage of revenues, were 22% and 39% for the years ended December 31, 2002 and 2001, respectively. The decrease in cost of goods sold as a percentage of revenue in 2002, when compared to 2001, was due to lower product costs of Actimmune associated with the transfer of manufacturing to BI Austria at the end of 2001.

Amortization and impairment of acquired product rights. We recorded amortization and impairment of acquired product rights of $3.6 million and $4.8 million for the years ended December 31, 2002 and 2001, respectively.

The amount in 2002 was comprised of an amortization charge related to the acquisition of Amphotec and Infergen product rights and interferon gamma-1b patents. The amount in 2001 was comprised of an amortization charge related to the acquisition of Amphotec and Infergen product rights and purchased rights to all of the Actimmune revenues and related expenses that we had previously contracted to Connetics. The amortization of the Actimmune rights was expensed based upon product units shipped under the previous contractual unit baseline for 2001. This amounted to $2.6 million for the period in 2001. These Actimmune rights were fully amortized by the end of the second quarter of 2001.

Research and development expenses. Research and development expenses were $129.6 million and $52.0 million for the years ended December 31, 2002 and 2001, respectively, representing an increase of $77.6 million or 149%. The increased spending in 2002 was primarily due to increased costs for Phase II and Phase III clinical trial expenses for Actimmune in new disease indications, clinical trial expenses and pre-FDA approval manufacturing qualification expenses for oritavancin, increased staffing and related expenses necessary to manage the expansion of our operations.

Selling, general and administrative expenses. Selling, general and administrative expenses were $62.8 million and $35.9 million for the years ended December 31, 2002 and 2001, respectively, representing an increase of $26.9 million or 75%. The increased spending in 2002 was primarily due to increased staffing and related expenses necessary to manage the growth of our operations, expansion of our field sales force, re-launch efforts for Infergen and the expansion into our new company headquarters in Brisbane, California.

Acquired research and development and milestone payments. We recorded charges for acquired research and development and milestone payments of $33.8 million and $56.4 million for the years ended December 31, 2002 and 2001, respectively.

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.

In 2002, we paid 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 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.

In 2001, we licensed worldwide rights to oritavancin from Lilly. We paid an up-front fee of $50.0 million to Lilly and an additional $1.0 million in related expenses. We expensed the $51.0 million 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 uses when acquired. We will also be obligated to pay Lilly significant milestone and royalty payments upon successful development and commercialization of oritavancin.

Also 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) for a total consideration of $29.0 million, plus development milestones and royalties. Under the agreement, we also have the exclusive right to clinically develop Infergen and PEG-Alfacon-1 for other indications in the United States and Canada. Based upon an independent appraisal, the fair value of the research and

development program for PEG- Alfacon-1 was determined to be $5.4 million. We expensed this amount as acquired research and development and milestone payments as PEG- Alfacon-1 was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses when acquired. The remainder of the purchase price of approximately $23.6 million was for Infergen this amount was allocated to developed technology and is being amortized over the estimated product life, which is ten years.

The value we assigned to the acquired research and development for the PEG-Alfacon-1 program was determined by estimating both the costs to develop the purchased in-process research and development into a commercially viable product, including development milestones, and the resulting net cash flows from the project, and discounting the net cash flows to their present value. We assigned a discount rate of 33% for valuing the in-process research and development, which was intended to be commensurate with our corporate maturity, PEG-Alfacon-1's stage of development and the uncertainties in the economic estimates described above.

Interest income. Interest income totaled $7.4 million and $11.3 million for the years ended December 31, 2002 and 2001, respectively. The decrease in interest income in 2002 was due to substantially lower market interest rates offset by an increase of average cash available as a result of the completion of a $104.5 million equity financing during the year.

Interest and other expense. Interest expense totaled $9.8 million and $4.8 million for the years ended December 31, 2002 and 2001, respectively. The increase in 2002 was due to a full year of interest expense on $149.5 million aggregate principal amount of our 5.75% convertible subordinated notes issued in July 2001, which mature in July 2006, and $1.0 million in interest expense related to the amortization of the deferred issuance cost.

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, 2002 and 2001.

Liquidity and Capital Resources

Since inception, we have funded our operations through issuances of equity and debt securities and sales of our products. At December 31, 2003, we had cash, cash equivalents and available-for-sale investments of $216.1 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 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 at an average effective maturity of generally less than 12 months.

Net cash used in operations for the year ended December 31, 2003 totaled $81.3 million, compared to $97.4 million for the year ended December 31, 2002 and $42.5 million for the year ended December 31, 2001. The decrease of cash used in operations of $16.1 million for the year ended December 31, 2003 was primarily due to the decrease in our net loss, offset by the net change in our operating assets and liabilities. Our net loss of $97.0 million for the year ended December 31, 2003 included non-cash charges of $0.9 million for the amortization of deferred stock compensation and non-cash stock compensation, $3.7 million for depreciation and amortization of deferred issuance costs, $8.4 million in amortization and impairment of acquired product rights, and $10.4 million in acquired research and development and milestone payments related to a milestone-based liability related to the completion of the Phase III clinical trial for oritavancin. The decrease in cash used for operations of $16.1 million for the year ended December 31, 2003 was offset by an increase in accounts receivable of $1.1 million resulting from increased product sales and an increase in product inventories of $13.5 million, less the impact of a $4.0 million increase in accounts payable and accrued compensation

expense. Increased sales levels and non-cancelable purchase commitments to acquire Actimmune led to the increase in product inventory and accounts payable.

Net cash provided by investing activities for the year ended December 31, 2003 was $19.9 million, compared to net cash used by investing activities of $32.1 million for the year ended December 31, 2002 and $157.4 million for the year ended December 31, 2001. For the year ended December 31, 2003, the net cash provided by investing activities was primarily due to the increase in the sale of our available-for-sale investments, offset by the payments for the purchase of acquired product rights, including research and development and milestone payments. The increase in the sale of available-for-sale investments for the year ended December 31, 2003 was primarily due to the cash requirements of funding our operations and the overall decrease of our cash portfolio balance. For the year ended December 31, 2002, the net cash used for investing activities was primarily due to the net purchases of short-term available-for-sale investments and cash used for the acquisition of product rights.

For the year ended December 31, 2001, the net cash used for investing activities was primarily due to the net purchases of short-term available-for-sale investments. Capital expenditures for equipment and leasehold improvements to support our operations were $1.5 million, $5.2 million and $7.5 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Net cash provided by financing activities for the year ended December 31, 2003 totaled $1.7 million, compared to $108.3 million for the year ended December 31, 2002 and $274.6 million for the year ended December 31, 2001. For the year ended December 31, 2003, the net cash provided by financing activities included the cash received for the issuance of common shares pursuant to our employee stock purchase program of $1.3 million, and the exercise of stock options by employees of $0.4 million.

For the year ended December 31, 2002, net cash provided by financing activities included $104.5 million received in net proceeds, after deducting underwriters' fees and expenses, from the sale of 3.0 million shares of common stock at $37.00 per share in a follow-on public offering, $2.3 million from stock option exercises and $1.5 million received under our employee stock purchase plan.

For the year ended December 31, 2001, net cash provided by financing activities included $128.8 million in net proceeds from the sale of common stock in a follow-on public offering, $144.4 million received from the sale of 5.75% convertible subordinated notes due 2006, $0.8 million from stock option exercises and $0.5 million received under our employee stock purchase plan.

Working capital of $201.9 million at December 31, 2003 decreased from $285.6 million at December 31, 2002. The decrease in working capital for the year ended December 31, 2003 was primarily due to funding our operating loss.

In December 2001, we filed a registration statement on Form S-3 to offer and sell our common stock in one or more offerings up to a total dollar amount of $150.0 million. Currently, $39.0 million remains available on the Form S-3. We have no current commitments to offer or sell any securities that may be offered or sold pursuant to such registration statement.

