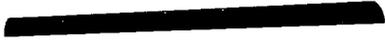


# intermune *INC* annual report 2005

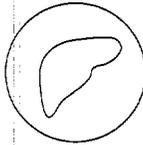
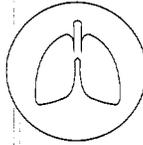
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## Important Scientific Presentations and Publications

We had a significant presence at four major medical conferences during 2005 highlighting our growing R&D capabilities. During the year, InterMune scientists, collaborators, and independent investigators presented more than 25 abstracts, posters and oral presentations of preclinical and clinical research involving InterMune drug compounds in both our pulmonology and hepatology portfolios.

During 2005, several important peer-reviewed articles relating to our development programs were published in leading scientific journals. These included three articles that supported the rationale and design of our Phase III INSPIRE trial, one that supported the endpoint of our planned Phase III pirfenidone program, CAPACITY, and one that advanced the understanding of the clinical course of patients with mild to moderate IPF.

## Other Corporate and Clinical Development Accomplishments

In 2005, we also achieved our corporate objective of divesting two non-core assets that remained from our prior interest in infectious diseases. In May, we sold Amphotec® to Three Rivers Pharmaceuticals and in late December we sold oritavancin to Targanta Therapeutics.

Supportive of our continued clinical development investment in Actimmune® (interferon gamma-1b), two composition-of-matter patents were issued by the U.S. Patent and Trademark Office that together cover the manufacture, use and sale of interferon gamma-1b. These new patents expire in 2022, extending the patent protection for interferon gamma-1b by eight years.

## Increased Financial Strength and Flexibility

We ended the year with a significantly stronger financial profile. As of December 31, 2005, we had \$216 million in cash, cash equivalents and available-for-sale securities. Our stronger financial position is due primarily to the cash infusion resulting from the sale of Infergen® and to decisions we have already implemented that we estimate will reduce our 2006 SG&A expense, compared to 2005, by approximately \$60 million.

## Looking to 2006

Having strengthened and focused the company, we move into 2006 fully committed to the rapid advancement of what we believe is the principal value driver for InterMune shareholders: our exceptional development pipeline of medicines to treat underserved patients suffering from serious hepatic or pulmonary diseases. During the year, we expect to complete enrollment of our Phase III INSPIRE trial in IPF, initiate enrollment of the Phase III CAPACITY program for IPF, and submit a European CTA for our HCV protease inhibitor.

We thank you for your continued support of InterMune, and we look forward to reporting our progress on our pipeline during 2006.

Sincerely,



Daniel G. Welch  
President and Chief Executive Officer

## Idiopathic Pulmonary Fibrosis (IPF)



IPF is a disabling and rapidly progressive disease that affects approximately 80,000 people in the United States, with approximately 30,000 new cases each year. Those diagnosed with IPF are usually between the ages of 40 and 70, and the disease tends to affect men more than women. IPF causes inflammation and scarring (fibrosis) in the lungs, reducing a person's ability to process oxygen and causing shortness of breath, dyspnea, and cough. IPF is a progressive disease, meaning that over time lung scarring and symptoms increase. Severe IPF is a deadly disease. Current median survival time from diagnosis is two to five years in patients with IPF. There are no drugs approved by the FDA or the EMA for the treatment of IPF.



## Hepatitis C Virus (HCV)



According to the Centers for Disease Control and Prevention, an estimated 3.8 million people in the United States have been infected with HCV, of whom an estimated 2.7 million are chronically infected. HCV causes an estimated 10,000 to 12,000 deaths annually in the United States and is the leading indicator for liver transplant. The prevalence of chronic HCV is increasing. First-line treatment for chronic hepatitis C virus (HCV) is pegylated interferon alpha 2b plus ribavirin. Approximately half of a patient's treated do not respond to first-line therapy, however, and a significant portion of HCV carriers have a high risk of rapidly progressing to liver disease, liver cirrhosis, liver failure, and liver cancer. There are no drugs approved by the FDA or the EMA for the treatment of HCV.

# to our shareholders

## 2005 was a year of major strategic change and significant accomplishment for InterMune.

In terms of major strategic change, in November 2005, we significantly tightened our strategic focus by announcing three important changes to our company. First, we divested Infergen® for \$120 million in up-front cash and approximately \$22 million in fixed and potential milestone payments. Second, we refined our Research and Development (R&D) strategy to focus our resources on the three programs with the greatest potential to deliver value to shareholders. Third, we committed to a plan to significantly reduce our annual Selling, General and Administrative (SG&A) expense.

These three initiatives have been fully implemented and, in doing so, we have substantially improved the focus and financial position of our company and enhanced our ability to create meaningful value for our shareholders. We believe that this stronger financial position will enable us to fund our development programs, while avoiding the need for a financing in the near term and providing more flexibility regarding partnering any of these programs. By dedicating our resources to our high-value programs, we believe we are in position to advance these programs more rapidly toward their respective milestones.

### Pulmonology:

#### Leaders in the Development of New Therapies for IPF

We believe that the approximately 83,000 people in the U.S. with idiopathic pulmonary fibrosis (IPF) represent a seriously underserved patient population and a major unmet medical need, as there is presently no therapy approved by the United States Food and Drug Administration (FDA) to treat patients with this condition. We believe we are well positioned to be a leader in delivering such a therapy, as we have the world's two most clinically advanced Phase III development programs for IPF. We are committed to the rapid development and, if data support it, the commercialization of Actimmune® and pirfenidone for patients with this terrible disease.

Our first program in IPF, the INSPIRE trial, is a Phase III, randomized, double-blind, placebo-controlled, multi-national study designed to inves-

tigate the effect of Actimmune® on survival in patients with IPF. INSPIRE is based on encouraging observations in a previous trial of Actimmune® in IPF, GIPF-001, in which patients with mild to moderate IPF treated with Actimmune® appeared to have an increased survival rate when compared to patients receiving placebo. We plan to complete enrollment in INSPIRE in the first half of 2006 and we expect to disclose top-line data from this study in early 2008.

Last October, we finalized the design of our Phase III program for pirfenidone, our second compound for the treatment of patients with IPF, after receiving input from both the FDA and European Medicines Evaluation Agency (EMA). This program, named CAPACITY, is expected to involve approximately 550 patients in two separate multi-national Phase III trials. Change in lung function, as measured by change in forced vital capacity, will be the primary endpoint, based on encouraging results from several Phase II studies. In the one controlled Phase II study conducted by Shionogi & Company, LTD and published in the American Journal of Respiratory and Critical Care Medicine<sup>1</sup>, the lead authors reported that treatment with pirfenidone reduced the rate of decline in lung capacity and decreased the frequency of acute exacerbations. We expect to initiate the CAPACITY program in the first half of 2006 and we plan to run the two trials concurrently. Data from CAPACITY are expected in early 2009.

### Hepatology:

#### Our HCV Protease Inhibitor Program

In hepatology, we are now focusing our resources on what we believe is the next-generation of HCV therapies – potent oral medicines, or small molecules – that possibly could offer a significant improvement to existing treatment for millions of HCV patients.

In 2005, we made significant progress on our preclinical HCV protease inhibitor program. During the year, we presented preclinical data demonstrating the favorable potency, pharmacokinetics and tolerability profile of our two lead compounds. In the third quarter, we chose a lead compound, ITMN 191 (formerly known as ITMN B), and we continued to make progress toward achieving our goal to submit the European equivalent of the U.S. Investigational New Drug application, known as a Clinical Trial Authorisation (CTA), in the third quarter of 2006. In addition, we continued a dedicated research program to develop follow-on compounds to ITMN 191 and second-generation protease inhibitors.



**Back Row:** Norman L. Halleen, Senior Vice President of Finance and Chief Financial Officer; Robin J. Steele, Esq., Senior Vice President, General Counsel and Corporate Secretary; Lawrence M. Blatt, Ph.D., Chief Scientific Officer; Daniel G. Welch, President and Chief Executive Officer; Thomas R. Kassberg, Senior Vice President of Corporate Development and Commercial Operations; Howard A. Simon, Esq., Senior Vice President of Human Resources and Corporate Services and Associate General Counsel

**Front Row:** Marianne T. Armstrong, Ph.D., Chief Medical Affairs and Regulatory Officer; Steven B. Porter, M.D., Ph.D., Chief Medical Officer; Williamson Z. Bradford, M.D., Ph.D., Vice President of Clinical Science; Cynthia Y. Robinson, Ph.D., Senior Vice President of Development Operations

# development pipeline

## pulmonology

**Interferon Gamma-1b**  
*Idiopathic pulmonary fibrosis*



**Pirfenidone**  
*Idiopathic pulmonary fibrosis*



**Next Generation  
Interferon Gamma**



## hepatology

**Protease Inhibitor**



# 2005 accomplishments

- o Significantly improved our financial flexibility and strategic focus by divesting interferon (interferon alfacon-1) for an up-front payment of \$120 million plus fixed and milestone payments that may reach an additional \$22 million and by implementing plans expected to reduce 2006 SG&A expenses by approximately \$60 million
- o With the increased financial flexibility, we decided not to partner our promising hepatitis C virus (HCV) protease inhibitor at least through Phase 1b; we completed important preclinical work and selected a lead candidate, TMN-191 (formerly known as TMN-B), with the intent of submitting a European Clinical Trial Authorisation (CTA) in the third quarter of 2006
- o Finalized the design of the Phase II pirfenidone development program, CAPACITY, with input from United States and European regulatory health authorities, for which patient enrollment is expected to begin in the first half of 2006
- o Achieved important patient enrollment targets for two Phase II clinical trials, INSPIRE (Actimmune (interferon gamma-1b) for the treatment of patients with idiopathic pulmonary fibrosis (IPF)) and DIRECT (interferon plus ribavirin for the treatment of non-responding patients with HCV)
- o Obtained new composition-of-matter patents for interferon gamma-1b (Actimmune), extending our exclusivity by eight years, through 2022
- o Divested two non-core assets, Amphotec and ortavancin, that remained from a prior corporate focus on infectious diseases

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

Form 10-K

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

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

For the fiscal year ended December 31, 2005

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

(State or other jurisdiction of  
incorporation or organization)

94-3296648

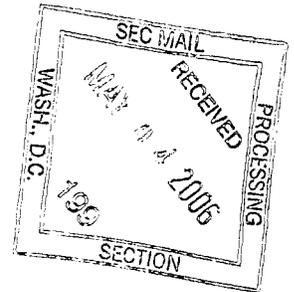
(IRS Employer  
identification No.)

3280 Bayshore Boulevard  
Brisbane, CA 94005

(Address of principal executive offices, including 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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of June 30, 2005, the aggregate market value (based upon the closing sales price of such stock as reported on the NASDAQ National Market on such date) of the voting and non-voting stock held by non-affiliates of the registrant was \$233,615,277. Excludes an aggregate of 14,674,040 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, 2005. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. As of February 28, 2006, the number of outstanding shares of the registrant's common stock was 33,527,830 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2006 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, 2005**  
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## PART I

### ITEM 1. BUSINESS

#### Forward Looking Statements

This Annual Report on Form 10-K (the "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements involve substantial risks and uncertainty. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "plan," "could," "should" and "continue" or similar words. These forward-looking statements may also use different phrases.

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

- product and product candidate development;
- governmental regulation and approval;
- sufficiency of our cash resources;
- future revenue, including those from product sales and collaborations, and future expenses;
- our research and development expenses and other expenses; and
- our operational and legal risks.

You should also consider carefully the statements under "Item 1A. 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 "Item 1A. Risk Factors" below. Because of the factors referred to above, as well as the factors discussed in this Report under "Item 1A. Risk Factors" below, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statement. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. When used in the Report, unless otherwise indicated, "InterMune," "we," "our" and "us" refers to InterMune, Inc.

#### Overview

We are an independent biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. Hepatology is the field of medicine concerned with the diagnosis and treatment of disorders of the liver. We were incorporated in California in 1998 and reincorporated in Delaware in 2000 upon becoming a public company. On April 26, 2001, we changed our name from InterMune Pharmaceuticals, Inc. to InterMune, Inc. During the past several years, we have reorganized our business by curtailing new investment in non-core areas and focusing our development and commercial efforts in pulmonology and hepatology. Until December 2005, our revenue base was provided primarily from sales of two products, Actimmune® (interferon gamma-1b) and Infergen® (consensus interferon alfacon-1). As part of our efforts to refocus our corporate strategy, we completed the sale of the Infergen® product, including related intellectual property rights and inventory, to a wholly-owned subsidiary of Valeant Pharmaceuticals International ("Valeant") in December 2005, for

approximately \$120.0 million in cash, of which \$6.5 million is attributed to the purchase of finished product inventory. As part of this transaction, we received a \$2.1 million promissory note from Valeant due in 2007 and may also receive up to approximately \$20.0 million in clinical related contingent milestone payments beginning in 2007. Concurrent with the above transaction, we made the decision to significantly reduce our investment in field-based idiopathic pulmonary fibrosis (“IPF”) disease awareness activities, which, when combined with the sale of our Infergen® assets, led to a significant headcount reduction of approximately 160 full time equivalent employees and resulting termination costs of approximately \$9.2 million. We also made the strategic decision to continue to advance our chronic hepatitis C virus (“HCV”) protease inhibitor at least through Phase Ib development without a partner. As a result of these decisions made during the latter part of 2005, we currently have three key development programs: Actimmune® for IPF, pirfenidone for IPF and the HCV protease inhibitor. During 2005, we divested the Amphotec® (amphotericin B cholesteryl sulfate complex for injection) product as well as the oritavancin compound. We have sustained losses in every year since inception and, as of December 31, 2005, we had an accumulated deficit of \$460.9 million.

Our total revenue, loss from continuing operations and net loss for each of the years ended, and our total assets as of, December 31, 2005, 2004, and 2003 are summarized in the following table:

	2005	2004	2003
	(In thousands)		
Total revenue*	\$110,496	\$128,680	\$144,862
Loss from continuing operations	(57,648)	(45,043)	(87,470)
Net loss	(5,235)	(59,478)	(97,001)
Total assets	263,452	266,011	288,501

\* Total revenue for each of the years ended 2005, 2004 and 2003 have been adjusted to reflect the reclassification of Infergen® revenue into discontinued operations.

### Approved Products

During 2005, our three approved products were Actimmune®, approved for the treatment of patients with severe, malignant osteopetrosis and chronic granulomatous disease (“CGD”), Infergen®, approved for the treatment of patients with compensated liver disease who have chronic HCV infections, and Amphotec®, approved for the treatment of invasive aspergillosis. In May 2005, we sold the Amphotec® product to Three Rivers Pharmaceuticals, LLC (“Three Rivers”). In December 2005, we sold the Infergen® product to Valeant. For the year ended December 31, 2005, Actimmune® accounted for a substantially all of our product revenue and substantially all of that revenue was derived from physicians’ prescriptions for the off-label use of Actimmune® in the treatment of IPF.

### Co-Promotion

On March 26, 2004, we entered into an agreement with Baxter Healthcare Corporation (“Baxter”) under which we co-promoted Baxter’s product Aralast® in the United States for the treatment of patients with hereditary emphysema. Under this agreement, we were compensated by Baxter based upon a percentage of Aralast sales. We were required to make a certain minimum number of visits to physicians’ offices on an annual basis to discuss Aralast, and among those visits a certain minimum number were required to be to offices of pulmonologists. We terminated this agreement with Baxter in December 2005 in connection with the decision to significantly reduce our field-based IPF disease awareness activities.

### Product Development

Drug development in the United States is a process that includes several steps required by the United States Food and Drug Administration (“FDA”). The process begins with the submission of an Investigational New Drug Application (“IND”) with the FDA, which if accepted by the FDA, allows for the opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of clinical trials prior to approval: Phase I, II and III. Within the pharmaceutical industry, clinical development takes approximately seven years of a

drug's total development time. The FDA may require, or companies may pursue, additional clinical trials, known as Phase IV clinical trials, after a product is approved. The results of Phase IV clinical trials can confirm the effectiveness of a drug and can provide important safety information to supplement the FDA's voluntary adverse drug reaction reporting system. The most significant costs associated with clinical development are Phase III clinical trials, as they tend to be the longest and largest studies conducted during the drug development process. It is possible for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous Phase III clinical trial.

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

We have a late-stage development pipeline in the pulmonology area and an early-stage development pipeline in the hepatology area.

### ***Pulmonology***

In pulmonology, we are developing two therapies for the treatment of IPF. IPF is a fatal disease characterized by progressive scarring, or fibrosis, of the lungs, which leads to the deterioration and destruction of lung function. There is no FDA approved therapy for IPF. Based on data developed by Policy Analysis Inc. from a claims database, we believe that approximately 83,000 people suffer from IPF in the United States. We are developing two clinically advanced compounds for the treatment of IPF, Actimmune® and pirfenidone.

We initiated a second Phase III clinical trial of Actimmune® for the treatment of patients with IPF (the "INSPIRE" trial) in December 2003. The INSPIRE trial required the enrollment of approximately 600 patients, all of which were enrolled by the end of 2005. However, to ensure the trial has adequate statistical power, we conducted a sample size re-evaluation and determined that the overall mortality rate observed at that early point in the trial was somewhat lower than forecast in the study protocol. Consequently, as provided in the protocol, we made the decision in October 2005 to increase the sample size of the trial by an additional 200 patients to increase the likelihood that the protocol-specified number of events will have occurred by the time the trial is scheduled to conclude in late 2007. If fully enrolled, these additional patients will bring the total size of the trial to approximately 800 patients. We expect to enroll the 800th patient in the first half of 2006, and we expect to disclose top-line data from the INSPIRE trial in early 2008.

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"), 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 are also developing pirfenidone for the treatment of IPF. In 2005 we finalized the design of a Phase III clinical program for pirfenidone after receiving input from the FDA and the European Medicines Agency ("EMA"). This program is designed to enroll approximately 550 patients with mild to moderate forms of IPF in two separate, concurrent multi-national Phase III trials. The primary endpoint of these trials will be lung function, as measured by change in forced vital capacity ("FVC"), which is believed to be an important measure of disease progression. Phase II studies of pirfenidone suggest that pirfenidone may be effective in preventing a decline in lung function and disease progression. We expect to initiate this Phase III clinical program for pirfenidone in the first half of 2006.

### ***Hepatology***

In hepatology, we are working to provide expanded treatment options for patients suffering from HCV infections. Prior to the end of 2005, we were focusing our hepatology efforts on those HCV patients that do not show

a sufficient and sustained virologic response to pegylated interferons plus ribavirin. These patients are referred to as HCV "PEG non-responders." Because we anticipate a shift in HCV treatment paradigm from non-specific immunomodulator drugs toward direct targeted therapies such as protease and polymerase inhibitors, we decided to divest our Infergen® product in 2005. In connection with the sale of the Infergen® product to Valeant, we are no longer limiting our hepatology efforts to the PEG non-responder patient population. We have now decided to focus our hepatology program on the development of small molecules for the treatment of HCV, the first of which is our protease inhibitor program which we believe may have a broad application in the overall HCV patient population. In this regard, we have transferred the Phase III trial of once-daily treatment with Infergen® in combination with ribavirin therapy for HCV PEG nonresponder patients (the "DIRECT trial") to Valeant. We have also decided not to proceed with the expansion phase of the Phase IIb clinical trial for once-daily Infergen® in combination with Actimmune®, with and without ribavirin for the treatment of HCV PEG non-responders. We are also no longer actively seeking a partner for the PEG-Alfacon-1 program due to limited interest by potential partners, long development timelines and high costs.

In September 2002, we entered into a drug discovery collaboration agreement with Array BioPharma, Inc. ("Array") to discover novel small molecule protease inhibitors for the treatment of hepatitis C. In late 2004, we amended the Array agreement to provide for the acquisition of certain intellectual property rights from Array. In April 2005, we initiated a second research collaboration with Array with respect to a new hepatology target.