In February 2004, we issued $170.0 million of 0.25% convertible senior notes due March 1, 2011 in a private offering. The notes are convertible into our common stock at a conversion price of approximately $21.63 per share, subject to adjustment in certain events and at the holders' option. Interest on these notes is payable semiannually in arrears on March 1 and September 1 of each year. We may not redeem any of these notes prior to maturity. We intend to use the net proceeds from this offering to purchase or redeem before and/or during the third quarter of 2004 our outstanding 5.75% convertible subordinated notes due 2006. However, we may determine not to purchase or redeem all of our 5.75% convertible subordinated notes due 2006. The 5.75% convertible subordinated notes proceeds were used for general working capital purposes.

In February 2004, we purchased $52.5 million in principal amount of our outstanding 5.75% convertible subordinated notes due 2006 with the proceeds received from our 0.25% convertible senior notes due March 1, 2011. We paid a total of $55.0 million related to the purchase, which included $0.4 million for accrued interest on the convertible subordinate notes, and a premium of $2.1 million recognized as a loss on the early extinguishment of debt.

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We have no commercial commitments or loans with related parties, except for ongoing payments in connection with the oritavancin acquisition from Lilly to the SGO Group LLC for which Nicholas Simon, a former member of our Board of Directors who resigned in February 2003, was a principal at time of acquisition. We have no loans with related parties, except for executive loans to Dr. Marianne Armstrong, our Senior Vice President Regulatory/Medical Affairs and Drug Safety, and Dr. Lawrence Blatt, our Senior Vice President of Preclinical and Applied Research. Both of these loans were in place prior to the enactment of the Sarbanes-Oxley Act of 2002.

We believe that we will continue to require substantial additional funding in order 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 2004. 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, costs 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 payments of annual interest on our long-term debt;
- whether we will purchase or redeem our outstanding 5.75% convertible subordinated debt prior to maturity; and
- whether we must repay the principal in connection with the issuance of 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. 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as that term is defined in Item 303 of Regulation S-K) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

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, 2003, aggregated by type (in millions):

Contractual obligations	Total	2004	2005-2006	2007-2008	After 2008
Long-term debt obligations(1)	$149.5	$ —	$149.5	$ —	$ —
Operating leases	27.2	3.7	7.0	7.3	9.2
Non-cancelable purchase obligations—Inventory	207.7	40.7	49.2	37.0	80.8
Non-cancelable purchase obligations—Other(2)	55.4	26.4	16.6	11.7	0.7
Research and development funding commitments	1.5	1.5	—	—	—
Total contractual cash obligations	$441.3	$72.3	$222.3	$56.0	$90.7

(1) Does not include our long-term debt obligations incurred in connection with the issuance of our 0.25% convertible senior notes due 2011 in February 2004. We are required to make $8.6 million per year in interest payments related to our long-term debt obligations as of December 31, 2003.

(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 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 over the length of the agreement. We do not currently use derivative financial instruments to mitigate this exposure.

Recent Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46, *"Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51"* ("FIN 46"). FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after March 15, 2004. The adoption of FIN 46 did not have an impact on our consolidated financial statements.

In March 2003, the EITF reached a consensus on Issue No. 00-21, *"Revenue Arrangements with Multiple Deliverables"* ("EITF 00-21"), which provides guidance on accounting for arrangements involving the delivery or performance of multiple products, services and/or rights to use assets. Specifically, EITF 00-21 addresses: (1) how to determine whether an arrangement with multiple deliverables contains more than one unit of accounting, and (2) how the arrangement consideration

should be measured and allocated among the separate units of accounting. The provisions of EITF 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have an impact on our consolidated financial statements.

In April 2003, the FASB issued SFAS No. 149, *"Amendment of Statement 133 on Derivative Instruments and Hedging Activities"* ("SFAS 149"), which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under FAS No.133, *"Accounting for Derivative Instruments and Hedging Activities."* SFAS 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS 149 did not have an impact on our consolidated financial statements.

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. At December 31, 2003, the average effective maturity of our available-for-sale securities was 186 days.

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, 2003 (in millions):

	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%	—	—	—	—

The table below presents the principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as December 31, 2002 (in millions):

	2003	2004	2005	2006	2007	Total	Fair value at December 31,2002
Assets:							
Available-for-sale securities	$259.8	$17.9	—		—	$277.7	$280.5
Average interest rate	1.7%	3.7%	—	—	—	—	—
Liabilities:							
5.75% convertible subordinated notes due 2006	—	—	—	$149.5	—	$149.5	$148.6
Average interest rate	—	—	—	5.75%	—	—	—

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
InterMune, Inc.

We have audited the accompanying consolidated balance sheets of InterMune, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of InterMune, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

ERNST & YOUNG LLP

Palo Alto, California
January 16, 2004, except for note 18
for which the date is February 26, 2004.

INTERMUNE, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,071	$ 101,683
Available-for-sale securities	174,036	214,728
Accounts receivable, net of allowances of $2,977 in 2003 and $3,415 in 2002	13,270	12,135
Inventories	20,062	6,604
Prepaid expenses	2,417	2,269
Total current assets	251,856	337,419
Property and equipment, net	9,621	10,833
Acquired product rights, net	21,978	30,336
Restricted cash	1,675	1,675
Notes receivable from employees	698	906
Other assets	2,673	3,712
Total assets	$ 288,501	$ 384,881
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 20,281	$ 16,843
Accrued compensation	6,357	5,353
Other accrued liabilities	23,363	29,590
Total current liabilities	50,001	51,786
Deferred rent	1,256	877
Convertible subordinated notes	149,500	149,500
Commitments		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2003 and 2002	—	—
Common stock, $0.001 par value, 51,000,000 authorized shares; 31,845,011 shares and 31,695,672 shares issued and outstanding at December 31, 2003 and 2002, respectively	32	32
Additional paid-in capital	483,697	481,881
Notes receivable from stockholder	—	(38)
Deferred stock compensation	(217)	(947)
Accumulated other comprehensive income	400	957
Accumulated deficit	(396,168)	(299,167)
Total stockholders' equity	87,744	182,718
Total liabilities and stockholders' equity	$ 288,501	$ 384,881

See Accompanying Notes.

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	For the year ended December 31,		
	2003	2002	2001
Product sales			
Actimmune	$141,402	$ 105,802	$ 36,320
Others	12,736	6,163	3,631
Total product sales, net	154,138	111,965	39,951
Costs and expenses:			
Cost of goods sold	36,309	24,161	15,474
Amortization and impairment of acquired product rights	8,358	3,593	4,805
Research and development	119,858	129,590	52,049
Selling, general and administrative	68,451	62,752	35,895
Acquired research and development and milestone payments	12,150	33,750	56,400
Total costs and expenses	245,126	253,846	164,623
Loss from operations	(90,988)	(141,881)	(124,672)
Other income (expense):			
Interest income	4,024	7,375	11,253
Interest and other expense	(10,037)	(9,803)	(4,772)
Net loss	$(97,001)	$(144,309)	$(118,191)
Basic and diluted net loss per common share	$ (3.06)	$ (4.72)	$ (4.67)
Shares used in computing basic and diluted net loss per common share	31,665	30,589	25,322

See Accompanying Notes

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 Compensation Related to Stock Options	Other income	Accumulated deficit	Total stockholders' equity
	Shares	Amount						
Balance at December 31, 2000	**23,898**	**$24**	**$239,620**	**$(95)**	**$(7,188)**	**$107**	**$ (36,667)**	**$195,801**
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(58)	—	(58)
Net loss	—	—	—	—	—	—	(118,191)	(118,191)
Comprehensive net loss	—	—	—	—	—	—	—	(118,249)
Exercise of stock options	189	—	835	—	—	—	—	835
Stock issued under employee stock purchase plan	25	—	534	—	—	—	—	534
Issuance of common stock in a public offering at $32.00 per share, net of issuance costs of $8,628	4,296	4	128,837	—	—	—	—	128,841
Issuance of common stock for technology license and common stock investment in a private company	43	—	2,160	—	—	—	—	2,160
Payment of note receivable net of accrued interest	—	—	—	39	—	—	—	39
Stock compensation related to options granted to consultants for services	—	—	1,324	—	—	—	—	1,324
Amortization of deferred stock compensation	—	—	—	—	3,774	—	—	3,774
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 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
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**

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	For the year ended December 31,		
	2003	2002	2001
Cash flows used for operating activities:			
Net loss	$(97,001)	$(144,309)	$(118,191)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization of deferred compensation, net of reversals	180	1,020	3,774
Non-cash stock compensation	682	1,770	1,324
Non-cash charge related to acquisition of technology license and common stock investment	—	—	2,160
Accretion of obligations payable to Connetics	—	—	30
Acquired research and development and milestone payments	12,150	33,750	56,400
Amortization	4,622	4,619	2,685
Depreciation	2,680	1,964	766
Deferred rent	379	496	381
Impairment of intangible asset	4,761	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(1,135)	(6,780)	(3,555)
Inventories	(13,458)	(2,682)	(2,873)
Prepaid expenses	(148)	(962)	(755)
Restricted cash	—	—	(1,425)
Other assets	222	(746)	(284)
Accounts payable and accrued compensation	4,042	11,041	8,313
Payable to Connetics	—	—	1,691
Other accrued liabilities	773	3,439	7,057
Net cash used for operating activities	(81,251)	(97,380)	(42,502)
Cash flows from investing activities:			
Purchase of property and equipment	(1,468)	(5,204)	(7,516)
Purchase of acquired product rights, including research and development and milestone payments	(18,750)	(22,250)	(87,000)
Purchases of available-for-sale securities	(256,156)	(223,869)	(407,146)
Maturities of available-for-sale securities	113,528	163,873	170,370
Sales of available-for-sale securities	182,763	55,328	173,895
Net cash provided by (used for) investing activities	19,917	(32,122)	(157,397)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	1,684	108,252	130,210
Proceeds from convertible subordinated notes, net	—	—	144,374
Repayment of notes receivable from stockholder	38	18	39
Net cash provided by financing activities	1,722	108,270	274,623
Net increase (decrease) in cash and cash equivalents	(59,612)	(21,232)	74,724
Cash and cash equivalents at beginning of period	101,683	122,915	48,191
Cash and cash equivalents at end of period	$ 42,071	$ 101,683	$ 122,915
Supplemental disclosure of cash flow information:			
Interest paid	$ 8,596	$ 8,836	$ 30
Schedule of non-cash transactions:			
Issuance of common stock for technology license and common stock investment	—	—	2,160
Payable for acquired product rights and milestone payments	10,400	2,000	2,000
Payable for royalty rate buy down	—	15,000	—

See Accompanying Notes.

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 products for the treatment of serious pulmonary and hepatic diseases. We have three marketed products and advanced-stage development programs addressing a range of diseases with attractive markets. Our three marketed products are Actimmune® (interferon gamma-1b), Infergen® (interferon alfacon-1) and Amphotec®/Amphocil® (amphotericin B cholesteryl sulfate complex for injection). Actimmune is approved in the United States for two rare congenital disorders, chronic granulomatous disease and severe, malignant osteopetrosis, and is in Phase III clinical development as a treatment for idiopathic pulmonary fibrosis. We market Infergen in the United States and Canada for the treatment of chronic hepatitis C virus (HCV) infections, and are planning a Phase III clinical trial for Infergen in combination with ribavirin for patients who have not responded to previous treatments for HCV. We have worldwide marketing rights to Amphotec for the treatment of invasive aspergillosis (see Note 3). Our late-stage development pipeline also includes programs focused on Actimmune for the treatment of ovarian cancer, and oritavancin for the treatment of serious hospital-based gram-positive infections. We also have development programs for pirfenidone for the treatment of idiopathic pulmonary fibrosis and a pegylated form of interferon alfacon-1 (PEG-Alfacon-1) for the treatment of chronic HCV infections. We also have strategic assets that do not fit within our core focus areas of pulmonology and hepatology. These assets are oritavancin, Amphotec and Actimmune for the treatment of ovarian cancer. InterMune was incorporated in the state of California in 1998 and reincorporated in Delaware in 2000.

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 intercompany 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 generally accepted accounting principles requires management to make estimates and assumptions that affect: (i) the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and (ii) 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, discounts and rebates; excess inventories; inventory purchase commitments; and accrued clinical and preclinical expenses. We base our estimates on historical experience and on other specific assumptions that we believe are reasonable under the circumstances, the results of which form the basis for our 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, which is 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.

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 help manage our inventory levels of Actimmune, we are conducting an ongoing study to determine whether its expiration period may be lengthened. 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.

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.

Fair value of other financial instruments

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value because of the short-term maturity of these instruments. The fair value of our convertible subordinated debt was $148.6 million at December 31, 2003, which we determined using available market information.

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 maintain safety and liquidity. We invest our excess cash in debt instruments of the U.S. government 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 at an average contractual maturity of generally less than two years.

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 when necessary. However, we generally do not require collateral on accounts receivable. See Note 13 for additional customer concentration details.

Risks from third-party manufacturer concentration

We rely on a single-source manufacturer for each of our products. Actimmune is produced solely by Boehringer Ingelheim Austria GmbH (BI Austria) for all clinical and commercial supplies. Infergen is produced solely by Amgen Inc. Amphotec, marketed as Amphocil outside of the United States, is

produced solely by Ben Venue Laboratories Inc. (Amphotec and Amphocil are referred to collectively in this Report as "Amphotec.") Any extended interruption in the supply of any of our products could cause us to fail to meet clinical or commercial demand.

We purchase some commercial and clinical products from BI Austria in a foreign currency. This exposes us to foreign currency exchange rate risk, which we monitor as part of our overall risk management program. There are no other significant sources of foreign currency exchange risk. We do not currently hedge this risk.

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. We expense as acquired research and development and milestone payments 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 future uses.

Acquired product rights in 2002 related to the acquisition of interferon gamma patents. Acquired product rights in 2001 related to the acquisition of Amphotec and Infergen. Accumulated amortization of these intangible assets was $14.1 million at December 31, 2003, which included a charge of $4.8 million for the impairment of Amphotec product rights recorded during 2003. See Note 3 below for additional disclosures concerning this impairment charge.

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. See Note 3 below for additional disclosures concerning the $4.8 million charge for the impairment of Amphotec.

Revenue recognition and revenue reserves

We recognize revenue upon shipment 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 our products that have reached their expiration date. We believe that we are able to make reasonable and reliable estimates of product returns 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.

Research and development expenses

Research and development, or 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 R&D 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 to the extent possible. However, if we underestimate activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods when the actual activity level becomes known. We charge all such costs to R&D expenses as incurred.

Advertising costs

We expense advertising costs as incurred. Advertising costs were $146,000, $93,000 and $130,000 for the years ended December 31, 2003, 2002 and 2001, 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.

Patent costs

We expense costs related to patents as incurred.

Stock-based compensation

As permitted by SFAS No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123"), we have elected to follow Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB 25"), and related Interpretations in accounting for stock-based employee compensation. Under APB 25, if the exercise price of our employee and director stock options equals or exceeds the deemed fair value of the underlying stock on the date of grant, no compensation expense is recognized.

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 original award, generally five years. 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 remeasure as the underlying options vest.

The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share data):

	Year Ended December 31,		
	2003	2002	2001
Net loss, as reported	$ (97,001)	$(144,309)	$(118,191)
Add: Stock-based employee compensation expense, included in reported net loss	180	2,790	5,098
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(24,999)	(30,611)	(20,158)
Pro forma net loss	$(121,820)	$(172,130)	$(133,251)
Net loss per share:			
Basic and diluted—as reported	$ (3.06)	$ (4.72)	$ (4.67)
Basic and diluted—pro forma	$ (3.85)	$ (5.63)	$ (5.26)

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 has been disclosed in the statements of stockholders' equity.