Results from scientific studies presented at the Digestive Disease Weekly medical conference in May 2005 have identified protease inhibitors as a promising therapeutic class. In 2005, we presented several abstracts demonstrating high potency, favorable pharmacokinetics, including uptake into the liver, and encouraging tolerability for our two lead oral HCV protease inhibitor compounds. In the third quarter of 2005, we chose "ITMN B" as our lead compound and are currently advancing this compound through toxicology and other IND-enabling studies. We expect to submit a Clinical Trial Authorization ("CTA") with European regulatory authorities for this lead compound in the third quarter of 2006. In addition, we are pursuing research related to other small molecules for follow-on compounds to ITMN B as well as second-generation protease inhibitors.

#### *Ovarian Cancer*

We also were evaluating Actimmune® in patients with ovarian cancer in a Phase III trial (the "GRACES" trial). On February 2, 2006, we announced our decision to discontinue the GRACES trial evaluating the safety and efficacy of Actimmune® in combination with standard of care chemotherapy in patients with advanced ovarian cancer. After reviewing the results of an analysis of progression free survival time and an interim analysis of overall survival time, an independent Data Safety Monitoring Board recommended the discontinuation of the ongoing post-treatment follow-up of patients in the study. This recommendation was based on a shorter overall survival time in patients who received Actimmune® plus standard of care chemotherapy compared to patients who received standard of care chemotherapy alone.

#### *Other Assets*

Our oritavancin and Amphotec® assets did not fit within our core focus areas of pulmonology and hepatology. Therefore, we divested these non-core assets during 2005.

## Product Development Status

The following chart shows the status of our product development programs as of December 31, 2005:

	<u>Preclinical</u>	<u>Phase I</u>	<u>Phase II</u>	<u>Phase III</u>
<b>Pulmonology</b>				
Actimmune® — Idiopathic pulmonary fibrosis . . . . .				X
Pirfenidone — Idiopathic pulmonary fibrosis . . . . .			X	
Next Generation Interferon Gamma . . . . .	X			
<b>Hepatology</b>				
PEG-Alfacon-1 — Chronic hepatitis C virus infections* . . . . .		X		
Protease Inhibitor Program . . . . .	X			

\* Please see “PEG-Alfacon-1 for Chronic Hepatitis C Virus Infections” below.

## Our Strategy

We intend to use our current capital resources and the anticipated revenue provided by sales of Actimmune® to fund the development of our advanced-stage pulmonology pipeline and our research-stage hepatology pipeline.

Our strategy for achieving these objectives include:

*Focusing our Development Efforts in the Areas of Pulmonology and Hepatology.* Historically, we have pursued development opportunities in the areas of pulmonology, hepatology, infectious disease and oncology. During 2003 and 2004, we narrowed our focus to development and commercial efforts in pulmonology and hepatology in order to more effectively compete, manage our resources and sustain our business. During 2005, we further narrowed our focus to three core development programs: Actimmune® in IPF, pirfenidone in IPF and our protease inhibitors in hepatology.

*Investing in Preclinical and Applied Research.* We have a preclinical and applied research group which focuses its research in pulmonology and hepatology. The hepatology research program includes our protease inhibitor program for the treatment of hepatitis C as well as a second small molecule program in hepatology. This group seeks to characterize mechanisms of action and biological, toxicology and pharmacology profiles of our product development candidates. Further, we expect that this group will explore expanded indications and additional formulations to enable us to continue the development of our marketed and late-stage products.

*Obtaining FDA Approval for our Compounds in Pulmonology and Hepatology.* We are developing Actimmune®, pirfenidone and our protease inhibitors for diseases for which preclinical studies and clinical trials have shown evidence that they may be potentially effective treatments. One of the diseases for which Actimmune® may demonstrate therapeutic activity is IPF. We believe that pirfenidone may also have potential as a treatment for IPF. We also believe that our protease inhibitors may have potential to treat patients with HCV infections.

*Establishing Appropriate Alliances.* We believe that we have significant opportunities to achieve additional revenue and to offset expenses by establishing appropriate development or commercial alliances in pulmonology and hepatology. Such alliances may help us accelerate our development efforts, offset our expenses and mitigate our risks. We are currently seeking a European development partner for pirfenidone and we may also decide to seek a development partner for our lead protease inhibitor compound ITMN B after Phase Ib trials are completed.

*Evaluating Appropriate Product Acquisition Candidates.* We continue to evaluate appropriate product acquisition candidates that we believe could complement our existing pulmonology and hepatology portfolios.

## Approved Product

Our sole approved product is Actimmune® which is approved by the FDA only for the treatment of two rare congenital disorders: CGD and severe, malignant osteopetrosis.

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

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

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

## **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. Based on data developed by Policy Analysis Inc. from a claims database, we believe that approximately 83,000 people suffer from IPF in the United States, approximately one-half of whom have mild to moderate disease severity. There is no FDA approved therapy available for the treatment of IPF.

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

*GIPF-001* In August 2002, we reported data from our Phase III clinical trial of Actimmune® for the treatment of patients with documented IPF who had not responded to previous treatment with corticosteroids and who had evidence of deteriorating lung function. This study was a randomized, double-blind, placebo-controlled Phase III clinical trial of 330 patients conducted at 58 centers in the United States, Canada, Europe and South Africa. Patients were randomized to receive either 200 micrograms of Actimmune® subcutaneously three times per week or placebo. All patients were to remain in the trial until the last patient received 48 weeks of therapy. There was no significant effect on the primary endpoint of progression-free survival time or on secondary endpoints of lung function and quality of life. However, there was a trend towards enhanced survival among patients receiving Actimmune®. In the overall population, there were 16/162 deaths in the Actimmune-treated group (9.9%) compared to 28/168 deaths in the placebo group (16.7%), representing a 40% reduction in the risk of death in patients treated with Actimmune® than those treated with the placebo ( $p = 0.084$ ). Actimmune® was generally well tolerated, but 24/162 of the treated patients (14.8%) experienced pneumonias while only 12/168 of the placebo group (7.1%) experienced pneumonias, although the incidence of severe or life-threatening respiratory infections was similar in the two groups. The most commonly observed side effects were flu-like symptoms, including fever, headache and chills.

*GIPF-007 — the INSPIRE Trial.* The initial results of the GIPF-001 trial suggested that the survival benefit was more pronounced in patients with less severe impairment in lung function. Accordingly, we designed a study to further investigate Actimmune® in this patient group. In December 2003, we initiated GIPF-007, the INSPIRE trial, a randomized, double-blind, placebo-controlled Phase III clinical trial. In January 2005, CHEST, the journal of the American College of Chest Physicians, published an important study analysis of variables that measure clinical outcomes in patients with IPF. This retrospective analysis was derived from a database from the GIPF-001 trial. In order to determine the most important study endpoint for INSPIRE, the authors of the study analysis examined the components of the composite primary efficacy endpoint for the GIPF-001 trial: death or disease progression. This study analysis showed that survival is the preferred outcome measured in future studies of Actimmune® in patients with IPF.

The INSPIRE trial is designed to evaluate the safety and efficacy of Actimmune® in IPF patients with less severe impairment in lung function. The primary endpoint of the trial is survival time. Patients were randomized at a ratio of 2:1 to receive either 200 micrograms of Actimmune® three times a week or a placebo. The INSPIRE trial required the enrollment of approximately 600 patients, all of which were enrolled by the end of 2005. The study is expected to conclude approximately two years after enrollment of the 600th patient. At the time that the 600th patient was enrolled, we conducted a sample size re-evaluation and determined that the overall mortality rate observed at that early point in the trial was somewhat lower than forecast in the study protocol. Consequently, as provided in the protocol, we made the decision in October 2005 to increase the sample size of the trial by an additional 200 patients to increase the likelihood that the protocol-specified number of events will have occurred by the time the trial is scheduled to conclude in late 2007. If fully enrolled, these additional patients will bring the total size of the trial to approximately 800 patients. We expect to enroll the 800th patient in the first half of 2006 and we expect to disclose top-line data from the INSPIRE trial in early 2008. Actimmune® has been granted orphan drug designation for IPF in the United States (see below for description of the FDA's Orphan Drug Act).

#### ***Pirfenidone for Idiopathic Pulmonary Fibrosis and HPS.***

Pirfenidone, which may have activity in multiple fibrotic indications, is currently in clinical development for the treatment of IPF and for pulmonary fibrosis associated with Hermansky-Pudlak Syndrome ("HPS"), a fatal, fibrotic lung disease caused by genetic factors for which there is no FDA approved therapy. 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. In May 2003, we concluded a 55-patient, proof-of-concept Phase II clinical trial of pirfenidone in IPF. We stopped this trial early to expedite the collection of preliminary safety and efficacy data and our assessment of whether these data support pirfenidone as a product candidate with potential benefits to IPF patients.

In 2004, we completed the data analysis and preclinical work necessary to design and conduct a pirfenidone registration program for IPF. In May 2005, the American Journal of Respiratory and Critical Care Medicine (AJRCCM) published results from a double-blind, randomized, placebo-controlled Phase II trial evaluating pirfenidone for the treatment of patients with IPF. This 107 patient study with a planned 12 month treatment period was conducted in Japan by Shionogi & Co., LTD and was terminated after only nine months based on the recommendation of an independent Data Safety Monitoring Board following an interim analysis. This analysis suggested favorable effects of pirfenidone on acute exacerbations and other efficacy parameters.

During 2005, we finalized the design of the Phase III program for pirfenidone in IPF after receiving input from the FDA and the EMEA. This program is designed to enroll a total of approximately 550 patients with mild to moderate forms of IPF in two separate, concurrent multi-national Phase III trials. The primary endpoint of these trials will be lung function as measured by change in forced vital capacity ("FVC"), which is believed to be an important measure of disease progression. Phase III studies of pirfenidone suggest that the pirfenidone may be effective in preventing a decline in lung function and disease progression. We expect to initiate the Phase III clinical program for pirfenidone in the first half of 2006.

In 2004, the FDA and the EMEA granted pirfenidone orphan drug designation for the treatment of IPF. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States.

This designation provides seven years of market exclusivity in the United States upon the FDA's first approval of the product for the orphan designation provided that the sponsor complies with certain FDA specified conditions. EMEA orphan drug designation provides for ten years of market exclusivity in the European Union. Because we do not have a commercial infrastructure outside of the United States, we are currently in discussions with several potential partners for the development of pirfenidone for IPF in Europe.

We are also supporting the development of pirfenidone for HPS by providing free pirfenidone drug product to the National Institute of Health ("NIH") for its continuing Phase III clinical work on HPS.

#### ***Next-Generation Interferon Gamma***

We have a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc. ("Maxygen"), to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune®. If preclinical data provide compelling proof of concept for a longer-acting interferon gamma compound, our plan would be 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***

Our second area of focus is developing therapeutics in the area of hepatology. Our development efforts in hepatology are currently directed at expanding treatment options for patients suffering from HCV infections. Prior to the end of 2005, we were focusing our hepatology efforts on the PEG non-responder population. In connection with the sale of the Infergen® product to Valeant, we are no longer limiting our efforts in hepatology to the PEG non-responder patient population. We have now decided to focus our investments on small molecules, the first of which is our protease inhibitor program which we believe could have a broad application in the overall HCV patient population. In this regard, we have transferred the Phase III DIRECT trial to Valeant as part of the sale of the Infergen® product to Valeant.

#### ***Protease Inhibitor Program***

Results from scientific studies presented at the Digestive Disease Weekly medical conference in May 2005 have identified protease inhibitors as a promising therapeutic class. In 2005, we presented several abstracts demonstrating high potency, favorable pharmacokinetics, including uptake into the liver, and encouraging tolerability for our two lead oral HCV protease inhibitor compounds. In the third quarter of 2005, we chose "ITMN B" as our lead compound and are currently advancing this compound through toxicology and other IND-enabling studies. We expect to submit a Clinical Trial Authorization ("CTA") with European regulatory authorities for this lead compound in the third quarter of 2006. In addition, we are pursuing research related to other small molecules for follow-on compounds to ITMN B as well as second-generation protease inhibitors. Although we have decided to retain full ownership rights in our protease inhibitor program and not to enter into a development partnership for such program through at least Phase Ib, we continue to maintain dialogue with a number of interested parties.

In September 2002, we entered into a drug discovery collaboration agreement with Array to discover novel small molecule protease inhibitors for the treatment of hepatitis C. In late 2004, we amended the Array agreement to provide for the acquisition of certain intellectual property rights from Array. In April 2005, we initiated a second research collaboration with Array with respect to a new hepatology target.

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

To further expand the limited treatments for HCV infections, we have derived a pegylated form of Infergen®, PEG-Alfacon-1, which was being designed to offer patients an alternative therapy with less frequent dosing than non-pegylated interferons, including Infergen®. In late 2003, we completed a Phase I clinical trial to evaluate PEG-Alfacon-1 as a potential treatment for chronic HCV infections. We presented the data from our Phase I clinical trial at a medical conference in 2005. We are no longer seeking a partner for the PEG-Alfacon-1 partner due to limited interest by potential partners, long development timelines and high costs. We do not expect to continue the development of PEG-Alfacon-1.

Under the terms of our agreement with Valeant for the purchase of Infergen<sup>®</sup>, Valeant has the option to acquire our rights to PEG Alfacon-1 at any time prior to the commencement of a Phase III clinical trial for PEG Alfacon-1, provided that we have incurred documented expenses by that time of at least \$7.0 million in the development of PEG Alfacon-1. If Valeant chooses to exercise this option, Valeant will be obligated to pay us an amount equal to 150% of our documented expenses directly incurred by us in connection with the development of PEG Alfacon-1. In addition, if we decide to accept an offer from a third party to acquire the rights to PEG Alfacon-1, we are required to deliver written notice to Valeant of such offer and Valeant has the option to acquire the rights to PEG Alfacon-1 on substantially the same terms and conditions as those offered to us by such third party.

### **Other Assets**

The oritavancin and Amphotec<sup>®</sup> assets did not fit within our core focus areas of pulmonology and hepatology. Therefore, we divested these assets during 2005. We also discontinued our Phase III clinical trial of Actimmune<sup>®</sup> for the treatment of ovarian cancer.

#### ***Divestiture of 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.

In two Phase III clinical trials with oritavancin for the treatment of complicated skin and skin-structure infections (“CSSSIs”), oritavancin achieved the primary efficacy endpoint and demonstrated that oritavancin was as effective as the comparator regimen of vancomycin followed by cephalexin, which is a commonly used regimen. However, the FDA requested an additional clinical safety study be completed prior to the submission of a New Drug Application, or NDA, for oritavancin for the treatment of CSSSIs. In December 2005, we sold our worldwide rights to oritavancin to Targanta Therapeutics (“Targanta”). The terms of the agreement included upfront and potential clinical related milestone payments of up to \$9.0 million. We also received a convertible promissory note that, assuming certain clinical milestones are achieved, could be valued at up to \$25.0 million in principal amount from Targanta, which note will be initially secured by the oritavancin assets. Upon the achievement by Targanta of certain corporate objectives, the notes will convert into capital stock of Targanta, subject to certain limitations in the amount of voting stock that we may hold. In connection with this transaction, Eli Lilly waived its right to collect a \$10.0 million milestone payment which had previously been accrued by us. We also received a seat on the Targanta board of directors.

#### ***Divestiture of Amphotec<sup>®</sup>***

Amphotec<sup>®</sup> 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<sup>®</sup>. This product is approved in the United States under the name Amphotec<sup>®</sup> and in more than 40 other countries under the name Amphocil<sup>®</sup>. In 2004, we announced our intent to divest Amphotec<sup>®</sup> and in May 2005, we sold Amphotec<sup>®</sup> to Three Rivers for cash consideration. In accordance with our agreement with Three Rivers, we may receive contingent payments based on Three Rivers meeting future specified sales targets of Amphotec<sup>®</sup>.

#### ***Discontinuation of Actimmune<sup>®</sup> Trial for Ovarian Cancer.***

We were conducting an 847-patient Phase III clinical trial of Actimmune<sup>®</sup> (the “GRACES” trial) in combination with carboplatin and paclitaxel for the first-line treatment of ovarian cancer in women who have undergone surgical resection. On February 2, 2006, we announced our decision to discontinue the GRACES trial evaluating the safety and efficacy of Actimmune<sup>®</sup> in combination with standard of care chemotherapy in patients

with advanced ovarian cancer. After reviewing the results of an analysis of progression free survival time and an interim analysis of overall survival time, an independent Data Safety Monitoring Board recommended the discontinuation of the ongoing post-treatment follow-up of patients in the study. This recommendation was based on a shorter overall survival time in patients who received Actimmune® plus standard of care chemotherapy compared to patients who received standard of care chemotherapy alone. As a result, we do not intend to conduct further development of Actimmune® for the treatment of ovarian cancer.

## **License and Other Agreements**

### ***Genentech, Inc. License Agreement (Actimmune®)***

In 1998, we obtained a license under Genentech's patents relating to Actimmune®. The license from Genentech terminates on the later of May 5, 2018 or the date that the last of the patents licensed under the agreement expires. Our licensed Actimmune® rights include exclusive and non-exclusive licenses. The exclusive licenses include the right to develop and commercialize Actimmune® in the United States and Canada for the treatment and prevention of all human diseases and conditions, including infectious diseases, pulmonary fibrosis and cancer, but excluding arthritis and cardiac and cardiovascular diseases and conditions. The non-exclusive licenses include the right to make or have made Actimmune® for clinical and commercial purposes within our field of use in the United States and Canada. In Japan, we have the exclusive license rights to commercialize Actimmune® for the treatment and prevention of all infectious diseases caused by fungal, bacterial or viral agents, including in patients with CGD or osteopetrosis. We also have the opportunity, under specified conditions, to obtain further rights to Actimmune® in Japan and other countries. In addition, we received an exclusive sublicense under certain of Genentech's patents outside the United States, Canada and Japan under the BI agreement discussed below. Under the Genentech license, we pay Genentech royalties on the revenue from sales of Actimmune®, and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the submission of a BLA with the FDA for approval to market Actimmune® for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune® for the treatment of particular categories of diseases and the achievement of certain annual revenue targets for Actimmune®. We had made royalty payments of approximately \$53.7 million, but no milestone payments, under this agreement in the aggregate through December 31, 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make further milestone payments of \$3.2 million. We must satisfy specified diligence obligations under the agreement with Genentech to maintain our license from Genentech. Our rights to certain therapeutic uses for Actimmune® under this agreement could revert to Genentech if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

### ***Boehringer Ingelheim International GmbH (Imukin®)***

In 2001, we formed a collaboration with BI 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'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 will pay us royalties on sales of the product when it meets a specified minimum sales level. BI 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 does not do so. If we opt to promote the product in those countries or for those new diseases for which BI does not, we will pay royalties to BI on sales of the product in those countries and/or for those new diseases. We had neither paid nor received any royalties under this agreement through December 31, 2005, and there are no milestone payments under this agreement. The agreement will expire, on a country-by-country basis, upon expiration of the parties' royalty obligations in each country covered by the agreement. Such royalty obligations generally expire fifteen years after regulatory approval of Imukin® for certain specified indications in the relevant country. If no such regulatory approvals are granted in a particular country, the royalty obligations in such country will expire in 2016. Prior to such expiration, either party

can terminate the agreement for the uncured material breach of the other party or for the insolvency of the other party. In addition, we have the right to terminate the agreement with respect to certain countries at any time subsequent to regulatory approval for IPF.

***Connetics Corporation (Actimmune®)***

Through an assignment and option agreement with Connetics, we paid Connetics \$5.7 million to acquire rights to Actimmune® and are obligated to pay to Connetics a royalty of 0.25% of our net United States sales for Actimmune® until our net United States sales cumulatively surpass \$1.0 billion. Above \$1.0 billion, we are obligated to pay a royalty of 0.5% of our net United States sales of Actimmune®. Through a separate purchase agreement, we paid Connetics \$0.4 million to acquire rights related to scleroderma and are obligated to pay Connetics a royalty of 4.0% on our net revenue from sales of Actimmune® for the treatment of scleroderma. We had made royalty payments of approximately \$1.2 million in the aggregate through December 31, 2005. There are no milestone payments pursuant to this agreement.

***Amgen Inc. (Infergen®, PEG-Alfacon-1 and Interferon Gamma)***

In 2001, we entered into a licensing and commercialization agreement with Amgen through which we obtained an exclusive license in the United States and Canada to Infergen® and the rights to an early stage program to develop a pegylated form of Infergen® PEG-Alfacon-1. Infergen® is currently approved in both the United States and Canada to treat chronic HCV infections. Under the agreement, we had the exclusive right to market Infergen® and clinically develop it for other indications in the United States and Canada. In December 2004, we amended our licensing and commercialization agreement with Amgen to remove certain non-competition restrictions on Amgen with respect to alpha interferons in exchange for a specified reduction in the royalties payable by us to Amgen on Infergen® sales should Amgen engage in certain competitive activities as well as Amgen's consent to transfer the manufacturing of Infergen® to a new supplier. (See section entitled "Manufacturing" below). We initially paid Amgen total consideration of \$29.0 million for up-front license and other fees and milestones with respect to our license, and had been 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 had made royalty and milestone payments of approximately \$40.0 million under this agreement in the aggregate through December 31, 2005. These rights and obligations with respect to Infergen® under the agreement have been assumed by Valeant as part of our sale of the Infergen® product to Valeant in December 2005. We do not expect to continue the development of PEG-Alfacon-1.

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

***Marnac, Inc./KDL GmbH (Pirfenidone)***

In 2002, we licensed from Marnac, Inc. ("Marnac") and its co-licensor, KDL GmbH ("KDL"), their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of \$18.8 million and future milestone and royalty payments. Future milestone payments will be based on the progress of clinical development of pirfenidone. We had made no royalty or milestone payments under this agreement through December 31, 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of \$14.5 million. Our rights to the licensed products under the agreement could revert to Marnac if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. The agreement will expire upon the later of the expiration of the primary patent licensed under the agreement; or on a disease-by-disease and country-by-country basis (as determined by reference to the indications for which pirfenidone is approved in such country) on the later of (i) the expiration of market exclusivity in such country (if any) resulting from the grant of orphan drug designation to pirfenidone for the treatment of a human fibrotic disease; and (ii) the expiration of the last valid and enforceable claim in a issued licensed patent claiming the use of pirfenidone to treat such disease in such country. Following expiration of the agreement, we will retain a fully paid-up, royalty-free, perpetual, irrevocable,

sublicenseable license to the patents, know-how, and other intellectual property rights licensed under the Agreement. We may terminate the agreement after giving the requisite notice to Marnac. In the event Marnac or KDL terminate the agreement, we have the right to seek specific performance of the agreement.

***Array BioPharma Inc. (Small Molecule Therapeutics)***

In 2002, we entered into a drug discovery collaboration agreement to create small molecule therapeutics targeting hepatitis with Array. We fund drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and we are 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 low single-digit royalties on net sales of products derived from the collaborative efforts. The original term of this agreement expired in September 2004 and has since been extended to August 2006, subject to certain conditions. In addition, in December 2004, the agreement was amended to provide a mechanism for us to purchase certain intellectual property rights arising from the collaboration. In April 2005, we initiated a second research collaboration with Array with respect to a new hepatology target. This research collaboration extends through March 2007.

Assuming that all of the remaining milestones under these agreements are achieved, we will be required to make milestone payments of \$9.0 million. Total research and development expenses related to this agreement were \$7.5, \$5.7 million and \$2.1 million for the years ended December 31, 2005, 2004 and 2003, respectively. Included in the \$5.7 million is a one-time non-refundable fee of \$2.5 million paid in connection with securing the right to purchase Array's ownership interest in certain collaboration patents.

***Shearwater Corporation (PEG-Alfacon-1)***

In June 2002, we entered into a development, license and manufacturing agreement with Shearwater Corporation ("Shearwater"), a wholly-owned subsidiary of Nektar Therapeutics, to access Shearwater's pegylation technology in order to develop a pegylated version of Infergen®. Under the terms of the agreement, we received a co-exclusive license with Maxygen from Shearwater in exchange for an up-front payment of \$500,000 and future milestone and royalty payments. We had paid \$250,000 in milestone payments, but no royalty payments, under this agreement in the aggregate through December 31, 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of \$8.3 million.

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

***Maxygen Holdings Ltd. (Next-Generation Interferon Gamma)***

We have a license and collaboration agreement with Maxygen to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune®. If preclinical data provide compelling proof of concept for a longer-acting interferon gamma compound, our plan would be to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. We have funded Maxygen's

optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. Our diligence obligations include a minimum level of clinical development expenditures for an initial period of time, as well as the general obligation to use commercially reasonable efforts to clinically develop, seek regulatory approval for and commercialize a product in specified major market countries. The agreement terms include up-front license fees and full research funding, as well as development and commercialization milestone payments, which are payable based on the progress of our clinical development program for next-generation interferon gamma products and the achievement of certain sales targets with respect to such products. In addition, Maxygen will receive royalties on product sales. We had made payments of approximately \$9.6 million under this agreement in the aggregate through December 31, 2005. We paid Maxygen a total of \$106,000 and \$228,000 for the years ended December 31, 2004 and 2003, respectively and did not make any payments in 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of \$43.0 million.

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

#### ***Eli Lilly & Company (Oritavancin)***

In 2001, we entered into an asset purchase and license agreement with Eli Lilly & Company ("Eli Lilly") pursuant to which we acquired worldwide rights to oritavancin. We assigned this agreement to Targanta in December 2005 in connection with Targanta's purchase of the oritavancin compound.

#### ***ALZA Corporation (Amphotec®)***

In 2001, we entered into a product acquisition agreement with ALZA Corporation, now a subsidiary of Johnson & Johnson) in which we acquired the rights to Amphotec®. We had made royalty payments of approximately \$1.3 million, but no milestone payments, under this agreement in the aggregate through December 31, 2005. We assigned this agreement to Three Rivers in May 2005 in connection with Three Rivers' purchase of the Amphotec® product.

#### **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 a supply agreement with BI for the clinical and commercial supply of Actimmune®. The agreement with BI generally provides for the exclusive supply by BI and exclusive purchase by us of Actimmune®. We are required to purchase a minimum amount of Actimmune® per year, and BI is required to supply Actimmune® to us, subject to certain limits. On July 26, 2005, we amended the supply agreement with BI pursuant to which BI agreed to waive certain of InterMune's minimum purchase commitments for Actimmune for 2005 and to reduce certain other minimum Actimmune® purchase requirements for 2006. With regard to certain minimum purchase requirements in 2007 and thereafter, BI has granted us the option of either taking delivery of Actimmune® or paying for the difference between the amount of product actually purchased and the minimum

purchase requirement. As of December 31, 2005, we were obligated to make aggregate minimum purchases of Actimmune® from BI in the years 2006 through 2012 of \$99.1 million. If BI 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 has informed us of its unwillingness or inability to meet our requirements. BI may have the right to terminate the agreement if we materially breach the minimum yearly purchase obligation for Actimmune® that is specified in the agreement. In the event that we decide that our minimum yearly purchase obligation under the agreement exceeds our annual requirements for Actimmune®, the agreement provides a mechanism by which we can decrease on a going-forward basis such purchase obligation, in exchange for appropriate adjustments to the financial terms of the agreement, to be negotiated by the parties at time of such adjustments. The agreement will expire on December 31, 2012. However, in the event that we were to proceed with a supplemental BLA for Actimmune®, we have the option to extend the initial term of the agreement up to December 31, 2021. The agreement continues to automatically renew for successive four-year periods, unless one party provides the other with a written notice of its election not to renew the agreement. In addition, we have the right to terminate the agreement immediately in the event that health authorities block the use in clinical trials or the marketing of Actimmune®.

***Amgen Inc. (Infergen®)***

As part of our 2001 license agreement with Amgen under which we licensed Infergen®, we entered into a manufacturing and supply arrangement under which Amgen was obligated to manufacture and supply our requirements of Infergen® for our sales in the United States and Canada. We assigned this agreement to Valeant in December 2005 in connection with Valeant's purchase of the Infergen® product.

***Boehringer Ingelheim Austria GmbH (Infergen®)***

On November 3, 2005, we entered into an agreement with BI for the future clinical and commercial supply of Infergen®. The agreement generally obligated BI to supply exclusively to us, and for us to purchase exclusively from BI, bulk Infergen® as well as the finished forms of Infergen® that are currently marketed. Amgen will remain the manufacturer for Infergen® until the transfer of the manufacturing process from Amgen to BI is completed and until BI is approved by the FDA as a manufacturer of Infergen®. Prior to and upon execution of the agreement, we made payments to BI of approximately \$16.8 million. We assigned this agreement and all future rights and obligations thereunder to Valeant as part of the sale of the Infergen® product to Valeant in December 2005.

***Cardinal Health PTS, Inc. (oritavancin and pirfenidone)***

In 2003, we entered into an agreement with Cardinal Health PTS, Inc. ("Cardinal Health") to supply us with oritavancin drug product. We assigned this agreement to Targanta in December 2005 in connection with Targanta's purchase of the oritavancin compound. Cardinal Health also formulates and encapsulates the active pharmaceutical ingredient ("API") in the manufacturing process for pirfenidone. We are in the process of completing the transfer of the manufacturing of the active pharmaceutical product ("API") for pirfenidone from Cardinal Health's Somerset, New Jersey facility to Cardinal Health's Winchester, Kentucky facility.

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

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

***Abbott Laboratories, Inc. (oritavancin)***

In 2001, we entered into an agreement with Abbott Laboratories, Inc. ("Abbott") to provide the bulk manufacturing of oritavancin active pharmaceutical ingredient (oritavancin API). We assigned this agreement to Targanta in December 2005 in connection with Targanta's purchase of the oritavancin compound.

### ***Ben Venue Laboratories Supply Agreement (Amphotec®)***

We assumed a manufacturing and supply agreement with Ben Venue Laboratories, Inc. ("Ben Venue") dated as of January 1, 1993 for the manufacture of Amphotec®. We assigned this agreement to Three Rivers in May 2005 in connection with Three Rivers' purchase of the Amphotec® product.

### **Patents and Proprietary Rights**

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

#### ***Actimmune***

We have acquired an exclusive license under certain Genentech patents to develop, use and sell interferon gamma-1b, the active ingredient in Actimmune®, in particular fields in the United States, Canada and Japan under our license agreement with Genentech. This license agreement covers more than 12 United States patents and related foreign patents and/or patent applications filed in Japan and Canada. Certain of the United States patents covering DNA vectors and host cells relating to interferon gamma-1b have or will expire in 2005 and in 2006 without material impact to our business. In addition, a United States patent relating to the composition of interferon gamma-1b expires in 2014. Other material United States patents expire between 2009 and 2013. Under the Genentech license, we pay Genentech royalties on the sales of Actimmune®, and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the submission of a BLA with the FDA for approval to market Actimmune® for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune® for the treatment of particular categories of diseases and the achievement of certain annual revenue targets for Actimmune®. Two United States composition-of-matter patents acquired from Amgen covering interferon-gamma analogs, including interferon gamma-1b, expire in 2022.

#### ***Pirfenidone***

We have acquired an exclusive license under certain Marnac/KDL patents and patent applications relating to the manufacture, use and sale of pirfenidone for antifibrotic use worldwide, excluding Japan, Korea and Taiwan. The Marnac/KDL patent in the United States will expire in 2011. When this patent expires in 2011, we will not be able to use this patent to block others from marketing pirfenidone for the treatment of fibrotic disorders in the United States. Under the terms of this license, we are required to pay Marnac and KDL milestone payments based on the progress of clinical development of pirfenidone, as well as royalties on future sales. The pirfenidone composition-of-matter patent has expired and Marnac has the right to license this compound for non-fibrotic diseases. For a description of certain intellectual property issues relating to this license, please see "Item 1A. Risk Factors-Over time, we will lose our ability to rely on the intellectual property we currently own to prevent competing products, which may impair our ability to generate revenue" below.

#### ***Protease Inhibitors***

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

### **Other Intellectual Property**

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

## **Competition**

### ***Actimmune® for CGD and Severe Malignant Osteopetrosis***

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

### ***Actimmune® and Pirfenidone for IPF***

There is no FDA approved therapy available for the treatment of IPF. We believe that the primary competition for Actimmune® or pirfenidone, if either is approved by the FDA for the treatment of IPF, will initially consist of products that are approved for other indications and for which clinical development for IPF is contemplated or underway, such as Enbrel®, Gleevec® and Tracleer®. In 2005, Phase II clinical trials for both Tracleer® and Enbrel® failed to reach their primary endpoints.

### ***Protease Inhibitor for HCV***

In the field of hepatology there are multiple drug candidates in development for hepatitis C, including immunomodulators, synthetic interferons, ribavirin analogs, protease inhibitors, polymerase inhibitors, viral budding inhibitors, monoclonal antibodies and RNAi knockdown techniques. In the field of HCV protease inhibitors, several other companies have protease inhibitor drugs in development, including Schering-Plough Corporation, Gilead Sciences, Merck & Co., Pfizer, Inc., GlaxoSmithKline, and Vertex Pharmaceuticals Incorporated. Many of these companies have substantially greater financial, technical and human resources than we do, have a significant lead in terms of timing of clinical development, and are more experienced in the development of new drugs than we are.

## **Commercial Operations, Product Distribution and Medical Affairs**

### ***Reorganization of Commercial Operations***

In connection with the divestiture of Inergen®, we also made significant reductions in our commercial operations in late 2005, including a significant reduction in our field-based IPF disease awareness activities. We plan to rebuild a commercial presence in the future when Phase III data from the research and development pipeline warrant that investment. We continue to have a strategic marketing group that will continue to support the supply and reimbursement of Actimmune® for its labeled indications, CGD and severe, malignant osteopetrosis. This group is also responsible for strategic planning in preparation for the potential launch of Actimmune® and pirfenidone for the treatment of IPF.

### **Product Distribution**

In the United States, our products are sold primarily to specialty pharmacies and to distributors who resell them to hospitals, pharmacies and physicians. During the year ended December 31, 2005, the primary specialty pharmacies and distributors for our products were CuraScript, Inc. (formerly Priority Healthcare, Inc.), Caremark, Inc. and Merck Medco, who accounted for 59%, 21% and 7%, respectively, of our total net product sales.

### **Medical Affairs**

We have a Medical Affairs Department that maintains current, scientific-based information about pulmonology and hepatology for the benefit of health care providers, patients and caregivers, as well as our employees. Our Medical Science Liaisons are responsible for maintaining relationships with physicians who are regional and national thought leaders, supporting clinical trial awareness and enrollment and supporting patient advocacy activities and investigator sponsored trials. Other functions of our Medical Affairs Department are medical education, medical information, publications and administration.

## Sales by Geographic Region

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
United States . . . . .	\$110,017	\$126,288	\$142,109
Rest of the world . . . . .	<u>479</u>	<u>2,392</u>	<u>2,753</u>
Totals* . . . . .	<u>\$110,496</u>	<u>\$128,680</u>	<u>\$144,862</u>

\* Total revenue for each of the years ended 2005, 2004 and 2003 have been adjusted to reflect the reclassification of Infergen<sup>®</sup> revenue into discontinued operations.

## 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 EMEA, or European Medicines Agency, is a centralized body of the European Union whose main responsibility is the protection and promotion of public health through the evaluation and supervision of medicines for human use. The EMEA coordinates the evaluation and supervision of medicinal products throughout the 25 European Union member states in a network of 42 national competent authorities.

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

- preclinical laboratory and animal tests;
- submission of an investigational new drug application (“IND”), which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- FDA approval of a new biologics license application (“BLA”), a new drug application (“NDA”), or a BLA or NDA supplement.

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

Prior to commencing a clinical trial, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the application. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence such a clinical trial. Further, an independent institutional review board (“IRB”) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences.

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

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- *Phase II:* Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosage frequency. These Phase II clinical trials may be divided into early Phase II clinical trials, which are referred to as Phase IIa clinical trials, during which pilot studies are

performed to determine initial activity and late Phase II clinical trials, which are referred to as Phase IIb clinical trials, that generally consist of controlled trials often involving several hundred patients in traditional drug development programs.

- *Phase III:* When Phase II clinical trials demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken to further evaluate dosage, to provide statistically and clinically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical study sites. It is possible for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous and reliable Phase III clinical trial. For example, after Actimmune® had shown promising results for the treatment of IPF in an investigator sponsored Phase II clinical trial, our initial Phase III study of Actimmune® for the treatment of IPF failed to show significant effect on the primary endpoint of progression-free survival or on secondary endpoints of lung function and quality of life.

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

We may not successfully complete Phase I, Phase II or Phase III clinical trial testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These are called Phase IV studies. The results of Phase IV studies can confirm the effectiveness of a drug and can provide important safety information to augment the FDA's adverse drug reaction reporting system.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA or NDA, or as part of a BLA or NDA supplement for approval as a treatment for a new disease if the product is already approved for a disease. The FDA may deny approval of a BLA, NDA or BLA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the BLA, NDA or BLA or NDA supplement does not satisfy the criteria for approval.

Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

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

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

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products or of approved products for new diseases for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for our product candidates or for use of our approved products for new diseases on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific diseases, patient subgroups and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, initial regulatory approval for any of our product candidates, or additional regulatory approvals for new indications of our approved products, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Any products we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with these products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and other government agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the good manufacturing practices regulations and other FDA regulatory requirements.

Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. For example, we are aware that physicians are prescribing Actimmune® for the treatment of IPF, although we do not promote Actimmune® for the treatment of IPF, and the FDA has not approved the use of Actimmune® for the treatment of this disease. Substantially all of our Actimmune® revenue is derived from physicians' prescriptions for off-label use for IPF. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use. Companies cannot promote FDA approved drugs for off-label uses. A company may engage in truthful, non-misleading, and non-promotional speech concerning its products. For example, we may inform physicians that we are conducting a clinical trial to evaluate the safety and effectiveness of Actimmune® in unapproved uses, such as our ongoing clinical trial to evaluate Actimmune® for the treatment of IPF, and encourage those physicians to refer eligible patients to enroll in the clinical trial. We may also educate physicians about a particular disease state and how that disease is properly diagnosed so that patients who qualify for the clinical trial might be identified. We also may survey physicians who are lawfully prescribing our products for off-label uses to monitor patients' experiences, particularly as to whether safety issues have arisen. We may also, pursuant to FDA policies, respond to unsolicited requests from health care professionals and engage in appropriate scientific exchange of information about unapproved uses. We have engaged in these lawful activities in the past and continue to engage in some of them today. We have policies and procedures in place to regulate the lawful promotion of our marketed products within their labeled indications. Employees are trained to follow these policies and procedures and must certify that they will abide by them. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. While we believe we are currently in compliance with the FDA's regulations relating to off-label promotion, the regulations are subject to varying interpretations which continue to evolve. Failure to comply with these requirements in the past or with respect to future activities can result in regulatory enforcement action by the FDA and other governmental bodies, which would have an adverse effect on our revenue, business and financial prospects. On November 9, 2004 we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune®, including information regarding the promotion and marketing of Actimmune®. We are cooperating with the Department of Justice in this inquiry. Although we cannot predict whether the outcome of this inquiry will have a material adverse effect on our business, it is possible that we will be required to pay a substantial civil fine in connection with the settlement of this matter. At this time we cannot predict the

magnitude of such a fine or the impact the payment of such a fine may have on our future business operations. For a more complete description of this matter see "Item 3. Legal Proceedings" below.

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA for that orphan indication. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation is the first to subsequently receive FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity for seven years in the United States, (i.e., the FDA may not approve any other applications to market the same drug for the same disease for seven years, except in very limited circumstances). Orphan drug designation exclusivity lasts for 10 years in the European Union. We have filed and intend to file for orphan drug designation for those diseases we target that meet the criteria for orphan drug exclusivity. For example, Actimmune® has orphan drug exclusivity for severe, malignant osteopetrosis. Actimmune® and pirfenidone have been granted orphan drug designation for the treatment of IPF by the FDA, and pirfenidone has been granted orphan drug designation by the EMEA. Although obtaining FDA and EMEA approval to market a product with orphan drug exclusivity can be advantageous, there can be no assurance that we will be able to maintain this designation for Actimmune® or pirfenidone, nor can there be any 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 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, substantially all of which are related to clinical trial expenses, were \$82.7 million, \$75.7 million and \$118.8 million for the years ended December 31, 2005, 2004 and 2003. Research and development expenses for each year presented have been adjusted to reflect the reclassification of Infergen® related activities into discontinued operations.