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,		
	2003	2002	2001
Options	5,728	4,491	2,988
Shares issuable upon conversion of convertible subordinated notes	3,893	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,		
	2003	2002	2001
Net loss	$(97,001)	$(144,309)	$(118,191)
Basic and diluted net loss per common share:			
Weighted-average shares of common stock outstanding	31,761	30,976	26,080
Less: weighted-average shares subject to repurchase	(96)	(387)	(758)
Weighted-average shares used in computing basic and diluted net loss per common share	31,665	30,589	25,322
Basic and diluted net loss per common share	$ (3.06)	$ (4.72)	$ (4.67)

Recent accounting pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46, "*Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*" ("FIN 46"). FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after March 15, 2004. The adoption of FIN 46 did not have an impact on our consolidated financial statements.

In March 2003, the EITF reached a consensus on Issue No. 00-21, "*Revenue Arrangements with Multiple Deliverables*" ("EITF 00-21"), which provides guidance on accounting for arrangements involving the delivery or performance of multiple products, services and/or rights to use assets. Specifically, EITF 00-21 addresses: (1) how to determine whether an arrangement with multiple deliverables contains more than one unit of accounting, and (2) how the arrangement consideration should be measured and allocated among the separate units of accounting. EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have an impact on our consolidated financial statements.

In April 2003, the FASB issued SFAS No. 149, "*Amendment of Statement 133 on Derivative Instruments and Hedging Activities*" ("SFAS 149"), which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under FAS No.133, "*Accounting for Derivative Instruments and Hedging Activities.*" SFAS 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS 149 did not have an impact on our consolidated financial statements.

3. ACQUIRED PRODUCT RIGHTS

Marnac, Inc. ("Marnac")

In 2002, we exclusively licensed from Marnac, Inc. and KDL GmbH their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Pirfenidone is not approved by the FDA and is currently in Phase II clinical development for fibrotic diseases of the lung and kidney. Under the terms of the

license agreement, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and potential 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.

Amgen Inc. ("Amgen")

In 2002, we acquired certain interferon gamma patents of Amgen Inc. 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.

In 2001, we entered into a license and commercialization agreement with Amgen through which we obtained the exclusive license in the United States and Canada to Infergen (interferon alfacon-1), an interferon alpha product, 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 PEG-Alfacon-1 and clinically develop them for other indications in the United States and Canada. Our rights to Infergen could revert to Amgen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. We paid Amgen up-front license fees, up-front milestones and other up-front fees totaling $29.0 million with respect to the acquisition of our license for both Infergen and PEG-Alfacon-1. We are obligated to pay royalties on sales of Infergen (included in cost of goods sold), and will be obligated to pay royalties on sales of PEG-Alfacon-1, as discussed below. 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.

We are also required to pay Amgen additional milestone payments on the PEG-Alfacon-1 program and royalties on sales of the resulting product, if any. We do not expect the PEG-Alfacon-1 program, which completed Phase I clinical development in 2003, to reach the FDA approval stage until 2010 at the earliest, if at all. In accordance with the agreement, we made a $1.5 million milestone payment in June 2003 due to the commencement of the Phase I clinical trial for PEG-Alfacon-1.

We determine the value assigned to acquired in-process research and technology by estimating both the costs to develop the purchased in-process research and development into a commercially viable product, including development milestones, and the resulting net cash flows from the project, and discounting the net cash flows to their present value. We used a discount rate of 33% for valuing the in-process research and development, which was intended to be commensurate with our corporate maturity, PEG-Alfacon-1's stage of development and the uncertainties in the economic estimates described above.

The estimates we used in valuing in-process research and development were based upon assumptions we believe to be reasonable but which are inherently uncertain and unpredictable. Our assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur. Accordingly, actual results may vary from the projected results of our PEG-Alfacon-1 program.

Eli Lilly and Company ("Lilly")

In 2001, we entered into an asset purchase and license agreement with Lilly pursuant to which we acquired Lilly's worldwide rights to oritavancin. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. Because oritavancin is not currently aligned with our strategic focus, we are seeking a commercial partner. In order to partner oritavancin, the agreement requires that we first offer Lilly the opportunity to enter into such a partnering relationship with us, which we have done. 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 Lilly. Our rights to oritavancin could revert to 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 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, Lilly may terminate the agreement and our rights to oritavancin would revert to Lilly. In any event, we may not assign the agreement to a potential acquirer without the advance, written consent of Lilly.

Pursuant to the agreement, we paid Lilly $50.0 million and will be obligated to pay Lilly significant milestone and royalty payments upon our successful development and commercialization of oritavancin. 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. In 2002, Lilly exercised its option under the agreement to reduce the agreed percentage of royalty payable by us to Lilly on oritavancin product sales. The exercise of this option required us to pay $15.0 million to Lilly, which was expensed as acquired research and development and milestone payments in 2002 and was paid during January 2003. In 2003, we accrued $10.0 million as a liability related to a milestone payment due to Lilly for the completion of the Phase III clinical trials for oritavancin. This amount was expensed as acquired research and development and milestone payments in 2003.

ALZA Corporation ("ALZA")

In 2001, we acquired from ALZA the worldwide rights to Amphotec (amphotericin B cholesteryl sulfate complex for injection), which is sold under the trade name Amphocil in certain countries outside the United States. Amphotec is currently approved in North America and many other countries for the treatment of invasive aspergillosis. 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 (included in cost of goods sold). We are also subject to certain royalty obligations to the University of California under this agreement. 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. 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.

During 2003, we recorded a charge of $4.8 million for the impairment of Amphotec product rights. The impairment charge reduced the remaining carrying value of the intangible asset that was originally recorded in 2001 when we acquired the product. We recognized this impairment charge as a result of sales levels being lower than we expected and our decision to seek a buyer or strategic partner for the product, as Amphotec is not aligned with our strategic focus in pulmonology and hepatology. We determined the remaining carrying value of the product based on the present value of expected future cash flows, and we believe it is not in excess of Amphotec's net realizable value. We are seeking to divest Amphotec, as it is no longer aligned with our strategic focus.

Genentech, Inc. ("Genentech")/Connetics Corporation ("Connetics")

At our formation in 1998, we entered into an agreement with Connetics under which we obtained an exclusive sublicense under the rights granted to Connetics by Genentech through a license agreement for Actimmune, in exchange for shares of our common stock. We also agreed to assume many of Connetics' obligations to Genentech under that license agreement. We entered into an agreement with Connetics in 1999 in order to broaden our scope of rights. In 2000, we entered into an assignment and option agreement with Connetics, by which Connetics assigned the Genentech license to us. In 2002, we entered into a purchase agreement with Connetics through which Connetics' option in the assignment agreement for any rights in the field of dermatology was terminated. 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 rights under Genentech's patents. The exclusive Actimmune rights include an exclusive license to develop and commercialize in the United States, Canada, and Japan for a broad range of diseases, including, but not limited to, chronic granulomatous disease, osteopetrosis, and pulmonary fibrosis. Actimmune is currently approved in the United States to treat chronic granulomatous disease and osteopetrosis. Under the Genentech license, we pay Genentech royalties on the sales of Actimmune (included in cost of goods sold), and are required to make one-time payments to Genentech upon the occurrence of specified milestone events. We must satisfy specified obligations under the agreement with Genentech to maintain our license from Genentech. We are obligated under the agreement to develop and potentially commercialize Actimmune for a number of diseases. Royalties are payable upon net sales of Actimmune to Connetics. Through an assignment and option agreement with Connetics, we became obligated to pay to Connetics, beginning on January 1, 2002, a royalty of 0.25% of net U.S. sales of Actimmune until net U.S. sales cumulatively surpass $1.0 billion. Above $1.0 billion, we are obligated to pay a royalty of 0.5% of net U.S. sales of Actimmune. Through a separate purchase agreement, we are obligated to pay Connetics a royalty of 4.0% on our net sales of Actimmune for the treatment of scleroderma.

4. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS

Array BioPharma Inc. ("Array")

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. Total research and development expenses related to this agreement were $2.1 million for the year ended December 31, 2003 and $593,000 for the year ended December 31, 2002.

Maxygen, Inc. ("Maxygen")

In 2001, we entered into a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, to develop and commercialize novel, next-generation interferon gamma products. Under this agreement, we will take forward into clinical development certain product candidates created by Maxygen. We will fund optimization and development of these next-generation interferon gamma products, and will retain exclusive worldwide commercialization rights for all human therapeutic indications. The agreement terms include up-front license fees, full research funding and development and commercialization milestone payments. We paid Maxygen a total of $228,000, $5.1 million, and $3.5 million for the years ended December 31, 2003, 2002 and 2001, respectively. The

payments were charged to research and development expense. In addition, Maxygen will receive royalties on product sales.

Boehringer Ingelheim International GmbH ("BI International")

In 2001, InterMune and BI International formed an international strategic collaboration to develop and commercialize Actimmune under BI International's trade name, Imukin®, in all countries outside of the United States, Canada and Japan. Indications to be developed include idiopathic pulmonary fibrosis (IPF), chronic granulomatous disease (CGD), osteopetrosis, as well as additional indications to be agreed upon later. During 2002, the strategic collaboration agreement was amended to include the additional indications of ovarian cancer, liver fibrosis and non-Hodgkin's lymphoma. This strategic alliance adds worldwide scope to our existing rights to develop and commercialize Actimmune in the United States, Canada and Japan.

Under the agreement, we will fund and manage clinical and regulatory development of Actimmune for all indications. BI International has an option to exclusively promote Imukin, and we may opt to promote the product where BI International does not do so. Furthermore, the two companies will share in the profits from commercializing Actimmune outside of North America and Japan through a specified royalty schedule. Prior to receiving the first regulatory approval for any of IPF, tuberculosis or systemic fungal infections, the agreement provides us with royalties on Imukin net sales above 2000 levels. No royalties have been earned or paid under the terms of this agreement. Imukin is currently approved and marketed for CGD in 36 countries. BI International is currently seeking EU approval for Imukin for the treatment of severe, malignant osteopetrosis, an indication for which Actimmune is already approved in the United States. We also plan to expand our Phase III clinical development programs to target approvals in the expanded international markets. No royalties have been earned to date. In addition to the above agreement, BI International's affiliate Boehringer Ingelheim Austria GmbH ("BI Austria") manufactures all commercial and clinical supply of Actimmune for us at contractually determined unit prices.

Mondobiotech SA. ("Mondobiotech")

In 2001, we paid cash and issued 42,822 shares of our common stock with an aggregate value of $3.7 million to Mondobiotech, a European privately held development stage company, in exchange for technology licenses and common stock. This amount was charged to research and development expense. The license agreement terms include up-front license fees and milestone payments. In addition, we will pay royalties on product sales in certain European countries upon regulatory approval. In December 2001, we expensed the equity component of this transaction because of the early stage of development of the investee and the uncertainty of future realization.

Funding Commitments

Our non-cancelable funding commitments under the above arrangements totaled $1.5 million at December 31, 2003, and these commitments are due during the year ending December 31, 2004.

5. AVAILABLE-FOR-SALE INVESTMENTS

The following is a summary of our available-for-sale investments as of December 31, 2003 and 2002 (in thousands):

December 31, 2003

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Obligations of U.S. federal and state governments	$ 99,987	$293	$(15)	$100,265
Corporate debt securities	83,550	144	(23)	83,671
Other debt securities	24,066	1	—	24,067
Total	$207,603	$438	$(38)	$208,003

Reported as:

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

December 31, 2002

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Obligations of U.S. federal and state governments	$ 64,733	$583	$—	$ 65,316
Corporate debt securities	106,606	376	(2)	106,980
Other debt securities	108,242	—	—	108,242
Total	$279,581	$959	$(2)	$280,538

Reported as:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents	$ 65,808	$ 3	$(1)	$ 65,810
Available-for sale securities	213,773	956	(1)	214,728
Total	$279,581	$959	$(2)	$280,538

The realized gains and losses for the years 2003 and 2002 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):

	2003		2002	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Mature in less than one year	$132,113	$132,438	$152,289	$152,606
Mature in one to three years	43,645	43,713	30,585	31,225
Mature in over three years	31,845	31,852	96,707	96,707
Total	$207,603	$208,003	$279,581	$280,538

6. INVENTORIES

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

	2003	2002
Raw materials	$ 552	$ 182
Finished goods	19,510	6,422
Total	$20,062	$6,604

For the year ended December 31, 2003, we recorded a total of $1.3 million to cost of goods for excess inventory.

7. PROPERTY AND EQUIPMENT

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

	2003	2002
Computer and laboratory equipment	$ 3,654	$ 2,322
Office furniture and fixtures	3,335	3,233
Leasehold improvements	7,862	8,172
	14,851	13,727
Less accumulated depreciation and amortization	(5,230)	(2,894)
Total	$ 9,621	$10,833

8. OTHER ACCRUED LIABILITIES

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

	2003	2002
Accrued clinical trial costs	$ 4,882	$ 4,342
Accrued interest	3,940	3,940
Payable to Amgen	—	2,000
Payable to Lilly	10,000	15,000
Royalties payable	4,254	4,101
Other accrued liabilities	287	207
Total other accrued liabilities	$23,363	$29,590

9. CONVERTIBLE SUBORDINATED NOTES

On July 5, 2001, we completed a public offering of $149.5 million aggregate principal amount of 5.75% convertible subordinated notes due July 15, 2006 ("the Notes"). The notes are unsecured and rank junior to all of our future unsecured and unsubordinated debts. The notes are convertible at any time at the option of the note holders into our common stock at a conversion price of $38.40 per share subject to adjustment in certain circumstances. Interest on the notes is payable semi-annually in arrears in January and July and we can redeem all or a portion of the notes at any time on or after July 15, 2004. We recognized $8.6 million in interest expense related to the Notes during each of the years ended December 31, 2003 and 2002. Offering expenses of $5.1 million related to the sale of the Notes have been included in other assets and are amortized to interest expense over the life of the Notes. The accumulated amortization of the debt issuance costs was $2.6 million at December 31, 2003. See Note 18 for additional details regarding the issuance of our 0.25% convertible senior notes due March 1, 2011.

10. STOCKHOLDERS' EQUITY

Common stock subject to repurchase

In connection with the issuance of common stock to founders and the exercise of options pursuant to our 1999 and 2000 Equity Incentive Plans, certain employees and non-employee directors entered into restricted stock purchase agreements. Under the terms of these agreements, upon termination of employment or service as a director, we have a right to repurchase any unvested shares at the original issuance price of the shares. With continuous employment or services provided, generally the repurchase rights lapse at a rate of 25% at the end of the first year and at a rate of 1/36th of the remaining purchased shares for each continuous month of service thereafter. The total number of shares subject to repurchase by us were 55,927 shares, 192,000 shares and 596,000 shares as of December 31, 2003, 2002 and 2001, respectively.

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 five 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 totaling 7,217 and 49,501 at a purchase price of $0.125 during 2003 and 2002, respectively. The shares repurchased in 2003 and 2002 were granted to employees under the 1999 Plan and are not available for future grant.