## **Facilities**

All of our facilities and long-lived assets are located in the United States. Our facilities currently consist of 55,898 square feet of office space located at our headquarters at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this facility. In January 2005, we entered into an operating lease agreement to sublease an additional 12,988 square feet of office space which consists of 11,444 square feet of usable area and 1,544 square feet of common area located at the second floor of 3240 Bayshore Boulevard, Brisbane, CA 94005. In connection with the divestiture of Infergen® and the reduction in our field-based IPF disease awareness activities, we no longer require the use of this space and have terminated this sublease effective April 2006. We believe that our facilities are adequate for our current needs, and that suitable additional or substitute space will be available in the future to replace our existing facility, if necessary, or accommodate expansion of our operations.

## **Employees**

As of January 31, 2006, we had 193 full-time employees. Of the full-time employees, 115 were engaged in research and development and 78 were engaged in general and administrative positions. In connection with the sale of the Infergen® product to Valeant and the significant reduction in our field-based IPF disease awareness activities in 2005, we eliminated approximately 160 employee positions. We believe that our relations with our employees are good.

## Available Information

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

## Executive Officers of the Registrant

The following table provides information regarding our executive officers and key employees as of February 28, 2006:

<u>Name</u>	<u>Age</u>	<u>Title</u>
Daniel G. Welch . . . . .	48	Chief Executive Officer and President
Marianne T. Armstrong, Ph.D. . . . .	51	Chief Medical Affairs and Regulatory Officer
Lawrence M. Blatt, Ph.D. . . . .	44	Chief Scientific Officer
Williamson Z. Bradford, M.D., Ph.D. . . . .	44	Vice President, Clinical Science
Norman L. Halleen . . . . .	52	Senior Vice President of Finance and Chief Financial Officer
Thomas R. Kassberg . . . . .	45	Senior Vice President, Corporate Development and Commercial Operations
Steven B. Porter, M.D., Ph.D. . . . .	49	Chief Medical Officer
Cynthia Y. Robinson Ph.D. . . . .	47	Senior Vice President, Development Operations
Howard A. Simon, Esq. . . . .	47	Senior Vice President, Human Resources and Corporate Services and Associate General Counsel
Robin J. Steele, Esq. . . . .	50	Senior Vice President of Legal Affairs, General Counsel and Corporate Secretary

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

*Marianne T. Armstrong, Ph.D.* Dr. Armstrong has served as our Chief Medical Affairs and Regulatory Officer since January 2006. From January 2004 to January 2006, Dr. Armstrong served as our Senior Vice President, Regulatory/Medical Affairs and Drug Safety. From April 2002 to January 2004, Dr. Armstrong served as our Senior Vice President of Global Regulatory Operations and Corporate Compliance. From December 1999 to April 2002, Dr. Armstrong served as senior director of clinical development/regulatory affairs at Genentech, Inc, a pharmaceutical company. From July 1998 to November 1999, Dr. Armstrong served as senior director of clinical development at PathoGenesis Corporation, a pharmaceutical company. From May 1995 to July 1998, Dr. Armstrong served as department head of clinical affairs for Amgen Inc., a pharmaceutical company. From January 1981 to April 1995, Dr. Armstrong held management positions in clinical development at Alcon Laboratories, Solvay Pharmaceuticals and Parke-Davis/Warner Lambert, each a pharmaceutical company, and was a regional sales representative at American McGaw, a division of American Hospital Supply. Dr. Armstrong holds a Ph.D. and M.S. from Florida State University.

*Lawrence M. Blatt, Ph.D.* Dr. Blatt has served as our Chief Scientific Officer since January 2006. Dr. Blatt served as our Senior Vice President of Preclinical and Applied Research from January 2004 to January 2006. From May 2002 to January 2004, Dr. Blatt served as our Vice President of Biopharmacology Research. From January 1998 to May 2002, Dr. Blatt served as vice president, research, at Ribozyme Pharmaceuticals., a pharmaceutical company. From August 1996 to January 1998, Dr. Blatt served as vice president, product development, at National Genetics Institute. From May 1984 to August 1996, Dr. Blatt was employed at Amgen Inc., a pharmaceutical company, most recently as product development team leader, interferons. Dr. Blatt holds a Ph.D. in Public Health Administration from the University of La Verne.

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

*Norman L. Halleen.* Mr. Halleen has served as our Senior Vice President of Finance and Chief Financial Officer since October 2004. Prior to joining InterMune, Mr. Halleen served as Vice President, Finance and Chief Financial Officer of Syrrx, Inc., a privately held drug discovery company, from April 2001 to June 2003. Prior to Syrrx, Mr. Halleen was Vice President, Finance and Chief Financial Officer at Aradigm Corporation, a publicly traded drug delivery company, from January 2000 to April 2001, and previously held the same positions at Collagen Corporation, a publicly traded biomaterials and medical device company, from January 1997 to October 1999. Mr. Halleen has also worked in various financial consulting and executive positions in Hong Kong and the United States including a ten-year tenure with Syntex Corporation. Mr. Halleen holds an A.B. from Stanford University and an M.B.A. from the Harvard Graduate School of Business.

*Thomas R. Kassberg.* Mr. Kassberg has served as our Senior Vice President, Corporate Development and Commercial Operations since January 2006. From August 2004 to January 2006, Mr. Kassberg served as our Senior Vice President, Business Development. From December 2000 to July 2004, Mr. Kassberg served as founder and Vice President of Business and Corporate Development of Plexxikon, Inc. From 1996 to 1999, Mr. Kassberg worked as Senior Director, Business Development at SUGEN, Inc., and later as Senior Director, Corporate Licensing for Pharmacia, Inc. following the acquisition of SUGEN by Pharmacia in August 1999 until December 2000. Mr. Kassberg began his career at Bristol-Meyers-Squibb Company, a pharmaceutical company, where he served in various commercial functions, including strategic planning, financial analysis, business development and managed care sales. Mr. Kassberg holds a Masters in Management degree from Northwestern University.

*Steven B. Porter, M.D., Ph.D.* Dr. Porter has served as our Chief Medical Officer since January 2006. Dr. Porter served as our Senior Vice President of Clinical Affairs from January 2004 to January 2006. From July 2001 to January 2004, Dr. Porter served as our Vice President of Clinical Research. From 1999 to June 2001, Dr. Porter was employed at IntraBiotics Pharmaceuticals, Inc., a pharmaceutical company, most recently as Senior Director, Clinical Science and Clinical Affairs. From 1997 to 1999, Dr. Porter served as Senior Director, Clinical Affairs at Shaman Pharmaceuticals, Inc., a pharmaceutical company and from 1996 to 1997, Dr. Porter served as Associate Director, Clinical Research at Bayer Corporation. Dr. Porter received his M.D., and Ph.D. from Vanderbilt University School of Medicine. He completed his residency in internal medicine at the University of California, San Francisco and his fellowship in infectious diseases at the University of California, San Francisco and Stanford University. He is currently an Assistant Clinical Professor of Medicine in the Division of Infectious Diseases at the University of California, San Francisco.

*Cynthia Y. Robinson, Ph.D.* Dr. Robinson has served as our Senior Vice President of Development Operations since January 2006. Dr. Robinson served as our Senior Vice President, Therapeutic Area Teams from November 2004 to January 2006. From 1996 to 2004, Dr. Robinson held various positions at Elan Pharmaceuticals,

Inc., a pharmaceutical company, serving most recently as Vice President, Project Management. From 1989 to 1996, Dr. Robinson was a scientist with Athena Neurosciences, Inc., a pharmaceutical company. From 1980 to 1982, Dr. Robinson was a Product Control Chemist with Texaco, Inc. Dr. Robinson holds a B.S. in Chemistry from the University of Alabama, Tuscaloosa, and a Ph.D. in Organic Chemistry from the University of Alabama, Birmingham.

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

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

#### **ITEM 1A. RISK FACTORS**

*An investment in our common stock is risky. Stockholders and potential purchasers of shares of our stock should carefully consider the following risk factors, which hereby update those risks contained in the "Risk Factors" section of our Quarterly Report on Form 10-Q that was filed with the SEC on November 7, 2005, 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 revenue.***

We commenced operations in 1998 and have incurred significant losses to date. Our revenue has been limited primarily to sales of Actimmune® derived from physicians' prescriptions for the off-label use of Actimmune® in the treatment of IPF. Although we are developing Actimmune® for the treatment of IPF, Actimmune® may not be marketed for IPF before 2008, if at all. We are developing pirfenidone for the treatment of IPF, but pirfenidone will not be marketed for any diseases before 2010, if at all.

We may fail to develop our products on schedule, or at all, for the reasons stated in this "Risks Related to the Development of Our Products and Product Candidates" section of Item 1A. If this were to occur, our costs would increase and our ability to generate revenue could be impaired. In addition, we may need to raise capital in amounts greater than we anticipate in order to continue our development activities as planned. If additional capital is not available, we may be forced to curtail our development activities or cease operations.

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay

or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, we have decided to end our investment in Actimmune® for patients with ovarian cancer as a result of our decision to discontinue the GRACES trial on the recommendation of an independent Data Safety Monitoring Board. As a result, we do not intend to conduct further development of Actimmune® for the treatment of ovarian cancer. In addition, we reported that our exploratory Phase II clinical trial evaluating Actimmune® for the potential treatment of advanced liver fibrosis caused by HCV in patients who have failed standard antiviral therapy failed to meet its primary endpoint. As a result, we do not intend to conduct further development of Actimmune® for the treatment of liver fibrosis.

We are conducting the INSPIRE trial, a second 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 seriously harm our business and would result in a significant decline in our expected Actimmune® revenue.

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

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

- the FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients experience adverse side effects;
- patients withdraw or die during a clinical trial for a variety of reasons, including adverse events associated with the advanced stage of their disease and medical problems that may or may not be related to our products or product candidates;
- the interim results of the clinical trial are inconclusive or negative;
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy;
- 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; or
- sufficient quantities of the trial drug are not available.

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 increased due to our need to conduct an additional Phase III clinical trial, as our first Phase III clinical trial of Actimmune® for the treatment of IPF failed to show a significant effect on the primary endpoint of progression-free survival or on secondary endpoints of lung function and quality of life. In addition, we conducted a blinded pre-specified sample size re-evaluation in the INSPIRE trial that was a part of the original study protocol to determine if the observed aggregate mortality rate to date was consistent with the mortality assumptions underlying the trial design. At this early stage of the trial, the aggregate mortality rate observed was somewhat lower than the projections used in designing the trial. To increase the likelihood of reaching the total number of deaths upon which the trial is powered by the time the trial is scheduled to conclude in late 2007, we decided to increase the trial size by an additional 200 patients, bringing the total trial size to approximately 800 patients if the trial is fully enrolled. However, there is no guarantee that this increase in patient numbers will in fact result in an aggregate mortality rate

necessary to reach the mortality projections. In this event, the scheduled completion of this trial would extend past late 2007. If there are any significant delays for this or any of our other current or planned clinical trials, our financial results and the commercial prospects for our products and product candidates will be harmed, and our prospects for profitability will be impaired.

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

We may determine that certain preclinical product candidates or programs do not have sufficient potential to warrant the allocation of resources toward them. Accordingly, we may elect to terminate our programs for and, in certain cases, our licenses to, such product candidates or programs. If we terminate a preclinical program in which we have invested significant resources, we will have expended resources on a program that will not provide a full return on our investment and missed the opportunity to have allocated those resources to potentially more productive uses.

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

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

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

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

In addition, some of the agreements pursuant to which we license our products, including our license agreement relating to Actimmune®, contain provisions requiring us to comply with applicable laws and regulations,

including the FDA's restriction on the promotion of FDA approved drugs for off-label uses. As a result, if it were determined that we violated the FDA's rules relating to off-label promotion in connection with our marketing of Actimmune®, we may be in material breach of our license agreement for Actimmune®. If we failed to cure a material breach of this license agreement, we could lose our rights to certain therapeutic uses for Actimmune® under the agreement.

***If the FDA imposes significant restrictions or requirements related to our products for any disease, or withdraws its approval of any of our products for any disease for which it has been approved, our revenue would decline.***

The FDA and foreign regulatory authorities may impose significant restrictions on the use or marketing of our products or impose additional requirements for post-approval studies. Later discovery of previously unknown problems with any of our products or their manufacture may result in further restrictions, including withdrawal of the product from the market. In this regard, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of observations." While we believe that all of these observations are being appropriately corrected, failure to correct any deficiency could result in manufacturing delays. Our existing approvals for diseases, and any new approval for any other disease that we target, if granted, could be withdrawn for failure to comply with regulatory requirements or to meet our post-approval commitments. For example, we have ongoing Phase IV post-marketing commitments to the FDA relating to Actimmune® for the treatment of osteopetrosis. Our failure to adequately address these ongoing Phase IV commitments could result in a regulatory action or restriction, such as withdrawal of the relevant product's approval by the FDA. If approval for a disease is withdrawn, we could no longer market the affected product for that disease. In addition, governmental authorities could seize our inventory of such product, or force us to recall any product already in the market, if we fail to comply with FDA or other governmental regulations.

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

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

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

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

The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. For example, in most foreign markets, the pricing and/or profitability of prescription pharmaceuticals are subject to governmental

control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. For example, federal legislation was enacted on December 8, 2003 that provides a new Medicare prescription drug benefit which began in 2006 and which mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this program, 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® or any other products that we may develop in the future, which would reduce our revenue and potential profitability.

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

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Subject to certain exceptions, the anti-kickback laws make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify “safe harbors” or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of Medicaid rebate information and other information affecting federal and state and third-party payment for our products, and the sale and marketing of our products, could become subject to scrutiny under these laws.

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

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

**Risks Related to Manufacturing and Our Dependence on Third Parties**

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

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

- It may not be technically feasible to scale up an existing manufacturing process to meet demand or such scale-up may take longer than anticipated; and
- Failure to comply with strictly enforced good manufacturing practices regulations and similar foreign standards may result in delays in product approval or withdrawal of an approved product from the market.

For example, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of observations." While we believe that all of these observations are being appropriately corrected without further comment or action from the FDA, failure to correct any deficiency could result in manufacturing delays.

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

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

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 Actimmune® for commercial purposes. These third parties include BI and Cardinal Health. We have a long-term supply contract with BI for Actimmune® and an agreement with Cardinal for the manufacture of the API for pirfenidone. However, if we do not perform our obligations under these agreements, these agreements may be terminated.

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

- If market demand for our products is less than our purchase obligations to our manufacturers, we may incur substantial penalties and substantial inventory write-offs. For example, in accordance with the terms of our amended agreement with BI, we have guaranteed a minimum annual purchase amount for Actimmune® in 2007 and through the remainder of the term of the agreement. In the event that we do not order a sufficient quantity of vials based on forecasted demand such that we do not meet the minimum annual purchase amount, we are required to pay to BI the difference. In any given year that we are required to make this payment, our gross margin percentage for Actimmune® would be adversely affected.
- Manufacturers of our products are subject to ongoing periodic inspections by the FDA and other regulatory authorities for compliance with strictly enforced good manufacturing practices regulations and similar foreign standards, and we do not have control over our third-party manufacturers' compliance with these regulations and standards.
- When we need to transfer between manufacturers, the FDA and foreign regulatory authorities must approve the new manufacturers' facilities and processes prior to our use or sale of products it manufactures for us. This requires demonstrated compatibility of product, process and testing and compliance inspections. Delays in transferring manufacturing technology between third parties could delay clinical trials, regulatory submissions and commercialization of our product candidates.
- Our manufacturers might not be able or refuse to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand.
- We may not have intellectual property rights, or may have to share intellectual property rights, to any improvements in the manufacturing processes or new manufacturing processes for our products.
- Our product costs may increase if our manufacturers pass their increasing costs of manufacture on to us.
- If third-party manufacturers do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to obtain or maintain regulatory approvals for our products and product candidates and will not be able to successfully commercialize our products and product candidates. In such event, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all.

- If our agreement with a third-party manufacturer expires, we may not be able to renegotiate a new agreement with that manufacturer on favorable terms, if at all. If we cannot successfully complete such renegotiation, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all.

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

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

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

#### **Risks Related to the Commercialization of Our Products and Product Candidates**

***We rely on one customer for approximately 60% of our total revenue. If this customer does not continue to sell Actimmune® at its current levels, our business will be harmed.***

During the fiscal year ended December 31, 2005, CuraScript, Inc. (formerly Priority Healthcare, Inc.) accounted for approximately 60% of our total product sales and 46% of our outstanding receivables. If this customer or any other customer that sells a significant portion of Actimmune® were to experience financial difficulties, or otherwise became unable or unwilling to sell Actimmune®, our business would be harmed. Additionally, any reduction, delay or loss of orders from our key customers could harm our revenue in any period or harm our business generally.

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

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

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

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

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

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

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

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

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

- private health insurers, including managed care organizations;
- governmental payors, such as Medicaid, the U.S. Public Health Service Agency or the Veterans' Administration; and
- other third-party payors.

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

Often, third-party payors make the decision to reimburse an off-label prescription based on whether that product has a compendia listing. A drug compendia is produced by a compendia body, such as the United States Pharmacopoeia Drug Information, that lists approved indications that a product has received from the FDA. The compendia bodies also evaluate all of the clinical evidence to determine whether an off-label use of a product should be listed in the compendia as medically appropriate. A compendia listing of an off-label use is a requirement of third-party payors, such as Medicare and private payors, to cover that use. Applications for a compendia listing are often based upon the publication of certain data in peer reviewed journals whose publication is often outside the applicant's control. If we are unable to achieve acceptance by a compendia body for Actimmune® for the treatment of IPF, additional third-party payors may decide to deny reimbursement for Actimmune® for the treatment of IPF, and fewer physicians may prescribe Actimmune® for such treatment. If either of these were to occur, sales of Actimmune® would decline and our revenue would suffer.

Some third-party payors have denied coverage for Actimmune® for the treatment of IPF for a variety of reasons, including the cost of Actimmune®, the fact that IPF is not an FDA approved indication for Actimmune® or

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

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

***Our supply agreement with BI may restrict our ability to establish alternative sources of Actimmune® in a timely manner or at an acceptable cost, which may cause us to be unable to meet demand for Actimmune® and to lose potential revenue.***

Our supply agreement with BI provides that BI is our exclusive source of supply for Actimmune®, except under certain circumstances. For example, BI is currently our exclusive manufacturer for Actimmune®. Under our agreement with BI, we cannot seek a secondary source to manufacture Actimmune® until BI has indicated to us its inability or unwillingness to meet our requirements. If we are delayed in establishing a secondary supply source for Actimmune®, or cannot do so at an acceptable cost, we may suffer a shortage of commercial supply of Actimmune® or a higher cost of product, either of which would have a material and adverse effect on our revenue, business and financial prospects.

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

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

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

Even if we are successful in developing effective drugs, our products may not compete effectively with our competitors' current or future products. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do. For more information, see "Item 1. Business-Competition."

## Risks Related to Our Intellectual Property Rights

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

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

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

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

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

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

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

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

Composition of matter patent protection for pirfenidone molecule has expired in the United States and elsewhere. Marnac and others have obtained patents in the United States and elsewhere relating to methods of use of pirfenidone for the treatment of certain diseases. We have licensed from Marnac and KDL rights to a U.S. patent related to the use of pirfenidone for the treatment of fibrotic disorders, including the use of pirfenidone for the treatment of IPF. Marnac has retained rights under other U.S. and foreign patents for the use of pirfenidone to treat

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

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

We have licensed certain patents relating to interferon gamma-1b, the active ingredient in Actimmune®, from Genentech. 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 also previously purchased certain patents relating to interferon gamma analogs from Amgen in 2002 including two U.S. patents that issued August 30, 2005 which will expire on August 30, 2022. When these various patents expire, we will be unable to use these patents to try to block others from marketing interferon gamma-1b in the United States.