In 2000, the Board of Directors adopted the 2000 Equity Incentive Plan and the 2000 Non-Employee Directors' Stock Option Plan. In 2000, a total of 2,000,000 shares of common stock were initially reserved for issuance under the 2000 Equity Incentive Plan and 180,000 shares under the 2000 Non-Employee Directors' Stock Option Plan. The 2000 Equity Incentive Plan and 2000 Non-Employee Directors' Stock Option Plans 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. Certain options are immediately exercisable, at the discretion of the board of directors. 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 4 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, 2000	1,705,000	1,222,653	$15.27
Authorized	896,939	—	—
Shares terminated under 1999 plan and not available for future grants	(41,000)	—	—
Granted	(2,094,501)	2,094,501	$35.59
Cancelled	139,668	(139,668)	$24.14
Exercised	—	(189,398)	$ 4.41
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

The following table summarizes information about options outstanding at December 31, 2003:

	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	379,877	8.2	$12.00	170,093	$ 6.11
$17.13 - $25.90	3,150,639	8.9	$21.53	759,101	$23.43
$26.34 - $41.25	1,072,202	7.6	$33.80	682,621	$33.41
$42.50 - $53.00	1,125,274	7.8	$43.53	714,159	$43.59
	5,727,992		$27.52	2,325,974	$31.28

Employee stock purchase plan

To provide employees with an opportunity to purchase our common stock through payroll deductions, we established the 2000 Employee Stock Purchase Plan. Under this plan, 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 15% of each employee's eligible compensation. Through the end of December 2003, we issued a total of 170,672 shares under this plan, and 1,022,070 shares remain available for future issuance.

Pro forma information

We account for our stock based compensation plans under the recognition and measurement principles of APB Opinion No. 25, *"Accounting for Stock Issued to Employees,"* and related Interpretations. Accordingly, we do not recognize compensation cost for options granted to employees with exercise prices greater than fair value of the underlying common stock on the date of grant. The effect on net loss and losses per share if we had applied the fair value recognition provisions of FASB Statement No. 123, *"Accounting for Stock-Based Compensation,"* to stock-based employee compensation is described in Note 2.

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:

	Years ended December 31,		
	2003	2002	2001
Expected stock price volatility	80%	85%	90%
Risk-free interest rate	3.3%	2.3%	3.7%
Expected life (in years)	4.9	3.4	3.3
Expected dividend yield	—	—	—

The weighted average fair value of options granted was $12.59 in 2003, $18.99 in 2002 and $20.99 in 2001.

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

	Years ended December 31,		
	2003	2002	2001
Expected stock price volatility	83%	78%	90%
Risk-free interest rate	2.3%	1.7%	5.0%
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, 2003, 2002 and 2001 was $16.63, $18.44 and $24.82, respectively.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because our stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, our management does not believe that the existing models necessarily provide a reliable single measure of the fair value of our options.

Stock compensation

In 2001, we granted a fully vested option to purchase 10,000 shares of common stock to a consultant, and recognized a stock compensation charge of $298,000 to selling, general and administrative expense related to this grant. Compensation expense is recorded upon grant, if the

option vests upon grant, or as the options vest based upon the fair value of the options, determined using the Black-Scholes pricing model. In 2003, we entered into an agreement with a former employee that allowed options held by the former employee to continue to vest through 2004. As a result of the agreement we recognized $367,000 to selling, general, and administrative expense in 2003. We also entered into an agreement in 2003 to issue a share award of 25,000 restricted shares to an employee. These restricted shares vest quarterly through June 30, 2006. As a result of the agreement, we recognized $157,000 to selling, general, and administrative expense during 2003. As the share award vests through 2006, we will continue to recognize selling, general, and administrative expense related to the grant of these restricted shares.

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 of approximately $0.6 million, $1.8 million, and $3.8 million for the years ended December 31, 2003, 2002 and 2001, respectively. Deferred stock compensation expense is being amortized using the graded vesting method over the vesting period of the individual award, generally five years. We reversed approximately $0.4 million and $0.8 million for the years ended December 31, 2003 and 2002, 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. At December 31, 2003, we had a total of $0.2 million to be amortized over the remaining vesting periods of the stock options. The amount of deferred stock compensation expense to be recorded in future periods could decrease if options, for which accrued but unvested compensation has been recognized, are forfeited prior to vesting.

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 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 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, 2003, common stock subject to future issuance is as follows:

Common stock issuable upon conversion of convertible subordinated debt	3,893,229
Outstanding common stock options	5,727,992
Common stock available for grant under stock option plans	1,311,685
Common stock available for grant under the 2000 Employee Stock Purchase Plan	1,022,070
	11,954,976

11. 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):

	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 95,000	$ 68,000
Research and development credits	8,000	3,000
Capitalized research and development costs	50,000	42,000
Other, net	5,000	2,000
Total deferred tax assets	158,000	115,000
Valuation allowance	(158,000)	(115,000)
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 $43.0 million, $59.9 million and $45.2 million during the years ended December 31, 2003, 2002 and 2001, respectively.

Deferred tax assets related to carryforwards at December 31, 2003 include approximately $4.7 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders equity.

As of December 31, 2003, we had net operating loss carryforwards for federal income tax purposes of approximately $275.5 million, which expire in the years 2018 through 2023, and federal research and development credits of approximately $4.5 million, which expire in the years 2018 through 2023. In addition, we have net operating loss carryforwards for state income tax purposes of approximately $30.1 million, which expire in the years 2008 through 2013 and state research and development tax credits of approximately $1.5 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.

12. COMMITMENTS AND CONTINGENCIES

Leases

We have two non-cancelable leases for facilities, which expire in 2004 and 2011. Total rent expense was approximately $3.7 million, $3.7 million and $2.6 million for the years ended December 31, 2003, 2002 and 2001, respectively. In addition, we have entered into 3-year auto leases for our field sales force.

In 2001, we subleased a former facility and recognized rental income of $126,000, $175,000 and $30,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Aggregate future rental income to be received amounts to $110,000 through 2004.

The following is a schedule by year of future minimum lease payments of all leases at December 31, 2003 (in thousands):

Year	Operating Leases
2004	$ 3,992
2005	3,769
2006	3,806
2007	3,870
2008	4,000
Thereafter	10,098
	$29,535

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, 2003 and 2002, restricted cash under these letters of credit amounted to $1.7 million for each year-end.

Purchase Commitments

We have purchase commitments with BI Austria and Amgen for the manufacture and supply of Actimmune and Infergen, respectively. These commitments are comprised of 12- and 24-month fixed purchase orders of $40.7 million and minimum purchase obligations through 2012 that total $167.0 million at December 31, 2003. Our contractual obligation to BI Austria is denominated in Euros. We currently do not use derivative financial instruments to mitigate this exposure.

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 $200.2 million if all of the milestones per the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

13. GEOGRAPHIC SALES AND SIGNIFICANT CUSTOMERS

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

	2003	2002	2001
Actimmune	$141,402	$105,802	$36,320
Infergen	9,275	2,931	766
Amphotec	3,461	3,232	2,865
Totals	$154,138	$111,965	$39,951

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

	2003	2002	2001
United States	$151,373	$109,537	$37,838
Rest of world	2,765	2,428	2,113
Totals	$154,138	$111,965	$39,951

Product sales to customers comprising 10% or more of total sales during 2003, 2002 and 2001 are as follows:

Customer	2003	2002	2001
AmerisourceBergen	2%	2%	22%
Cardinal Healthcare	2%	3%	18%
Caremark	11%	10%	—
Merck Medco	10%	11%	—
McKesson HBOC	3%	2%	23%
Priority Healthcare	59%	57%	21%

Concentrations of credit risk, with respect to accounts receivable, exist to the extent of amounts presented in the financial statements. No other customer represented 10% or more of accounts receivable at December 31, 2003 or December 31, 2002.

Customer	2003	2002
Caremark	10%	12%
Merck Medco	10%	12%
Priority Healthcare	59%	58%

14. RELATED PARTY TRANSACTIONS

In connection with the acquisition of the rights to oritavancin from Eli Lilly and Company in the fourth quarter of 2001 (see Note 3), we paid an execution fee of $1.0 million to the SGO Group LLC. Mr. Simon, a member of our Board of Directors at the time of the acquisition of the oritavancin rights from Lilly was, at the same time, a principal with the SGO Group and, as such, received compensation in connection with this transaction. The $1.0 million fee was charged to acquired research and development and milestone payments as part of the acquisition costs of oritavancin. In addition to the fee, we are obligated to pay the SGO Group certain pro-rated fees on the achievement of development milestones for oritavancin. During 2003, we expensed a total of $10.4 million as acquired research and development and milestone payments, related to a $10.0 million milestone payment due to Lilly for the completion of the Phase III clinical trials for oritavancin and $0.4 million due to the SGO Group that was included in accrued liabilities at December 31, 2003.

15. EMPLOYEE SAVINGS PLAN

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

16. LEGAL PROCEEDINGS

On June 25, 2003, a purported securities class action was filed in the United States District Court for the Northern District of California. The complaint named us and our former Chief Executive 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 Securities Exchange Act of 1934, and Rule 10b-5. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 6, 2003 through June 11, 2003. Additional class action complaints have since been filed in the same court, each making identical or similar allegations against us, our former Chief Executive Officer and our current Chief Financial Officer. We believe that we have meritorious defenses to the allegations contained in the securities class action complaints and intend to defend ourselves vigorously. We expect that these complaints will eventually be consolidated into a single action. No trial date has been scheduled.

On July 30, 2003, a stockholder purporting to act on our behalf filed a derivative action in the California Superior Court for the County of San Mateo against our directors, our former Chief Executive Officer and our current 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. We believe we have meritorious defenses to the allegations contained in the derivative action complaint and intend to defend ourselves vigorously. No trial date has been scheduled.

We have assessed the allegations and circumstances underlying these claims, and at this time we cannot predict or determine the eventual outcome or potential loss or range of losses that would be incurred if an unfavorable outcome were to occur.

17. 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, 2003.

18. SUBSEQUENT EVENTS

In February 2004, we issued 0.25% convertible senior notes due March 1, 2011 in an aggregate principal amount of $170.0 million (Convertible Notes). The Convertible Notes are convertible into our common stock at a conversion price of approximately $21.63 per share, subject to adjustment in certain events and at the holders' option. Interest on the Convertible Notes is payable semiannually in arrears on March 1 and September 1 of each year. The Convertible Notes are unsecured and will rank on parity with all of our other existing and future senior unsecured debt and prior to all subordinated indebtedness. We may not redeem any of the notes at our option prior to maturity. We intend to use the net proceeds from this offering to purchase or redeem, before and/or during the third quarter of 2004, our outstanding 5.75% convertible subordinated notes due 2006. However, we may determine not to purchase or redeem all of our 5.75% convertible subordinated notes due 2006. We plan to file a shelf registration statement covering the resale of the Convertible Notes and the common stock issuable upon conversion of the Convertible Notes.

In February 2004, we purchased $52.5 million in principal amount of our outstanding 5.75% convertible subordinated notes due 2006 with the proceeds received from our 0.25% convertible senior notes due March 1, 2011. We paid a total of $55.0 million related to the purchase, which included $0.4 million for accrued interest on the convertible subordinated notes, and a premium of $2.2 million recognized as a loss on the early extinguishment of debt. We will also recognize an $0.8 million loss on unamortized deferred issuance costs associated with the extinguished debt.

19. QUARTERLY FINANCIAL DATA (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(In thousands, except per share amounts)				
2003					
Product sales					
Actimmune	$ 37,925	$ 33,073	$ 35,048	$ 35,356	$ 141,402
Others	2,481	2,666	3,138	4,451	12,736
Total product sales, 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					
Product sales					
Actimmune	$ 17,714	$ 22,596	$ 28,531	$ 36,961	$ 105,802
Others	1,038	1,062	1,706	2,357	6,163
Total product sales, 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)	$ (4.71)

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. Based on our management's evaluation, and with the participation of our Chief Executive Officer and Chief Financial Officer, as of the end of the period covered by this Report, our Chief Executive Officer and Chief Financial Officer have concluded that, subject to limitations described below, our disclosure controls and procedures (as defined in Securities Exchange Act Rules 13a-15(e) and 15d-15(e)) are effective to ensure that the information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in internal controls. There was no change in our internal control over financial reporting during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls. Our management, including our chief executive officer and chief financial officer, does not expect that our control systems will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. 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 InterMune have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation as of the end of the period covered by this Report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant will 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 the Company's Annual Meeting of Stockholders to be held at 9:45 a.m. on May 27, 2004 (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, 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 "Proposal 3—Approval of an Amendment to the InterMune, Inc. 2000 Equity Incentive Plan, as amended, to Increase the Number of Shares Authorized for Issuance—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 5—Ratification of Selection of Independent Auditors."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(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, 2003, 2002 and 2001

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, 2003	$3,415	$12,495	$(12,933)	$2,977
Year Ended December 31, 2002	949	10,811	(8,345)	3,415
Year Ended December 31, 2001	418	3,986	(3,455)	949
Reserves of excess inventory and non-cancelable purchase obligations:				
Year Ended December 31, 2003	$ —	$ 1,292	$ (371)	$ 921
Year Ended December 31, 2002	—	—	—	—
Year Ended December 31, 2001	—	—	—	—

(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.(17)
4.1	Specimen Common Stock Certificate.(1)
4.2	Amended and Restated Investor Rights Agreement, dated January 7, 2000, between Registrant and certain holders of the common stock.(1)
4.3	Indenture, dated as of July 5, 2001, between Registrant and The Bank of New York.(8)
4.4	Stockholder Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(9)
4.5	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock.(9)
4.6	Indenture, dated as of February 17, 2004, between Registrant and The Bank of New York.
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.
10.1+	Form of Indemnity Agreement.(1)
10.2+	1999 Equity Incentive Plan and related documents.(1)
10.3+	2000 Equity Incentive Plan and related documents.(1)
10.4+	2000 Employee Stock Purchase Plan and related documents.(1)
10.5+	2000 Non-Employee Directors' Stock Option Plan and related documents.(1)
10.6	Lease Agreement, dated November 9, 1999, between Registrant and American Heart Association, Western States Affiliate.(1)
10.7+	Employment Agreement, dated April 27, 1999, between Registrant and W. Scott Harkonen.(1)
10.9+	Employment Offer Letter, dated October 22, 1999, between Registrant and Peter Van Vlasselaer.(1)
10.11+	Secured Loan Agreement, Secured Promissory Note, and Security Agreement, dated July 1, 1999, between Registrant and W. Scott Harkonen.(1)
10.12*	Amended and Restated Exclusive Sublicense Agreement, dated April 27, 1999, between Registrant and Connetics Corporation.(1)
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)
10.22+	Employment Offer Letter, dated March 3, 2000, between Registrant and Stephen N. Rosenfield.(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)
10.28	Lease Agreement, dated May 15, 2000, between Registrant and American Heart Association, Western States Affiliate.(4)
10.29	Form of Common Stock Purchase Agreement, dated August 11, 2000, between the Company and Investors.(5)
10.30+	Employment Offer Letter, dated May 15, 2000, between Registrant and John Wulf.(2)
10.31	Lease Agreement, dated December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)