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

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

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

Our commercial success depends in part on our ability and the ability of our collaborators to avoid infringing patents and proprietary rights of third parties. As noted in the immediately preceding risk factor, third parties may accuse us or our collaborators of employing their proprietary technology in our products, or in the materials or processes used to research or develop our products, without authorization. Any legal action against our collaborators or us claiming damages and/or seeking to stop our commercial activities relating to the affected products, materials and processes could, in addition to subjecting us to potential liability for damages, require our collaborators or us to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. We cannot predict whether we, or our collaborators, would prevail in any of these

actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If we are unable to obtain such a license, we, or our collaborators, may be unable to continue to utilize the affected materials or processes or manufacture or market the affected products or we may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if we are able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair our prospects for profitability. Accordingly, we cannot predict whether or to what extent the commercial value of the affected product or products or our prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from our core business.

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

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

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

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

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

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

## 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 revenue will decline.*

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

- Actimmune® is not approved by the FDA for the treatment of IPF, and we therefore are unable to market or promote Actimmune® for the treatment of IPF;
- in our initial Phase III clinical trial, Actimmune® failed to meet the primary and secondary endpoints;
- physicians prefer to enroll their patients in our Phase III clinical trial of Actimmune® or another trial for the treatment of IPF, including our planned Phase III pirfenidone trials;
- Actimmune® does not have a drug compendia listing, often a criterion used by third-party payors to decide whether or not to reimburse off-label prescriptions;
- physicians' patients are unable to receive or lose reimbursement from a third-party reimbursement organization;
- physicians are not confident that Actimmune® has a clinically significant treatment effect for IPF;
- a competitor's product shows a clinically significant treatment effect for IPF; or
- physicians believe that the article and editorial in the January 8, 2004 issue of the New England Journal of Medicine were negative concerning Actimmune® as a treatment for IPF.

Net sales of Actimmune® for the year ended December 31, 2005 were \$107.6 million, compared to \$125.0 million for the year ended December 31, 2004, a decline of 14%. If physicians do not prescribe Actimmune® for the treatment of IPF for the above reasons or any other reasons, our Actimmune® revenue will continue to decline. Revenue for Actimmune® may have been adversely affected by the publication of an article and a related editorial in the January 8, 2004 issue of the New England Journal of Medicine regarding the results of our initial Phase III trial of Actimmune® or the treatment of IPF. The article concluded that "(i)n a well-defined population of patients with idiopathic pulmonary fibrosis, (Actimmune) did not affect progression-free survival, pulmonary function, or the quality of life. Owing to the size of and duration of the trial, a clinically significant survival benefit could not be ruled out." The related editorial that appeared in the January 8, 2004 New England Journal of Medicine, among other things, cast doubt on our study's indication of "increased survival among patients who were compliant with interferon gamma-1b treatment" by stating, "(i)t should be emphasized that survival data based on one year of observation in a disease with an unknown date of onset and a life expectancy of two to five years after diagnosis may be very misleading." The editorial concluded by stating, "(s)tudies of other promising agents . . . are indicated, since interferon gamma-1b has not proved to be the answer."

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

We believe our existing cash, cash equivalents and available-for-sale securities, together with anticipated cash flows from our operations, will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the end of 2007. 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 incurred net losses since inception, and our accumulated deficit was approximately \$460.9 million at December 31, 2005. 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 revenue primarily through the sale of Actimmune®. However, Actimmune® sales have decreased in recent periods and Actimmune® is currently our sole marketed product. We have not generated operating profits to date from our products. If the time required for us to achieve profitability is longer than we anticipate, we may not be able to continue our business.

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

We base many of our operating decisions on anticipated revenue trends and competitive market conditions, which are difficult to predict. Based on projected revenue trends, we acquired inventories and entered into non-cancelable purchase obligations in order to meet anticipated increases in demand for our products. However, more recent projected revenue trends resulted in us recording charges of \$9.1 million during 2005 for excess inventories from previous years' contractual purchases. If revenue levels experienced in future quarters are substantially below our expectations, especially revenue from sales of Actimmune®, we could be required to record additional charges for excess inventories and/or non-cancelable purchase obligations. For additional information relating to difficulties we have experienced forecasting revenue, see the risk factor titled, "We may fail to meet our publicly announced revenue and/or expense projections and/or other financial guidance, which would cause our stock to decline in value" below.

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

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

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

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

***We face certain litigation risks that could harm our business.***

On November 9, 2004, we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune®, including information regarding the promotion and marketing of Actimmune®. We are cooperating with the Department of Justice in this inquiry. Although we cannot predict whether the outcome of this inquiry will have a material adverse effect on our business, it is possible that we will be required to pay a substantial civil fine in connection with the settlement of this matter. At this time we cannot predict the magnitude of such a fine or the impact the payment of such a fine may have on our future business operations.

***Insurance coverage is increasingly difficult to obtain or maintain.***

While we currently maintain clinical trial and product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and warehouse and transit insurance, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policies may impact our future ability to obtain or maintain insurance coverage at reasonable costs, if at all.

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

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

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

We had 193 full-time employees as of January 31, 2006, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop relationships with leading academic scientists. Competition for personnel and academic collaborations is intense. We are highly dependent on our current management and key scientific and technical personnel, including Daniel G. Welch, our Chief Executive Officer and President, as well as the other principal members of our management. None of our employees, including members of our management team, has a long-term employment contract, and any of our employees can leave at any time. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. In addition, we may need to hire additional personnel and develop additional academic collaborations as we continue to expand our research and development activities. 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.

**Risks Related to our Common Stock**

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

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

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

- we may not be able to accurately calculate the number of patients using the product;
- we may not be able to supply enough product to meet demand;
- there may be current and future competitive products that have greater acceptance in the market than our products do;
- we may decide to divest a product;
- our development activities may proceed faster than planned;
- we may decide to change our marketing and educational programs;
- clinical trial participation may reduce product sales; or
- physicians' prescriptions or patient referrals for Actimmune® may decline.

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

***Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.***

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC require annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm attesting to and reporting on these assessments. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot in the future favorably assess, or our independent registered public accounting firm is unable to provide an unqualified attestation report on our assessment of, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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

The trading price of our common stock has been and is likely to continue to be extremely volatile. During the twelve-month period ended December 31, 2005, the closing price of our common stock on the NASDAQ National Market ranged from \$9.99 to \$18.14. Our stock price could be subject to wide fluctuations in response to a variety of factors, including, but not limited to all the factors discussed in this "Risk Factors" section.

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.

***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, 2005, our directors, executive officers and greater than 5% stockholders and their affiliates beneficially owned approximately 48% of our issued and outstanding common stock. Accordingly, they collectively may have the ability to significantly influence the election of all of our directors and to significantly influence the outcome of corporate actions requiring stockholder approval, such as mergers or a financing in which we sell more than 20% of our voting stock at a discount to market price. They may exercise this ability in a manner that

advances their own best interests and not necessarily those of other stockholders. This concentration of ownership could also depress our stock price.

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

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

We have filed registration statements covering the approximately 9,271,426 shares of common stock that are either issuable upon the exercise of outstanding options or reserved for future issuance pursuant to our stock plans as of December 31, 2005. We have also filed a shelf registration statement covering the resale of our 0.25% convertible senior notes due in 2011 and the 7,858,811 shares of common stock issuable upon conversion of those notes. In addition, some of the holders of common stock that are parties to our amended and restated investor rights agreement are entitled to registration rights with respect to approximately 6,500,000 shares of our common stock as of December 31, 2005.

On October 29, 2004, we entered into an Amended and Restated Standstill Agreement with Warburg Pincus Equity Partners, L.P. and certain of its affiliates (“Warburg Pincus”) that permits Warburg Pincus to acquire up to 25% of our outstanding common stock in the open market. Under this agreement, Warburg Pincus may acquire up to 25% of our outstanding common stock and we have granted Warburg Pincus certain registration rights with respect to its holdings. The restriction on Warburg Pincus’ acquisition of additional shares of our common stock expires on October 29, 2007. In exchange for allowing Warburg Pincus to increase its ownership stake, Warburg Pincus has granted the independent members of our board of directors the right to vote the shares of InterMune common stock owned by Warburg Pincus in excess of 19.9%. In addition, Warburg Pincus has agreed to certain limitations on the manner in which it may dispose of its ownership interest in InterMune. In connection with this transaction, we also amended our stockholder Rights Plan to allow Warburg Pincus to acquire up to 25% of our outstanding common stock. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P.

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

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

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

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

### **Risks Related to our Outstanding Notes**

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

As of December 31, 2005, our annual debt service obligation on the \$170.0 million in aggregate principal amount of our 0.25% convertible senior notes due March 1, 2011 was \$0.4 million. We intend to fulfill our current debt service obligations, including repayment of the principal, both from cash generated by our operations and from our existing cash and investments. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our current debt service obligations, including repayment of the principal, we may have to delay or curtail research and development programs.

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

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

- requiring the dedication of a substantial portion of our expected cash flow from operations to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes, including capital expenditures;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

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

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

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

Our facilities currently consist of approximately 55,898 square feet of office space located at our headquarters at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this building. On January 13, 2005, we entered into an operating lease agreement to sublease an additional 12,988 square feet of office space which consists of 11,444 square feet of usable area and 1,544 square feet of common area located at the second floor of 3240 Bayshore Boulevard, Brisbane, CA 94005. In connection with the divestiture of Infergen® and the reduction in our field-based IPF disease awareness activities, we no longer require the use of this space and have terminated this sublease effective April 2006. We believe that our facilities are adequate for our current needs, and that suitable additional or substitute space will be available in the future to replace our existing facility, if necessary, or accommodate expansion of our operations.

## **ITEM 3. LEGAL PROCEEDINGS**

On June 25, 2003, a purported securities class action entitled *Johnson v. Harkonen and InterMune, Inc.*, No. C 03-2954-MEJ, was filed in the United States District Court for the Northern District of California. Three additional class action complaints entitled *Lombardi v. InterMune, Inc., Harkonen and Surrey-Barbari*, No. C 03 3068 MJJ (filed on July 1, 2003); *Mahoney Jr. v. InterMune Inc., Harkonen and Surrey-Barbari*, No. C 03-3273 SI (filed on July 14, 2003); and *Adler v. Harkonen and InterMune Inc.*, No. C 03-3710 MJJ (filed on August 3, 2003), were filed in the same court, each making identical or similar allegations against us, our former chief executive officer and our former chief financial officer. On November 6, 2003, the various complaints were consolidated into one case by order of the court, and on November 26, 2003, a lead plaintiff, Lance A. Johnson, was appointed. A consolidated complaint titled *In re InterMune Securities Litigation*, No. C 03-2954 SI, was filed on January 30, 2004. The consolidated amended complaint named us, and our former chief executive officer and our former chief financial officer, as defendants and alleges that the defendants made certain false and misleading statements in violation of the federal securities laws, specifically Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. The lead plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 7, 2003 through June 11, 2003. The parties settled this case in May 2005 and a final settlement was approved by the court in August 2005.

On July 30, 2003, a stockholder, Michael Adler, purporting to act on our behalf filed a derivative action entitled *Adler v. Harkonen, et al.*, No. CIV 433125, in the California Superior Court for the County of San Mateo against our directors, our former chief executive officer and our former chief financial officer. We were also named as a nominal defendant solely in a derivative capacity. The derivative action was based on the same factual allegations and circumstances as the securities class actions and alleged state law claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. The derivative action sought unspecified damages, injunctive relief and restitution. The parties settled this case in August 2005.

On March 19, 2004, plaintiff Joan Gallagher filed an action against us and other defendants in the United States District Court for the Eastern District of Pennsylvania. Ms. Gallagher alleged that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune® for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Ms. Gallagher alleged that she was wrongfully terminated from InterMune in violation of public policy due to her refusal to engage in the alleged off-label marketing. The parties settled this case in July 2005.

On November 9, 2004, we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune®, including information regarding the promotion and marketing of Actimmune®. We are cooperating with the Department of Justice in this inquiry. Although we cannot predict whether the outcome of this inquiry will have a material adverse effect on our business, it is possible that we will be required to pay a substantial civil fine in connection with the settlement of this matter. At this time we cannot predict the magnitude of such a fine or the impact the payment of such a fine may have on our future business operations.

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

None.

**PART II**

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

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

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

<u>Fiscal Year:</u>	<u>High</u>	<u>Low</u>
2005		
First Quarter . . . . .	\$13.51	\$ 9.99
Second Quarter . . . . .	13.22	10.15
Third Quarter . . . . .	18.14	13.16
Fourth Quarter . . . . .	17.23	13.22
2004		
First Quarter . . . . .	\$24.55	\$17.76
Second Quarter . . . . .	20.61	13.66
Third Quarter . . . . .	14.61	9.74
Fourth Quarter . . . . .	13.59	10.77

As of January 31, 2006, we had 109 stockholders of record. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

**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, 2005, 2004 and 2003, respectively, and the selected consolidated balance sheet data as of December 31, 2005 and 2004, 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, 2002 and 2001, respectively, and the selected consolidated balance sheet data as of December 31, 2003, 2002 and 2001, respectively, are derived from audited financial statements not included in this Report.

In December 2005, we sold our Infergen® product, including related intellectual property rights and inventory, to Valeant. The operating results of our Infergen® activities, which include allocations of research and development and selling, general and administrative expenses, have been reclassified as discontinued operations for all periods presented.

	Years Ended December 31,				
	2005	2004	2003	2002	2001
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenue, net:					
Actimmune .....	\$ 107,633	\$ 124,980	\$ 141,402	\$ 105,802	\$ 36,320
Others .....	2,863	3,700	3,460	3,232	2,863
Total revenue, net .....	110,496	128,680	144,862	109,034	39,183
Costs and expenses:					
Cost of goods sold .....	33,842	33,139	33,233	23,396	15,261
Amortization and impairment of acquired product rights(1) .....	1,180	743	5,998	1,233	3,534
Research and development .....	82,736	75,683	118,771	128,326	49,718
Selling, general and administrative .....	58,854	55,132	56,167	54,233	34,543
Acquired research and development and milestone (credits) payments(2) .....	(10,000)	—	12,150	33,750	51,000
Restructuring charges .....	5,549	—	—	—	—
Total costs and expenses .....	172,161	164,697	226,319	240,938	154,056
Loss from operations .....	(61,665)	(36,017)	(81,457)	(131,904)	(114,873)
Interest income .....	3,965	3,490	4,024	7,375	11,253
Interest and other income (expense) .....	52	(12,516)	(10,037)	(9,803)	(4,772)
Loss from continuing operations .....	(57,648)	(45,043)	(87,470)	(134,332)	(108,392)
Discontinued operations:					
Loss from discontinued operations .....	(32,925)	(14,435)	(9,531)	(9,977)	(9,799)
Gain on sale of discontinued operations (net of transaction costs) .....	85,338	—	—	—	—
Net income (loss) from discontinued operations .....	52,413	(14,435)	(9,531)	(9,977)	(9,799)
Net loss .....	<u>\$ (5,235)</u>	<u>\$ (59,478)</u>	<u>\$ (97,001)</u>	<u>\$ (144,309)</u>	<u>\$ (118,191)</u>
Basic and diluted net loss per share:					
Continuing operations .....	\$ (1.79)	\$ (1.42)	\$ (2.76)	\$ (4.39)	\$ (4.28)
Discontinued operations .....	\$ 1.63	\$ (0.45)	\$ (0.30)	\$ (0.33)	\$ (0.39)
Net loss per share .....	<u>\$ (0.16)</u>	<u>\$ (1.87)</u>	<u>\$ (3.06)</u>	<u>\$ (4.72)</u>	<u>\$ (4.67)</u>
Shares used in computing basic and diluted net loss per share .....	32,220	31,760	31,665	30,589	25,322

	As of December 31,				
	2005	2004	2003	2002	2001
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and available-for-sale securities . . . . .	\$ 215,525	\$ 183,025	\$ 216,107	\$ 316,411	\$ 332,067
Working capital . . . . .	185,295	185,133	201,855	285,633	320,345
Total assets . . . . .	263,452	266,011	288,501	384,881	387,246
Long-term obligations . . . . .	170,000	170,000	149,500	149,500	149,500
Accumulated deficit . . . . .	(460,881)	(455,646)	(396,168)	(299,167)	(154,858)
Total stockholders' equity . . . . .	31,767	32,791	87,744	182,718	215,059

- (1) The amortization and impairment of acquired product rights also included charges of \$0.6 million and \$4.8 million for the impairment of Amphotec® product rights recognized during 2005 and 2003, respectively.
- (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. The 2005 balance reflects the reversal of the milestone liability in connection with the divestiture of oritavancin. Please see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Results of Operations" and Note 5 of the Notes to Consolidated Financial Statements.

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

### Overview

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

### Significant License/Acquisition Agreements

We are highly dependent on technology we license or acquire from third parties. Actimmune®, which is currently our sole marketed product, is subject to a license agreement with Genentech, Inc. 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 "Item. Business — License and Other Agreements," Notes 6 and 7 of the Notes to Consolidated Financial Statements, and under the heading "Results of Operations" below.

We will be required to make contingent milestone payments in accordance with all of our license and acquisition agreements in the aggregate amount of \$136.4 million if all of the milestones defined in each of the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

### Our Need for Additional Capital

We commenced operations in 1998 and have incurred significant losses to date. Our revenue has been limited primarily to sales of Actimmune® derived from physicians' prescriptions for the off-label use of Actimmune® in the treatment of IPF. We expect to continue to incur net losses over the next several years as we continue the development of our advanced-stage pulmonology pipeline and our research-stage hepatology pipeline, apply for regulatory approvals and grow our operations. Although we believe that 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 2007, we believe that we will continue to require substantial additional funding to complete the research and

development activities currently contemplated and to commercialize our product candidates. 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. If additional capital is not available, we may be forced to curtail our development activities or cease operations.

### **Critical Accounting Policies**

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

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

### **Revenue Recognition and Revenue Reserves**

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

### **Clinical Trial Accruals**

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

## **Inventory Reserves and 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, 2005, our minimum purchase obligations totaled \$99.6 million and are committed through the year 2012. Of these commitments, we have \$7.0 million and \$16.1 million of outstanding fixed purchase order commitments that become due and payable in 2006 and 2007, respectively.

We write off the cost of inventory and reserve for future minimum purchase commitments that we consider to be in excess of forecasted future demand. We define excess inventory as inventory that will expire before it can be sold, based on future sales forecasts. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels. We are also required to monitor the expiration dates of our products, since our products can no longer be used after their respective expiration dates. In 2004, in an effort to best manage the procurement and distribution of levels of Actimmune®, we successfully completed the necessary testing to extend the expiration period of Actimmune® from 30 months to a total of 36 months. As part of our excess inventory assessment for all of our products, we also estimate the expiration dates of our products to be manufactured in the future.

Projected revenue trends resulted in us recording charges during 2005 and 2004 for excess inventories and non-cancelable purchase obligations. If Actimmune® revenue levels experienced in future quarters are substantially below our expectations, we could be required to record additional charges for excess inventories and/or non-cancelable purchase obligations. For the year ended December 31, 2005, we recorded a total of \$9.1 million, or \$0.28 per share, to cost of goods sold for excess inventory from previous years' contractual purchases. Please refer to the statements under "Item 1A. 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**

The following discussion of our results of operations for each of the comparative periods excludes Infergen® revenues and related expenses. These amounts are reflected in discontinued operations as a result of the sale of the Infergen® product to Valeant in December 2005.

### *Comparison of years ended December 31, 2005 and 2004*

#### *Revenue*

For the year ended December 31, 2005, InterMune recorded total net revenue of \$110.5 million, compared to \$128.7 million for the same period in 2004, a decrease of 14%. Net sales of Actimmune® for 2005 were \$107.6 million, compared to \$125.0 million for 2004, a decline of 14%. For each of the years ended December 31, 2005 and 2004, Actimmune® accounted for approximately 97% of our total net revenue and substantially all of these sales were derived from physicians' prescriptions for the off-label use of Actimmune® in the treatment of IPF.

Actimmune® sales declined during the year ended December 31, 2005 compared to the corresponding period in 2004 due to a decrease in the underlying demand for Actimmune®. We believe that rate of patient referrals by physicians and the average duration of therapy are among the key uncertainties that affect demand for Actimmune® and our Actimmune® revenue and total product revenue. The patient referral rate reflects the number of new patients who are prescribed Actimmune® and who call the call center that coordinates with all of our specialty distributors, although these patients may elect not to have those prescriptions filled. We believe that the following factors are among those that may affect the patient referral rate for Actimmune®: physician screening of patients who are likely to pursue treatment with Actimmune®; physician or patient interest; the publication of the results of our initial Phase III IPF clinical trial, GIPF-001, in the *New England Journal of Medicine* and the negative editorial that accompanied the publication; and the extent to which physicians enroll their patients in our Phase III IPF clinical trial, GIPF-007, who would otherwise be put on Actimmune® therapy. During the year ended December 31, 2005, the patient referral rate that we observed for Actimmune® was significantly lower than for the same period in 2004;

however, the average duration of therapy that we observed was greater than expected. In 2006, we expect Actimmune® revenue to be in a range of \$80.0 million to \$100.0 million.

#### *Cost of Goods Sold*

Cost of goods sold included product manufacturing costs, royalties and distribution costs associated with our revenue and inventory reserves. Cost of goods sold for the year ended December 31, 2005 was \$33.8 million, or approximately 31% of total net revenue, compared to \$33.1 million, or approximately 26% of total net revenue, in the corresponding period of 2004. The increase in cost of goods sold primarily reflects a charge of \$9.1 million taken for excess inventory from previous years' contractual purchases compared to a \$4.7 million charge taken in 2004 for the same reason. Excluding these charges for excess inventory, cost of goods sold was approximately 22% of total revenue for each of the years ended December 31, 2005 and 2004. In 2006, we expect cost of goods sold to be approximately 21% to 23% of total revenue.

Exchange rate fluctuations on inventory purchases may affect cost of goods sold on Actimmune® inventory purchased from BI. We have utilized forward exchange contracts to partially offset the effect of exchange rate fluctuations in the past, but we did not enter into any new contracts in 2005.

#### *Amortization and Impairment of Acquired Product Rights*

We recorded amortization and impairment of acquired product rights for the years ended December 31, 2005 and 2004 of \$1.2 million and \$0.7 million, respectively. The acquired product rights were related to the acquisition of Amphotec® and interferon gamma-1b patents. In March 2005, we recorded an impairment charge of \$0.6 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® was not aligned with our new strategic focus in pulmonology and hepatology. In May 2005, we divested the Amphotec® product line, including all related assets, to Three Rivers for cash consideration.

#### *Research and Development Expenses*

Research and development expenses were \$82.7 million and \$75.7 million for the years ended December 31, 2005 and 2004, respectively, representing an increase of \$7.1 million or 9%. The increase in 2005 reflects a greater level of spending to support our Phase III IPF clinical trials and our HCV protease inhibitor program.

The following table lists our current product development programs and the research and development expenses recognized in connection with each program during the indicated periods. The category titled "Programs — Non-specific" is comprised of facilities and personnel costs that are not allocated to a specific development program or discontinued programs. Our management reviews each of these program categories in evaluating our business. For a discussion of the risks and uncertainties associated with developing our products, as well as the risks and uncertainties associated with potential commercialization of our product candidates, see the specific sections under "Item 1A. Risk Factors" above.

<u>Development Program</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
		(In thousands)	
Pulmonology . . . . .	\$34,779	\$19,589	\$ 12,552
Hepatology . . . . .	17,820	15,253	16,226
Oncology . . . . .	14,156	18,307	17,859
Anti-infectives(1) . . . . .	637	2,561	41,300
Programs — Non-specific . . . . .	<u>15,344</u>	<u>19,973</u>	<u>30,834</u>
<b>Total</b> . . . . .	<u>\$82,736</u>	<u>\$75,683</u>	<u>\$118,771</u>

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

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

- the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety;
- the submission of an IND with the FDA to conduct human clinical trials for drugs;
- the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and
- the submission by a company and acceptance and approval by the FDA of an NDA or BLA for a drug product to allow commercial distribution of the drug.

In light of the factors mentioned above, we consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Due to these factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs. Based on our existing budgeted programs, we expect research and development expenses to be in a range of \$80.0 million to \$90.0 million in 2006.

#### *Selling, General and Administrative Expenses*

Selling general and administrative expenses were \$58.9 million and \$55.1 million for the years ended December 31, 2005 and 2004, respectively, representing an increase of \$3.7 million, or 7%. The increased spending for the year ended December 31, 2005 compared to the same period in 2004 was primarily due to \$5.6 million in expenses related to litigation, legal settlements and ongoing legal matters. In 2006, we expect selling, general and administrative expenses to be in a range of \$25.0 million to \$35.0 million, or a decrease of approximately 40% to 60% from 2005 continuing operations expense levels.

#### *Acquired Research and Development and Milestone (Credits) Payments*

There were no charges for acquired research and development and milestone payments in the years ended December 31, 2005 and 2004. Included in our charges for 2003 was \$10.0 million for a milestone payable to Eli Lilly for oritavancin. We initially expensed this amount as acquired research and development as oritavancin at the time was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses. In connection with the divestiture of oritavancin to Targanta in December 2005, we have received a waiver from Eli Lilly for making this payment and thus reversed the accrued liability for this milestone.

#### *Restructuring Charges*

In the fourth quarter of 2005, our board of directors approved a restructuring plan recommended by our Chief Executive Officer and senior management that was designed to help streamline our operations and reduce our operating expenses in 2006. The plan, which consisted of a significant reduction in our investment in field-based IPF disease awareness activities, was implemented concurrently with the divestiture of Infergen® in December 2005. These combined actions led to a significant headcount reduction of approximately 160 employees and resulting termination costs of approximately \$9.2 million. Restructuring charges comprised approximately \$5.5 million of this amount which were recorded as a separate component of operating expenses in the statement of operations, with the remainder allocated to discontinued operations. See "Loss from Discontinued Operations" discussion below. The majority of the 160 employees left InterMune at the end of the fourth quarter of 2005, with the remainder expected to leave during the first quarter of 2006.

The \$5.5 million restructuring charge was comprised of approximately \$4.7 million for cash severance and related benefits and approximately \$0.8 million for non-cash stock compensation, consisting of an allocation of option acceleration costs for approximately 400,000 shares of our common stock. We expect to pay out substantially all of the \$4.7 million severance and related benefits during the first quarter of 2006.

#### *Interest Income*

Interest income increased to \$4.0 million for the year ended December 31, 2005 compared to \$3.5 million for the year ended December 31, 2004. The increase in interest income in the year ended December 31, 2005 reflects the increase in interest rates that we received on our invested cash and securities, partially offset by our declining cash and short-term investment balances up to our receipt of \$120.0 million in proceeds from the sale of Infergen® in December 2005.

#### *Interest Expense*

Interest expense decreased to \$1.3 million for the year ended December 31, 2005 compared to \$5.1 million for the year ended December 31, 2004. The decrease in interest expense in the year ended December 31, 2005 reflects the 2004 repurchase of all of our \$149.5 million 5.75% convertible subordinated notes, and the impact of the lower interest rate on our \$170.0 million principal amount 0.25% convertible senior notes, issued in February 2004. At the time of repurchase of the 5.75% convertible subordinated notes, we paid accrued interest charges of \$3.2 million.

#### *Other Income (Expense)*

Other income (expense) improved to income of \$1.3 million in the year ended December 31, 2005 compared to an expense of \$7.4 million in 2004. Other income in 2005 included a \$1.0 million cash payment received from Targanta in connection with the divestiture of oritavancin. Other expense of \$7.4 million for the year ended December 31, 2004 included a charge of \$5.0 million for the repurchase of all our outstanding \$149.5 million principal amount 5.75% convertible subordinated notes, and the accelerated amortization of \$2.1 million of the deferred issuance costs associated with these notes. Also included in other expense for the year ended December 31, 2004 was a \$0.3 million foreign currency exchange loss on our unhedged foreign currency payables for inventory and clinical material purchases from BI at year-end.

#### *Loss from Discontinued Operations*

The loss from discontinued operations reflects the divestiture of our Infergen® product line to Valeant which was completed in December 2005. The loss from discontinued operations of \$32.9 million in the year ended December 31, 2005 compares to a loss of \$14.4 million in the year ended December 31, 2004. The components of the loss from discontinued operations for each of the years included net revenue of Infergen®, the related cost of goods sold and amortization of acquired product rights, as well as certain allocated research and development and selling general and administrative expenses specific to Infergen®. The increased loss in 2005 compared to 2004 was the result of a greater level of sales and marketing expenses to support Infergen®, including the 31-representative sales force hired in the fourth quarter of 2004, and the full year impact of the Phase III trial of once-daily treatment with Infergen® in combination with ribavirin therapy for hepatitis C PEG nonresponder patients. These increased expenses were offset by the gross margin on higher levels of Infergen® revenue (see Note 3 of Notes to Consolidated Financial Statements). The loss in 2005 also included employee termination costs of approximately \$3.7 million.

#### *Gain on Sale of Discontinued Operations*

The gain on sale of discontinued operations in 2005 was comprised of the \$120.0 million in cash proceeds and a \$2.1 million note received from Valeant in connection with the sale of Infergen®, offset by the net book value of the assets sold and direct transaction costs. These assets included intellectual property rights, payments to a contract manufacturer, and inventory with a net book value of approximately \$36.5 million at the time of the transaction. In addition, we incurred approximately \$0.3 million of direct transaction costs related to the sale of Infergen®.

### *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, 2005 and 2004. As of December 31, 2005, we had federal net operating loss carryforwards of approximately \$384.1 million. The net operating loss carryforwards will expire at various dates beginning in 2019 through 2025 if not utilized. We also have federal research and development tax credits of approximately \$13.4 million that will expire in the years 2018 through 2025. In addition, we had net operating loss carryforwards for state income tax purposes of approximately \$72.6 million that expire in the years 2006 through 2015 and state research and development tax credits of approximately \$4.8 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, 2004 and 2003*

#### *Revenue*

For the year ended December 31, 2004, InterMune recorded total net revenue of \$128.7 million, compared to \$144.9 million for the same period in 2003, a decrease of 11%. Net sales of Actimmune® for 2004 were \$125.0 million, compared to \$141.4 million for 2003, a decline of 12%. For the years ended December 31, 2004 and 2003, Actimmune® accounted for approximately 97% and 98%, respectively, of our total net revenue, and substantially all of these sales were derived from physicians' prescriptions for the off-label use of Actimmune® in the treatment of IPF.

Actimmune® sales declined during the year ended December 31, 2004 compared to the corresponding period in 2003 due to a decrease in the underlying demand for Actimmune®. During the year ended December 31, 2004, the patient referral rate that we observed for Actimmune® was significantly lower than for the same period in 2003; however, the average duration of therapy that we observed was greater than observed in prior years.

#### *Cost of Goods Sold*

Cost of goods sold included product manufacturing costs, royalties and distribution costs associated with our revenue and inventory reserves. Cost of goods sold for the year ended December 31, 2004 was \$33.1 million, approximately 26% of total net revenue, compared to \$33.2 million, or approximately 23% of total net revenue, in the corresponding period of 2003. The increase in cost of goods sold as a percentage of total net revenue primarily reflects a charge of \$4.7 million recorded for obsolete inventory and contractual purchase commitments in excess of our forecasts compared to \$1.3 million in 2003.

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

#### *Amortization and Impairment of Acquired Product Rights*

We recorded amortization and impairment of acquired product rights for the years ended December 31, 2004 and 2003 of \$0.7 million and \$6.0 million, respectively. The acquired product rights related to the acquisition of Amphotec® and interferon gamma-1b patents. The decrease for the 2004 period compared to the same period in 2003 was primarily due to a charge of \$4.8 million taken in the third quarter of 2003 for the impairment of Amphotec® product rights which reduced the remaining carrying value of the intangible asset being amortized.

#### *Research and Development Expenses*

Research and development expenses were \$75.7 million and \$118.8 million for the years ended December 31, 2004 and 2003, respectively, representing a decrease of \$43.1 million or 36%. The decrease in 2004 was largely attributable to the focusing of our research and development investment for clinical trials in the areas of hepatology

and pulmonology and discontinuing a number of programs outside of these two core areas, particularly anti-infectives.

#### *Selling, General and Administrative Expenses*

Selling general and administrative expenses were \$55.1 million and \$56.2 million for the years ended December 31, 2004 and 2003, respectively, a decrease of \$1.0 million, or 2%. The slight decrease in spending reflected our intent not to increase our investment in other areas of our business while we focused our efforts and investments on expanding the Infergen® brand. Selling, general and administrative expenses related to Infergen have been reclassified to discontinued operations in connection with our divestiture of Infergen® to Valeant.

#### *Acquired Research and Development and Milestone (Credits) Payments*

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

#### *Interest Income*

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

#### *Interest Expense*

Interest expense decreased to \$5.1 million for the year ended December 31, 2004 compared to \$9.6 million for the comparable period ended December 31, 2003. The decrease in interest expense in the year ended December 31, 2004 reflects the repurchase of all of our outstanding \$149.5 million principal amount 5.75% convertible subordinated notes, and the impact of the lower interest rate on our \$170.0 million 0.25% convertible senior notes.

#### *Other Expense*

Other expense of \$7.4 million for the year ended December 31, 2004 includes a charge of \$5.0 million for the repurchase of all \$149.5 million of our 5.75% convertible subordinated notes due in July 2006, and the accelerated amortization of \$2.1 million of the deferred issuance costs associated with these notes. Also, included in other expense for the year ended December 31, 2004 was a \$0.3 million foreign currency exchange loss on our unhedged foreign currency payables for inventory and clinical material purchases from BI at year-end.

#### *Loss from Discontinued Operations*

The loss from discontinued operations reflects the divestiture of our Infergen® product line to Valeant which was completed in December 2005. The loss from discontinued operations of \$14.4 million in the year ended December 31, 2004 compares to a loss of \$9.5 million in the year ended December 31, 2003. The components of the loss from discontinued operations for each of the years included net revenue of Infergen®, the related cost of goods sold and amortization of acquired product rights, as well as certain allocated research and development and selling general and administrative expenses specific to Infergen®. The increased loss in 2004 compared to 2003 was the result of a greater level of sales and marketing expenses to support Infergen®, including the 31-representative sales force hired in the fourth quarter of 2004. These increased expenses were offset by the gross margin on higher levels of Infergen® revenue.

### *Provision for Income Taxes*

Due to our continuing operating losses and the uncertainty of our recognizing the potential future benefits from these losses, we recorded no provision or benefit for income taxes for the years ended December 31, 2004 and 2003.

### *Liquidity and Capital Resources*

At December 31, 2005, we had cash, cash equivalents and available-for-sale securities of \$215.5 million compared to \$183.0 million at December 31, 2004, an increase of \$32.5 million. The \$32.5 million increase was the result of the \$120.0 million in proceeds we received from the sale of Infergen® to Valeant, partially offset by our cash used for operating activities of \$70.8 million and \$16.8 million in payments we made for manufacturing technology rights. Concurrent with our decision to divest Infergen®, we also made the decision to significantly reduce our investment in field-based IPF disease awareness activities, which, when combined with the sale of our Infergen® assets, led to a significant headcount reduction of approximately 160 full time equivalent employees and resulting cash severance and related benefit payments of approximately \$7.9 million in the first quarter of 2006. We believe that this headcount reduction will reduce our annual operating expenses by up to approximately \$50.0 million. With the \$120.0 million in proceeds we received from the sale of our Infergen® assets, continued revenue from sales of Actimmune® and our reduced spending levels, we now believe we have sufficient capital to continue to fund our primary development programs for at least the next two years: Actimmune® for IPF, pirfenidone for IPF and the HCV protease inhibitor program.

The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. federal and state governments and their agencies and high-quality corporate issuers, and, by policy, restrict our exposure by imposing concentration limits and credit worthiness requirements for all corporate issuers.

Operating activities used \$70.8 million in cash during the year ended December 31, 2005, primarily due to the loss from operations of \$61.7 million (\$71.7 million excluding the expense reversal recognized as a result of Eli Lilly's waiver of a previously accrued milestone payment). These cash outflows were partially offset by an increase in accrued compensation of \$6.4 million and a decrease in inventory of \$14.1 million. The increase in accrued compensation was due to the accruals made for the termination costs of approximately 160 employees as a result of the divestiture of Infergen® and reduction in field-based IPF disease awareness activities. The decrease in inventory was primarily due to the \$9.1 million write-off of excess inventory. Details concerning the loss from operations can be found above in this report under the heading "Results of Operations."

Investing activities provided \$200.3 million in cash flows during the year ended December 31, 2005, primarily due to the \$120.0 million in proceeds from the divestiture of Infergen®, partially offset by the \$16.8 million in payments made for manufacturing technology rights. The cash outflows for manufacturing technology rights relate to the agreement that we signed with BI in November 2005 for the future clinical and commercial supply of Infergen®. We assigned this agreement and all future rights and obligations thereunder to Valeant as part of the sale of Infergen® to Valeant in December 2005. We also had maturities and sales of available-for-sale securities totaling \$176.4 million, offset by \$77.4 million of available-for-sale securities purchases.

Cash provided by financing activities of \$2.1 million for the year ended December 31, 2005 was due to the proceeds from the issuance of our common stock under our employee stock plans.

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We have no commercial commitments with related parties. We have no loans with related parties, except for executive loans to Dr. Marianne Armstrong, our Chief Medical Affairs and Regulatory Officer in the amount of \$0.2 million (due April 2007), and Dr. Lawrence Blatt, our Chief Scientific Officer, in the amount of \$0.1 million (due May 2007). Both of these loans were in place prior to the enactment of the Sarbanes-Oxley Act in 2002.

We believe that we will continue to require substantial additional funding to complete the research and development activities currently contemplated and to commercialize our product candidates. We believe that 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 2007. However, this forward-looking statement involves risks and

uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under “Item 1A. Risk Factors.” This forward-looking statement is also based upon 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 Actimmune® or any of our product candidates in development that receive commercial approval;
- our ability to partner our development and commercialization programs;
- the progress of our research and development efforts;
- the scope and results of preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory reviews;
- determinations as to the commercial potential of our product candidates in development;
- the pace of expansion of administrative expenses;
- the status of competitive products and competitive barriers to entry;
- the establishment and maintenance of manufacturing capacity through third-party manufacturing agreements;
- the pace of expansion of our sales and marketing capabilities, in preparation for product launches;
- the establishment of collaborative relationships with other companies;
- the payments of annual interest on our long-term debt; and
- whether we must repay the principal in connection with our convertible debt obligations.

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

### Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities, such as milestone payments, for which we cannot reasonably predict future payments. The following chart represents our contractual obligations as of December 31, 2005, aggregated by type (in millions):

<u>Contractual Obligations</u>	<u>Total</u>	<u>2006</u>	<u>2007-2008</u>	<u>2009-2010</u>	<u>After 2010</u>
Long-term debt obligations(1) . . . . .	\$172.7	\$ 0.4	\$ 0.9	\$ 0.9	\$170.5
Operating leases . . . . .	22.6	4.2	8.2	8.5	1.7
Non-cancelable purchase obligations — Inventory . . . . .	99.6	7.0	31.4	30.6	30.6
Non-cancelable purchase obligations — Other(2) . . . . .	4.4	3.8	0.3	0.3	—
Research and development funding commitments . . . . .	<u>5.2</u>	<u>4.9</u>	<u>0.3</u>	<u>—</u>	<u>—</u>
Total contractual cash obligations . . . . .	<u>\$304.5</u>	<u>\$20.3</u>	<u>\$41.1</u>	<u>\$40.3</u>	<u>\$202.8</u>

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

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

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

The majority of our non-cancelable purchase obligations for inventory are denominated in foreign currencies, principally the purchase of Actimmune® inventory, which is denominated in Euros. We assumed an average foreign currency exchange rate of euros to U.S. dollars of 1.20 over the length of the agreement.