NUMBER	DESCRIPTION OF DOCUMENT
10.32	First Amendment to Brisbane Technology Park Lease, effective as of December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.33+	Employment offer letter, dated November 27, 2000, between Registrant and Dr. James E. Pennington, M.D.(7)
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)
10.36	Lease Agreement, dated February 14, 2001, between Registrant and Harvard Investment Company.(7)
10.37+	Amendment to Employment Agreement, dated January 1, 2001, between Registrant and Dr. W. Scott Harkonen.(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.(10)
10.40	Letter Amendment, dated August 1, 2001, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(11)
10.41*	Agreement for Consulting Services, dated August 1, 2001, between Registrant and The SGO Group LLC.(11)
10.42*	Asset Purchase and License Agreement, dated September 19, 2001, between Registrant and Eli Lilly and Company.(11)
10.43*	Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbot Laboratories.(12)
10.45+	2000 Equity Incentive Plan, as amended as of June 19, 2002.(13)
10.46+	2000 Non-Employee Directors' Stock Option Plan, amended as of May 29, 2003(17)
10.47+	Employment Offer Letter, dated April 5, 2002, between Registrant and Marianne Armstrong, Ph.D.(14)
10.48+	Bonus Plan Memorandum, dated April 18, 2002, from Registrant to Marianne Armstrong, Ph.D.(14)
10.49+	Secured Promissory Note, dated May 1, 2002, between Registrant and Marianne Armstrong, Ph.D.(14)
10.50*	Amendment No. 1, dated April 26, 2002, to the Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(14)
10.51*	Amendment No. 1, dated April 25, 2002, to the License and Commercialization Agreement (dated June 15, 2001), between Registrant and Amgen Inc.(14)
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.(14)
10.53	Letter Amendment, dated May 28, 2002, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(14)
10.54	Letter Amendment, dated July 1, 2002, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(14)
10.55+	Employee Offer Letter, dated August 29, 2002, between Registrant and Sharon Surrey-Barbari.(15)
10.56+	Amendment to Proprietary Information and Inventions Agreement, dated September 3, 2002, between Registrant and Sharon Surrey-Barbari.(15)

NUMBER	DESCRIPTION OF DOCUMENT
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.(16)
10.58+	Employment Offer Letter, dated April 30, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(17)
10.59+	Bonus Plan Memorandum, dated May 22, 2002, from Registrant to Lawrence M. Blatt, Ph.D.(17)
10.60+	Promissory Note, dated May 22, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(17)
10.61+	Employment Offer Letter, dated April 30, 2003, between Registrant and Frederick J. Schreiber.(17)
10.62+	Employment Offer Letter, dated July 2, 2003, between Registrant and Roger L. Hawley.(17)
10.63+	Resignation Letter, dated July 14, 2003, between Registrant and W. Scott Harkonen.(17)
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.(18)
10.66+	Consulting Agreement and Mutual Releases, dated September 25, 2003, between Registrant and Scott Harkonen.(18)
10.67+	Escrow Agreement, dated September 25, 2003, among Registrant, Scott Harkonen and U.S. Bank, National Association.(18)
10.68**	License Agreement, dated March 29, 2002, among Registrant, Marnac, Inc., KDL, Inc., KDL GmbH, Dr. Solomon Margolin and Dr. Shitotomo Yamauchi.
10.69+	Stock Bonus Award Agreement, dated November 5, 2003, between Registrant and William R. Ringo, Jr.
10.70+	Separation Agreement, dated November 26, 2003, between Registrant and John Wulf.
10.71+	Separation Agreement, dated January 15, 2004, between Registrant and Dr. James E. Pennington.
10.72+	Separation Agreement, dated January 23, 2004, between Registrant and Frederick J. Schreiber.
21.1	List of Subsidiaries.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
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).
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) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 8, 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 10, 2001.

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

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

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

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

(13) 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).

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

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

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

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

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

(b) Reports on Form 8-K

On October 30, 2003, we filed a current report on Form 8-K describing and furnishing the press release announcing our earnings for the quarter ended September 30, 2003, which press release included our condensed consolidated balance sheets and statements of operations for the period.

On November 21, 2003, we filed a current report on Form 8-K describing and filing the press release announcing that the submission of the New Drug Application with the FDA for oritavancin will be delayed.

(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/ SHARON SURREY-BARBARI

SHARON SURREY-BARBARI
Senior Vice President of Finance Administration and Chief Financial Officer

Dated: March 12, 2004

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sharon Surrey-Barbari 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 or her 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 12, 2004
/s/ DANIEL G. WELCH Daniel G. Welch	President and Chief Executive Officer and Director (principal executive officer)	March 12, 2004
/s/ SHARON SURREY-BARBARI Sharon Surrey-Barbari	Senior Vice President of Finance Administration and Chief Financial Officer (principal financial and accounting officer)	March 12, 2004
/s/ WILLIAM A. HALTER William A. Halter	Director	March 10, 2004

SIGNATURES	TITLE	DATE
/s/ JAMES I. HEALY James I. Healy	Director	March 12, 2004
/s/ WAYNE T. HOCKMEYER Wayne T. Hockmeyer	Director	March 12, 2004
/s/ THOMAS R. HODGSON Thomas R. Hodgson	Director	March 12, 2004
/s/ JONATHAN S. LEFF Jonathan S. Leff	Director	March 12, 2004
/s/ MICHAEL L. SMITH Michael L. Smith	Director	March 12, 2004

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EXECUTIVE MANAGEMENT

Daniel G. Welch
Chief Executive
Officer and President

Roger L. Hawley
Executive Vice President of
Commercial Operations

Stephen N. Rosenfield
Executive Vice President
of Legal Affairs; General Counsel
and Secretary

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

Sharon A. Surrey-Barbari
Chief Financial Officer and Senior Vice
President of Finance and
Administration

Peter Van Vlasselaer, Ph.D.
Senior Vice President of Technical
Operations

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

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

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

BOARD OF DIRECTORS

William R. Ringo
Chairman of the Board
InterMune, Inc.

Daniel G. Welch
Chief Executive Officer
InterMune, Inc.

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

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

Wayne T. Hockmeyer, Ph.D.
Founder and Chairman of
the Board of Directors
MedImmune, Inc.

BOARD OF DIRECTORS (CONT'D)

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

Jonathan S. Leff
Partner
Warburg Pincus LLC

Michael L. Smith
Executive Vice President & Chief
Financial and Accounting Officer
Anthem Blue Cross and Blue Shield

ANNUAL MEETING

The annual stockholders meeting
will be held on May 27, 2004 at
10:15 a.m. at InterMune, Inc.,
3280 Bayshore Boulevard,
Brisbane, CA.

LEGAL COUNSEL

Cooley Godward LLP
Palo Alto, CA

CORPORATE SECRETARY

Stephen N. Rosenfield
Executive Vice President of Legal
Affairs; General Counsel and 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

INVESTOR SERVICES

A copy of the Company's Form 10-K, which is filed with the Securities and Exchange Commission, is available without charge upon request to:

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 29, 2004, there were 149 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) intends to make Infergen an important source of revenue growth; (iii) believes that once-daily doses of Infergen, in combination with ribavirin, may have the potential to address the serious unmet medical need of HCV nonresponders; (iv) believes that Infergen and Actimmune combination therapy represents a significant opportunity for InterMune; (v) believes that Actimmune and pirfenidone are the two most clinically advanced compounds for the treatment of IPF; (vi) believes that PEG-Alfacon and pirfenidone have encouraging results; (vii) is seeking another company to assume the future development investment in oritavancin and to purchase Amphotec®. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in detail under the heading "Risk Factors" and the other risks and factors discussed in InterMune's 10-K report filed with the SEC on March 12, 2004 and enclosed herewith, and other periodic reports (i.e., 10-Q and 8-K) filed with the SEC, which are incorporated herein by reference. The risks and other factors that follow, concerning the forward-looking statements in this letter, should be considered only in connection with the fully discussed risks and other factors discussed in detail in the 10-K report and InterMune's other periodic reports filed with the SEC. The forward-looking statements above are subject to additional risks and uncertainties, including without limitation, the following: (i) clinical development is long, expensive, risky and uncertain; (ii) planned clinical trials may not begin on time, or at all; (iii) if InterMune fails to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained, it could result in regulatory enforcement action by the FDA or other government authorities, which would harm InterMune's business; (iv) there are significant regulatory, supply, intellectual property and competitive barriers to entry to marketing or developing Infergen for the chronic HCV infections market; (v) InterMune's competitors may limit our products' revenues potential or render them obsolete; (vi) 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.

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