### **Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which is a revision of SFAS 123. SFAS 123R supersedes APB 25. SFAS 123R requires all share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values, beginning with the first quarterly period after June 15, 2005, with early adoption permitted. On April 14, 2005, the Securities and Exchange Commission adopted a new rule that amended the compliance dates for SFAS 123R such that we were allowed to adopt the new standard effective January 1, 2006. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. We adopted SFAS 123R on January 1, 2006.

Under SFAS 123R, we must determine the appropriate fair value model and related assumptions to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and retroactive adoption options. Under the retroactive method, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We have been evaluating the requirements of SFAS 123R as well as option valuation methodologies related to our employee and director stock options and employee stock purchase plan. Effective January 1, 2006, we expect to adopt the modified prospective method as our transition method and the Black-Scholes valuation model to determine the fair value of our stock options as provided by the provisions of SFAS 123. We expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations and net loss per share. The impact of adoption of SFAS 123R will depend on, among other things, the levels of share-based payments granted in the future and the option valuation method used.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections," a replacement of Accounting Principles Board Opinions No. 20, "Accounting Changes", and Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements." Statement 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles were recognized by including in net income during the period of change the cumulative effect of changing to the new accounting principle. Statement 154 requires retrospective application to prior periods' financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Statement 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, Statement 154 does not change the transition provisions of any existing accounting pronouncements. We believe that the adoption of Statement 154 will not have a material effect on our consolidated financial position, results of operations or cash flows.

In November 2005, the FASB issued FSP FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 is required to be applied to reporting periods beginning after December 15, 2005. We are currently evaluating the effect that the adoption of FSP 115-1 will have on our consolidated results of operations and financial condition, but we do not expect it to have a material effect.

## Material Weakness and Remediation

In connection with management's assessment of its internal control over financial reporting as of December 31, 2005, we have concluded that we no longer have a material weakness in our financial statement close process, primarily related to the preparation and review of the annual consolidated financial statements and accompanying footnote disclosures in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. Previous insufficient controls at December 31, 2004 included a lack of finance staff with the proficiency to interpret such principles and rules, and inadequate review and approval procedures to prepare external financial statements in accordance with U.S. Generally Accepted Accounting Principles and the rules and regulations of the SEC. As a result of last year's material weakness, management made material revisions to the 2004 annual consolidated financial statements and footnote disclosures before they were issued.

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

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

Our efforts to enhance our systems of internal control by adding additional qualified personnel and our continuing compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related audit of that assessment by our registered public accounting firm has required, and will continue to require, the commitment of significant financial and managerial resources. Our internal control systems are designed to provide reasonable assurance to management and our board of directors that our internal control over financial reporting is adequate, but there can be no guarantee that such controls will be effective.

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

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

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

The table below presents the principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as of December 31, 2005 by effective maturity (in millions, except percentages):

	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010 and beyond</u>	<u>Total</u>	<u>Fair value at December 31, 2005</u>
Assets:							
Available-for-sale securities . . . .	\$78.2	\$1.0	—	\$6.7	\$ —	\$ 85.9	\$ 86.1
Average interest rate . . . . .	4.0%	2.2%	—	2.8%	—	4.0%	—
Liabilities:							
0.25% convertible senior notes due 2011 . . . . .	—	—	—	—	\$170.0	\$170.0	\$151.1
Average interest rate . . . . .	—	—	—	—	0.25%	0.25%	—

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

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

**Foreign Currency Market Risk**

We have obligations denominated in euros for the purchase of Actimmune® inventory. In 2004, we used foreign currency forward contracts to partially mitigate this exposure, but did not enter into any new foreign currency forward contracts in 2005. We regularly evaluate the cost-benefit of entering into such arrangements, and presently have no foreign currency hedge agreements outstanding.

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

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON FINANCIAL STATEMENTS**

The Board of Directors and Stockholders  
InterMune, Inc.

We have audited the accompanying consolidated balance sheets of InterMune, Inc. (the "Company") as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of InterMune, Inc. at December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of InterMune Inc.'s internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2006, expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

San Jose, California  
March 10, 2006

**INTERMUNE, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2005	2004
	(In thousands, except per share data)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 187,335	\$ 55,769
Available-for-sale securities .....	28,190	127,256
Accounts receivable, net of allowance of \$4,234 in 2005 and \$3,403 in 2004. ....	13,433	12,098
Inventories, net .....	12,437	31,196
Prepaid expenses and other current assets .....	3,942	3,478
Assets of discontinued operations .....	—	17,043
Total current assets .....	245,337	246,840
Property and equipment, net. ....	7,274	8,261
Acquired product rights, net. ....	1,667	3,626
Other assets .....	9,174	7,284
Total assets .....	\$ 263,452	\$ 266,011
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 26,655	\$ 29,448
Accrued compensation .....	14,188	7,746
Other accrued liabilities .....	19,199	24,513
Total current liabilities .....	60,042	61,707
Deferred rent .....	1,643	1,513
Convertible notes .....	170,000	170,000
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value; 5,000 shares authorized, no shares issued and outstanding at December 31, 2005 and 2004, respectively .....	—	—
Common stock, \$0.001 par value, 70,000 shares authorized; 32,589 and 32,583 shares issued and outstanding at December 31, 2005 and 2004, respectively .....	33	33
Additional paid-in capital .....	493,953	492,663
Deferred stock compensation .....	(2,092)	(5,845)
Accumulated other comprehensive income .....	754	1,586
Accumulated deficit .....	(460,881)	(455,646)
Total stockholders' equity .....	31,767	32,791
Total liabilities and stockholders' equity .....	\$ 263,452	\$ 266,011

See Accompanying Notes to Consolidated Financial Statements

**INTERMUNE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>For the Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
	(In thousands, except per share amounts)		
Revenue, net			
Actimmune .....	\$107,633	\$124,980	\$141,402
Others .....	<u>2,863</u>	<u>3,700</u>	<u>3,460</u>
Total revenue, net .....	110,496	128,680	144,862
Costs and expenses:			
Cost of goods sold .....	33,842	33,139	33,233
Amortization and impairment of acquired product rights .....	1,180	743	5,998
Research and development .....	82,736	75,683	118,771
Selling, general and administrative .....	58,854	55,132	56,167
Acquired research and development and milestone (credits) payments ..	(10,000)	—	12,150
Restructuring charges .....	<u>5,549</u>	<u>—</u>	<u>—</u>
Total costs and expenses .....	<u>172,161</u>	<u>164,697</u>	<u>226,319</u>
Loss from operations .....	(61,665)	(36,017)	(81,457)
Other income (expense):			
Interest income .....	3,965	3,490	4,024
Interest expense .....	(1,261)	(5,065)	(9,626)
Other income (expense) .....	<u>1,313</u>	<u>(7,451)</u>	<u>(411)</u>
Loss from continuing operations .....	(57,648)	(45,043)	(87,470)
Discontinued operations:			
Loss from discontinued operations .....	(32,925)	(14,435)	(9,531)
Gain on sale of discontinued operations (net of transaction costs) .....	<u>85,338</u>	<u>—</u>	<u>—</u>
Income (loss) from discontinued operations .....	<u>52,413</u>	<u>(14,435)</u>	<u>(9,531)</u>
Net loss .....	<u>\$ (5,235)</u>	<u>\$ (59,478)</u>	<u>\$ (97,001)</u>
Basic and diluted net loss per common share .....			
Continuing operations .....	\$ (1.79)	\$ (1.42)	\$ (2.76)
Discontinued operations .....	<u>\$ 1.63</u>	<u>\$ (0.45)</u>	<u>\$ (0.30)</u>
	<u>\$ (0.16)</u>	<u>\$ (1.87)</u>	<u>\$ (3.06)</u>
Shares used in computing basic and diluted net loss per common share ..	<u>32,220</u>	<u>31,760</u>	<u>31,665</u>

See Accompanying Notes to Consolidated Financial Statements

INTERMUNE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholder	Deferred Stock Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount						
	(In thousands, except per share data)							
<b>Balance at December 31, 2002</b>	31,696	\$32	\$481,881	\$(38)	\$ (947)	\$ 957	\$(299,167)	\$182,718
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(557)	—	(557)
Net loss	—	—	—	—	—	—	(97,001)	(97,001)
Comprehensive net loss								(97,558)
Exercise of stock options	74	—	413	—	—	—	—	413
Stock issued under employee stock purchase plan	74	—	1,272	—	—	—	—	1,272
Repurchase of common stock at \$0.125 per share	(7)	—	(1)	—	—	—	—	(1)
Reversal of deferred stock compensation due to employees termination	—	—	(550)	—	161	—	—	(389)
Payment of note receivable net of accrued interest	—	—	—	38	—	—	—	38
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, net of reversals	—	—	—	—	569	—	—	569
<b>Balance at December 31, 2003</b>	31,845	\$32	\$483,697	\$ —	\$ (217)	\$ 400	\$(396,168)	\$ 87,744
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(638)	—	(638)
Net unrealized/realized gain on foreign exchange contract	—	—	—	—	—	1,824	—	1,824
Net loss	—	—	—	—	—	—	(59,478)	(59,478)
Comprehensive net loss								(58,292)
Exercise of stock options	109	—	879	—	—	—	—	879
Stock issued under employee stock purchase plan	97	—	1,161	—	—	—	—	1,161
Stock compensation related to the modification of unvested stock options	—	—	110	—	—	—	—	110
Stock compensation related to options granted to consultants for services	—	—	45	—	—	—	—	45
Issuance of restricted stock to employees	532	1	8,129	—	(8,067)	—	—	63
Reversal of deferred stock compensation due to employee terminations	—	—	(1,358)	—	1,193	—	—	(165)
Amortization of deferred stock compensation, net of reversals	—	—	—	—	1,246	—	—	1,246
<b>Balance at December 31, 2004</b>	32,583	\$33	\$492,663	\$ —	\$(5,845)	\$ 1,586	\$(455,646)	\$ 32,791
Net unrealized gain on available-for-sale securities	—	—	—	—	—	173	—	173
Net unrealized/realized loss on foreign exchange contract	—	—	—	—	—	(1,005)	—	(1,005)
Net loss	—	—	—	—	—	—	(5,235)	(5,235)
Comprehensive net loss								(6,067)
Exercise of stock options	19	—	236	—	—	—	—	236
Stock issued under employee stock purchase plan	203	—	1,847	—	—	—	—	1,847
Stock compensation related to the modification of unvested stock options	—	—	1,301	—	—	—	—	1,301
Issuance of restricted stock to employees	11	—	175	—	—	—	—	175
Reversal of deferred stock compensation due to employee terminations	(227)	—	(2,269)	—	2,269	—	—	—
Amortization of deferred stock compensation, net of reversals	—	—	—	—	1,484	—	—	1,484
<b>Balance at December 31, 2005</b>	32,589	\$33	\$493,953	\$ —	\$(2,092)	\$ 754	\$(460,881)	\$ 31,767

See Accompanying Notes to Consolidated Financial Statements

**INTERMUNE, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Year Ended December 31,		
	2005	2004	2003
	(In thousands)		
<b>Cash flows used for operating activities:</b>			
Net loss	\$ (5,235)	\$ (59,478)	\$ (97,001)
Adjustments to reconcile net loss to net cash used for operating activities:			
Gain on sale of discontinued operations	(85,338)	—	—
Restructuring charges	5,549	—	—
Amortization of deferred compensation, net of reversals	1,484	1,081	180
Non-cash stock compensation	660	217	682
Acquired research and development and milestone (credits) payments	(10,000)	—	12,150
Amortization	4,555	4,264	4,622
Depreciation	2,860	2,700	2,680
Deferred rent	130	257	379
Impairment of intangible asset	600	—	4,761
(Gain) loss on foreign currency hedge	(1,005)	1,096	—
Loss on early extinguishment of debt	—	7,072	—
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable, net	(1,335)	1,172	(1,135)
Inventories, net	14,053	(12,928)	(13,458)
Prepaid expenses	(291)	(332)	(148)
Other assets	(760)	32	222
Accounts payable and accrued compensation	(1,084)	10,556	4,042
Other accrued liabilities	4,386	1,150	773
Net cash used for operating activities	(70,771)	(43,141)	(81,251)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(2,144)	(1,340)	(1,468)
Purchase of acquired product rights, including research and development and milestone payments	—	—	(18,750)
Proceeds from the divestiture of Infergen	120,000	—	—
Purchase of manufacturing technology rights	(16,832)	—	—
Purchases of available-for-sale securities	(77,353)	(139,617)	(256,156)
Maturities of available-for-sale securities	103,516	124,287	113,528
Sales of available-for-sale securities	72,903	61,471	182,763
Other	163	—	—
Net cash provided by investing activities	200,253	44,801	19,917
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock, net	2,084	2,040	1,684
Proceeds from convertible senior notes, net	—	164,221	—
Repurchase of convertible subordinated notes	—	(154,451)	—
Repayment of notes receivable from stockholder	—	228	38
Net cash provided by financing activities	2,084	12,038	1,722
Net increase (decrease) in cash and cash equivalents	131,566	13,698	(59,612)
Cash and cash equivalents at beginning of period	55,769	42,071	101,683
Cash and cash equivalents at end of period	<u>\$187,335</u>	<u>\$ 55,769</u>	<u>\$ 42,071</u>
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 425	\$ 3,903	\$ 8,596
<b>Schedule of non-cash transactions:</b>			
(Credit) payable for acquired product rights and milestone payments	(10,000)	—	10,400
Note receivable from Valeant	2,130	—	—

See Accompanying Notes to Consolidated Financial Statements

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. ORGANIZATION**

*Overview*

InterMune, Inc. ("InterMune," "the company," "we," "our," or "us") is an independent biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology. Our revenue is provided primarily from sales of Actimmune®. We also have a number of advanced stage clinical programs addressing a range of unmet medical needs with attractive potential commercial markets.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of Consolidation*

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

*Use of Estimates*

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

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

*Cash, Cash Equivalents and Available-For-Sale Securities*

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

*Fair Value of Other Financial Instruments*

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at historical cost, which we believe approximates fair value because of the short-term maturity of these instruments. The fair value of our convertible senior debt was \$151.1 million at December 31, 2005, which we determined using available market information.

*Inventory Reserves and 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 2004, in an effort to best manage the procurement and distribution of levels of Actimmune®, we

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

successfully completed the necessary testing to extend the expiration period of Actimmune® from 30 months to a total of 36 months. As part of our excess inventory assessment for all of our products, we also consider the expiration dates of our products to be manufactured in the future under non-cancelable purchase obligations.

Significant differences between our current estimates and judgments and future estimated demand for Actimmune® and the useful life of our inventories may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on our financial condition and results of operations during the period in which we recognize an inventory reserve. During the years ended December 31, 2005, 2004 and 2003, we charged \$9.1 million, \$4.7 million and \$1.3 million, respectively to cost of goods sold for excess inventory and contractual purchase commitments for inventory in excess of forecasted needs.

***Concentration of Risks***

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

***Foreign Currency and Derivative Instruments***

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

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

At December 31, 2005, net gains on derivative instruments expected to be reclassified from accumulated other comprehensive income to earnings ratably with sales of Actimmune® were \$0.8 million. At December 31, 2004, the

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

fair value of the derivative instrument was recorded in "Prepaid expenses and other current assets" on the balance sheet. The forward contract expired in early 2005.

***Inventories***

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

***Property and Equipment***

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

***Acquired Product Rights***

Initial payments for the acquisition of products that, at the time of acquisition, are already marketed or are approved by the FDA for marketing are capitalized and amortized ratably over the estimated life of the products, typically ten years. At the time of acquisition, the product life is estimated based upon the term of the agreement, the patent life of the product and our assessment of future sales and profitability of the product. We assess this estimate regularly during the amortization period and adjust the asset value or useful life when appropriate. Initial payments for the acquisition of products that, at the time of acquisition, are under development or are not approved by the FDA for marketing, have not reached technical feasibility and have no foreseeable alternative uses are expensed as research and development costs. Acquired product rights consist of payments made for the acquisition of rights to interferon gamma (see Note 6). Accumulated amortization of this intangible asset was \$1.8 million and \$1.3 million at December 31, 2005 and 2004, respectively. Amortization expense for acquired product rights for each of the next four years until fully amortized is as follows: 2006 — \$0.5 million; 2007 — \$0.5 million; 2008 — \$0.5 million; 2009 — \$0.2 million.

***Impairment of Long-Lived Assets***

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

***Revenue Recognition and Revenue Reserves***

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

On March 26, 2004, we entered into an agreement with Baxter under which we co-promoted Baxter's product Aralast® in the United States for the treatment of patients with hereditary emphysema. Under this agreement, we were compensated by Baxter based upon a percentage of Aralast sales. We recognized Aralast co-promotion revenue upon receipt of the co-promotion funds from Baxter. The co-promotion revenue calculation is dependent

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

upon national sales data which lags one quarter for reporting purposes, therefore estimates were not used. Co-promotion revenue was based on a percentage of Baxter's sales of Aralast to pulmonologists. We terminated this agreement with Baxter in December 2005 in connection with the decision to significantly reduce our field-based IPF disease awareness activities.

***Research and Development Expenses***

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

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

***Advertising Costs***

We expense advertising costs as incurred. Advertising costs were \$313,000, \$520,000 and \$95,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

***Income Taxes***

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

***Comprehensive Income (Loss)***

SFAS No. 130, "Reporting Comprehensive Income," requires components of other comprehensive income, including unrealized gains or losses on our available-for-sale securities, to be included in total comprehensive income (loss). Total comprehensive loss for each of the periods presented is disclosed in Note 10 below. Also, other comprehensive income (loss) includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in other comprehensive income (loss) changes in the fair value of our available-for-sale investments and derivatives designated as effective cash flow hedges.

***Net Loss Per Share***

We compute basic net loss per share by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. We deduct shares subject to repurchase by us from the outstanding shares to arrive at the weighted average shares outstanding. We compute diluted net loss per share by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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,		
	2005	2004	2003
Options .....	6,449	4,945	5,728
Shares issuable upon conversion of convertible notes .....	7,859	7,859	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,		
	2005	2004	2003
Net loss .....	<u>\$ (5,235)</u>	<u>\$ (59,478)</u>	<u>\$ (97,001)</u>
Basic and diluted net loss per common share:			
Weighted-average shares of common stock outstanding .....	32,577	32,089	31,761
Less: weighted-average shares subject to repurchase .....	<u>(357)</u>	<u>(329)</u>	<u>(96)</u>
Weighted-average shares used in computing basic and diluted net loss per common share .....	<u>32,220</u>	<u>31,760</u>	<u>31,665</u>
Basic and diluted net loss per common share .....	<u>\$ (0.16)</u>	<u>\$ (1.87)</u>	<u>\$ (3.06)</u>

***Stock-Based Compensation***

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

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

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss, as reported . . . . .	\$ (5,235)	\$ (59,478)	\$ (97,001)
Add: Stock-based employee compensation expense, included in reported net loss . . . . .	2,960	1,081	180
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards . . . . .	<u>(17,003)</u>	<u>(9,549)</u>	<u>(24,999)</u>
Pro forma net loss . . . . .	<u><u>\$(19,278)</u></u>	<u><u>\$(67,946)</u></u>	<u><u>\$(121,820)</u></u>
Net loss per share:			
Basic and diluted — as reported . . . . .	\$ (0.16)	\$ (1.87)	\$ (3.06)
Basic and diluted — pro forma . . . . .	\$ (0.60)	\$ (2.14)	\$ (3.85)

The pro forma impact of applying SFAS 123 for the years ended December 31, 2005, 2004 and 2003, respectively, does not necessarily represent the pro forma impact in future quarters or years.

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Expected stock price volatility . . . . .	72%	74%	80%
Risk-free interest rate . . . . .	4.0%	3.6%	3.3%
Expected life (in years). . . . .	6.5	6.0	4.9
Expected dividend yield . . . . .	—	—	—

The weighted average fair value per share of options granted was \$8.46 in 2005, \$9.21 in 2004 and \$12.59 in 2003.

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Expected stock price volatility . . . . .	75%	80%	83%
Risk-free interest rate . . . . .	3.0%	2.5%	2.3%
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, 2005, 2004 and 2003 was \$8.38, \$12.76, and \$16.63, respectively.

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

***Recent Accounting Pronouncements***

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which is a revision of SFAS 123. SFAS 123R supersedes APB 25. SFAS 123R requires all share-based payments to

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values, beginning with the first quarterly period after June 15, 2005, with early adoption permitted. On April 14, 2005, the Securities and Exchange Commission adopted a new rule that amended the compliance dates for SFAS 123R such that we were allowed to adopt the new standard effective January 1, 2006. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. We adopted SFAS 123R on January 1, 2006.

Under SFAS 123R, we must determine the appropriate fair value model and related assumptions to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We have been evaluating the requirements of SFAS 123R as well as option valuation methodologies related to our employee and director stock options and employee stock purchase plan. Effective January 1, 2006, we expect to adopt the modified prospective method as our transition method and the Black-Scholes valuation model to determine the fair value of our stock options as provided by the provisions of SFAS 123. We expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations and net loss per share. The impact of adoption of SFAS 123R will depend on, among other things, the levels of share-based payments granted in the future and the option valuation method used.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections," a replacement of Accounting Principles Board Opinions No. 20, "Accounting Changes", and Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements." Statement 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles were recognized by including in net income during the period of change the cumulative effect of changing to the new accounting principle. Statement 154 requires retrospective application to prior periods' financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Statement 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, Statement 154 does not change the transition provisions of any existing accounting pronouncements. InterMune believes adoption of Statement 154 will not have a material effect on InterMune's consolidated financial position, results of operations or cash flows.

In November 2005, the FASB issued FASB Staff Position ("FSP") FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 is required to be applied to reporting periods beginning after December 15, 2005. InterMune is currently evaluating the effect that the adoption of FSP 115-1 will have on its consolidated results of operations and financial condition, but does not expect it to have a material effect.

### 3. DISCONTINUED OPERATIONS

#### *Product Acquisition Agreement*

We entered into a Product Acquisition Agreement (the "Agreement") with Valeant Pharmaceuticals International ("Valeant") on November 28, 2005, whereby Valeant agreed to purchase all of the rights to Infergen® from us. Valeant agreed to acquire certain assets, including intellectual property rights and inventory, as of December 30,

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

2005 (the "Closing Date") for approximately \$122.1 million, including a fixed payment of approximately \$2.1 million in 2007. Of the \$122.1 million, \$6.5 million is related to the purchase of finished product inventory. The Agreement also states that we are entitled to receive approximately \$20.0 million contingent upon Valeant achieving certain clinical related milestones beginning in 2007. The operating results of our Infergen® activities, which include allocations of research and development and selling, general and administrative expenses, have been reclassified as discontinued operations for all periods presented.

We had acquired rights to Infergen® in a licensing and commercialization agreement with Amgen in 2001 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. 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 had been obligated to pay royalties on sales of Infergen®. Based upon an 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 was being amortized over ten years. At December 30, 2005, the net book value of this asset was \$12.9 million.

***Manufacturing Technology Rights***

On November 3, 2005, we entered into an agreement with BI for the future clinical and commercial supply of Infergen®. The agreement generally obligated BI to supply exclusively to us, and for us to purchase exclusively from BI, bulk Infergen® as well as the finished forms of Infergen® that are currently marketed. Amgen will remain the manufacturer for Infergen® until the transfer of the manufacturing process from Amgen to BI is completed and until BI is approved by the FDA as a manufacturer of Infergen®. Prior to and upon execution of the agreement, we made payments to BI of approximately \$16.8 million. We assigned this agreement and all future rights and obligations thereunder to Valeant as part of the sale of the Infergen® product to Valeant in December 2005.

***Purchase Option***

Under the terms of our agreement with Valeant for the purchase of Infergen®, Valeant has the option to acquire our rights to PEG Alfacon-1 at any time prior to the commencement of a Phase III clinical trial for PEG Alfacon-1, provided that we have incurred documented expenses by that time of at least \$7.0 million in the development of PEG Alfacon-1. If Valeant chooses to exercise this option, Valeant will be obligated to pay us an amount equal to 150% of our documented expenses directly incurred by us in connection with the development of PEG Alfacon-1. In addition, if we decide to accept an offer from a third party to acquire the rights to PEG Alfacon-1, we are required to deliver written notice to Valeant of such offer and Valeant has the option to acquire the rights to PEG Alfacon-1 on substantially the same terms and conditions as those offered to us by such third party.

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

***Results of Discontinued Operations***

Summarized balance sheet information for the discontinued operations is as follows (in thousands):

	<b>December 31, 2004</b>
<b>ASSETS</b>	
Inventories, net . . . . .	\$ 1,794
Acquired product rights, net . . . . .	<u>15,249</u>
Assets of discontinued operations . . . . .	<u>\$17,043</u>
<b>LIABILITIES</b>	
Liabilities of discontinued operations:	<u>\$ —</u>

Summary operating results for the discontinued operations through the Closing Date are as follows (in thousands):

	<b>For the Year Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Infergen revenue, net . . . . .	\$ 36,399	\$ 22,307	\$ 9,276
Costs and expenses:			
Cost of goods sold . . . . .	17,296	7,723	3,076
Amortization and impairment of acquired product rights . . . . .	2,360	2,360	2,360
Research and development . . . . .	13,652	5,636	1,087
Selling, general and administrative . . . . .	<u>36,016</u>	<u>21,023</u>	<u>12,284</u>
Total costs and expenses . . . . .	<u>69,324</u>	<u>36,742</u>	<u>18,807</u>
Loss from discontinued operations . . . . .	<u>\$(32,925)</u>	<u>\$(14,435)</u>	<u>\$(9,531)</u>

The loss from discontinued operations in 2005 includes a write-off of \$3.2 million for inventory not acquired by Valeant and severance related costs of approximately \$3.7 million, including \$0.5 million of option acceleration costs for approximately 400,000 shares of our common stock.

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

***Gain on Sale of Discontinued Operations***

The gain on sale of discontinued operations is calculated as follows (in thousands):

Cash proceeds received from sale .....	\$120,000
Note receivable from Valeant .....	<u>2,130</u>
	122,130
Less Infergen® assets sold:	
Acquired product rights, net .....	(12,889)
Manufacturing technology rights .....	(16,832)
Inventories .....	(6,500)
Property and equipment, net .....	(271)
Less direct transaction costs:	
Legal, accounting and regulatory .....	<u>(300)</u>
Total .....	<u>\$ 85,338</u>

**4. RESTRUCTURING CHARGES**

In the fourth quarter of 2005, our Board of Directors approved a restructuring plan recommended by our Chief Executive Officer and senior management that was designed to help streamline our operations and reduce our operating expenses in 2006. The plan, which consisted of a significant reduction in our investment in field-based IPF disease awareness activities, was implemented concurrently with the divestiture of Infergen® in December 2005 (see Note 3). These combined actions led to a significant headcount reduction of approximately 160 employees and resulting termination costs of approximately \$9.2 million. Restructuring charges comprised approximately \$5.5 million of this amount which were recorded as a separate component of operating expenses in the statement of operations, with the remainder allocated to discontinued operations. The majority of the 160 employees left InterMune at the end of the fourth quarter of 2005 with the remainder expected to leave during the first quarter of 2006.

The \$5.5 million restructuring charge is comprised of approximately \$4.7 million for cash severance and related benefits and approximately \$0.8 million for non-cash stock compensation, consisting of an allocation of option acceleration costs for approximately 400,000 shares of our common stock. We expect to pay out substantially all of the \$4.7 million severance and related benefits during the first quarter of 2006.

The activity in the accrued restructuring balance, included within accrued compensation on the balance sheet, was as follows for 2005 (in thousands):

	Restructuring Liabilities at December 31, 2004	Severance Charges	Cash Payments	Restructuring Liabilities at December 31, 2005
Workforce reduction .....	\$—	\$4,733	\$—	\$4,733

**5. AMPHOTEC® AND ORITAVANCIN**

In 2001, we acquired worldwide rights from ALZA, (now a subsidiary of Johnson & Johnson) to Amphotec® (sold under the trade name Amphocil® in certain countries outside the United States). The transaction terms included an up-front product acquisition fee of \$9.0 million which was capitalized as acquired product rights and was being amortized over its estimated useful life of ten years. During September 2003, we reduced the remaining carrying value of the intangible asset by recording an impairment charge of \$4.8 million. In 2004, we decided to

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

divest Amphotec®. In March 2005, we recorded an additional impairment charge of \$0.6 million. These impairment charges were 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.

In May 2005, we divested the Amphotec® product line, including all related assets, to Three Rivers for cash consideration. The resulting loss, which was not material, is included in other income in our 2005 results of operations. In accordance with our agreement with Three Rivers, we may receive contingent payments based on Three Rivers meeting future specified sales targets of Amphotec®.

In 2001, we entered into an asset purchase and license agreement with Eli Lilly pursuant to which we acquired worldwide rights to oritavancin. The agreement provided us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. Pursuant to the agreement, we paid Eli Lilly \$50.0 million and would have been obligated to pay Eli Lilly significant milestone payments and royalties on product sales. We expensed the \$50.0 million during 2001 since oritavancin was in clinical development, had not reached technical feasibility and had no foreseeable alternative uses. We had made no royalty or milestone payments under this agreement through December 31, 2005. In September 2002, Eli Lilly exercised its option under the agreement to reduce the agreed percentage of royalties on product sales. The exercise of this option required us to pay \$15.0 million to Eli Lilly, and we made the actual payment to Eli Lilly during January 2003. In September 2003, we expensed \$10.0 million related to a milestone payment due to Eli Lilly for the completion of the Phase III clinical trials for oritavancin. This amount was recorded as a milestone-based liability at December 31, 2003 as a result of an understanding between Eli Lilly and ourselves.

In December 2005, we sold the oritavancin compound to Targanta Therapeutics (“Targanta”). The terms of the agreement included upfront and clinical related contingent milestone payments of up to \$9.0 million. A \$1.0 million upfront payment from Targanta has been included in other income in our 2005 statement of operations. We also received a convertible promissory note that, assuming certain clinical milestones are achieved, could be valued at up to \$25.0 million in principal amount from Targanta, which note will be initially secured by the oritavancin assets. Upon the achievement by Targanta of certain corporate objectives, the notes will convert into capital stock of Targanta, subject to certain limitations in the amount of voting stock that we may hold. Based on Targanta’s early stage of development, significant uncertainty exists regarding the realization of the convertible promissory note, and thus we have fully reserved this amount in the accompanying financial statements. InterMune also received a seat on the Targanta Board of Directors. In connection with the Targanta transaction, Eli Lilly waived its right to collect the \$10.0 million milestone payment which had previously been accrued. As a result, we reversed this liability in 2005 (reflected as a credit to acquired research and development expenses in the accompanying statement of operations).

**6. ACQUIRED PRODUCT RIGHTS**

*Marnac, Inc./KDL GmbH (Pirfenidone)*

In 2002, we licensed from Marnac and its co-licensor, KDL, their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an upfront cash payment of \$18.8 million and future milestone and royalty payments. We expensed the \$18.8 million as acquired research and development and milestone payments in the first quarter of 2002 since pirfenidone was in clinical development, had not reached technical feasibility and had no foreseeable alternative future uses. Future milestone payments will be based on the progress of clinical development of pirfenidone. We had made no royalty or milestone payments under this agreement through December 31, 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of \$14.5 million. Our rights to the licensed products under the agreement could revert to Marnac if we do not meet our diligence obligations or

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

otherwise commit a material breach of the agreement. The agreement will expire upon the later of the expiration of the primary patent licensed under the agreement or on a disease-by-disease and country-by-country basis (as determined by reference to the indications for which pirfenidone is approved in such country) on the later of (i) the expiration of market exclusivity in such country (if any) resulting from the grant of orphan drug designation to pirfenidone for the treatment of a human fibrotic disease; and (ii) the expiration of the last valid and enforceable claim in a issued licensed patent claiming the use of pirfenidone to treat such disease in such country. Following expiration of the agreement, we will retain a fully paid-up, royalty-free, perpetual, irrevocable, sublicenseable license to the patents, know-how, and other intellectual property rights licensed under the Agreement. We may terminate the agreement after giving the requisite notice to Marnac. In the event Marnac or KDL terminate the agreement, we have the right to seek specific performance of the agreement.

***Amgen Inc. (Interferon Gamma)***

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

***Shearwater Corporation (PEG-Alfacon-1)***

In June 2002, we entered into a development, license and manufacturing agreement with Shearwater, a wholly owned subsidiary of Nektar Therapeutics, to access Shearwater's pegylation technology in order to develop a pegylated version of Infergen®. Under the terms of the agreement, we received a co-exclusive license with Maxygen from Shearwater in exchange for an up-front payment of \$500,000 and future milestone and royalty payments. We had paid \$250,000 in milestone payments, but no royalty payments, under this agreement in the aggregate through December 31, 2005. Assuming that all the milestones under this agreement are achieved, we will be required to make additional milestone payments of \$8.3 million.

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

***Genentech, Inc. License Agreement (Actimmune®)***

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 agreement discussed below. Under the Genentech license, we pay Genentech royalties on the revenue from sales of Actimmune® and are required to make one-time payments to Genentech upon the occurrence of specified milestone events, which include the submission of a filing a BLA with the FDA for approval to market Actimmune® for the treatment of particular categories of diseases, the receipt of FDA approval to market Actimmune® for the treatment of particular categories of diseases and the achievement of certain annual revenue targets for Actimmune®. We had made royalty payments of approximately \$53.7 million, but no milestone payments, under this agreement in the aggregate through December 31, 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make milestone payments of \$3.2 million. We must satisfy specified diligence obligations under the agreement with Genentech to maintain our license from Genentech. Our rights to certain therapeutic uses for Actimmune® under this agreement could revert to Genentech if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

*Connetics Corporation (Actimmune®)*

Through an assignment and option agreement with Connetics, we paid Connetics \$5.7 million to acquire rights to Actimmune® and are obligated to pay to Connetics a royalty of 0.25% of our net United States sales for Actimmune® until our net United States sales cumulatively surpass \$1.0 billion. Above \$1.0 billion, we are obligated to pay a royalty of 0.5% of our net United States sales of Actimmune®. Through a separate purchase agreement, we paid Connetics \$0.4 million to acquire rights related to scleroderma and are obligated to pay Connetics a royalty of 4.0% on our net revenue from sales of Actimmune® for the treatment of scleroderma. We had made royalty payments of approximately \$1.2 million in the aggregate through December 31, 2005. There are no milestone payments pursuant to this agreement.

**7. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS**

*Array BioPharma Inc. (Small Molecule Therapeutics)*

In 2002, we entered into a drug discovery collaboration agreement to create small molecule therapeutics targeting hepatitis with Array. We fund drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and we are responsible for all development and commercialization. Array is entitled to receive milestone payments based on the selection and progress of clinical drug candidates, as well as low single digit royalties on net sales of products derived from the collaborative efforts. The original term of this agreement expired in September 2004 and has since been extended to August 2006, subject to certain conditions. In addition, in December 2004, the agreement was amended to provide a mechanism for us to purchase certain intellectual property rights arising from the collaboration. In April 2005, we initiated a second research collaboration with Array with respect to a new hepatology target. This research collaboration extends through March 2007. Assuming that all of the remaining milestones under these agreements are achieved, we will be required to make milestone payments of \$9.0 million. Total research and development expenses related to these agreements were \$7.5 million, \$5.7 million, and \$2.1 million for the years ended December 31, 2005, 2004 and 2003, respectively. Included in the \$5.7 million is a one-time non-refundable fee of \$2.5 million paid in connection with securing the right to purchase Array's ownership interest in certain collaboration patents.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

***Maxygen Holdings Ltd. (Next-Generation Interferon Gamma)***

We have a license and collaboration agreement with Maxygen to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than Actimmune®. If preclinical data provide compelling proof of concept for a longer-acting interferon gamma compound, our plan would be to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. We have funded Maxygen's optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. Our diligence obligations include a minimum level of clinical development expenditures for an initial period of time, as well as the general obligation to use commercially reasonable efforts to clinically develop, seek regulatory approval for and commercialize a product in specified major market countries. The agreement terms include up-front license fees and full research funding, as well as development and commercialization milestone payments, which are payable based on the progress of our clinical development program for next-generation interferon gamma products and the achievement of certain sales targets with respect to such products. In addition, Maxygen will receive royalties on product sales. We paid Maxygen a total of \$106,000 and \$228,000 for the years ended December 31, 2004 and 2003, respectively and did not make any payments in 2005. Assuming that all of the milestones under this agreement are achieved, we will be required to make additional milestone payments of \$43.0 million.

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

***Boehringer Ingelheim International GmbH (Imukin®)***

In 2001, we formed a collaboration with BI 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'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 will pay us royalties on sales of the product when it meets a specified minimum sales level. BI 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 does not do so. If we opt to promote the product in those countries or for those new diseases for which BI does not, we will pay royalties to BI on sales of the product in those countries and/or for those new diseases. We had neither paid nor received any royalties under this agreement through December 31, 2005, and there are no milestone payments under this agreement. The agreement will expire, on a country-by-country basis, upon expiration of the parties' royalty obligations in each country covered by the agreement. Such royalty obligations generally expire fifteen years after regulatory approval of Imukin® for certain specified indications in the relevant country. If no such regulatory approvals are granted in a particular country, the royalty obligations in such country will expire in 2016. Prior to such expiration, either party

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

can terminate the agreement for the uncured material breach of the other party or for the insolvency of the other party. In addition, we have the right to terminate the agreement with respect to certain countries at any time subsequent to regulatory approval for IPF.

*Funding Commitments*

Our non-cancelable funding commitments under the above sponsored research, license and collaboration agreements total \$5.2 million as of December 31, 2005, of which \$4.9 million and \$0.3 million are due during the years ending December 31, 2006 and 2007, respectively.

**8. AVAILABLE-FOR-SALE INVESTMENTS**

The following is a summary of our available-for-sale investments as of December 31, 2005 and 2004 (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
December 31, 2005				
Obligations of U.S. federal and state governments . . .	\$46,865	\$ 6	\$(57)	\$46,814
Corporate debt securities . . . . .	30,531	5	(19)	30,517
Auction rate preferred stock and other debt securities . . . . .	<u>8,727</u>	<u>—</u>	<u>—</u>	<u>8,727</u>
Total . . . . .	<u>\$86,123</u>	<u>\$11</u>	<u>\$(76)</u>	<u>\$86,058</u>

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Reported as:				
Cash equivalents . . . . .	\$57,858	\$11	\$ (1)	\$57,868
Available-for-sale securities . . . . .	<u>28,265</u>	<u>—</u>	<u>(75)</u>	<u>28,190</u>
Total . . . . .	<u>\$86,123</u>	<u>\$11</u>	<u>\$(76)</u>	<u>\$86,058</u>

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

The realized gains and losses for the years 2005 and 2004 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):

	<u>2005</u>	
	<u>Amortized Cost</u>	<u>Fair Value</u>
Mature in less than one year .....	\$78,507	\$78,456
Mature in one to three years .....	954	949
Mature in over three years .....	<u>6,662</u>	<u>6,653</u>
Total .....	<u>\$86,123</u>	<u>\$86,058</u>

**9. BALANCE SHEET DETAIL**

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

	<u>2005</u>	<u>2004</u>
Raw materials .....	\$ —	\$ 550
Finished goods .....	<u>12,437</u>	<u>30,646</u>
Total .....	<u>\$12,437</u>	<u>\$31,196</u>

For the years ended December 31, 2005, 2004 and 2003, we recognized a total of \$9.1 million, \$4.7 million and \$1.3 million, respectively, in cost of goods for excess inventory and non-cancelable purchase commitments in excess of forecasted demand.

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

	<u>2005</u>	<u>2004</u>
Computer and laboratory equipment .....	\$ 6,125	\$ 4,802
Office furniture and fixtures .....	3,577	3,407
Leasehold improvements .....	<u>8,122</u>	<u>7,982</u>
	17,824	16,191
Less accumulated depreciation and amortization .....	<u>(10,550)</u>	<u>(7,930)</u>
Total .....	<u>\$ 7,274</u>	<u>\$ 8,261</u>

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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

	<u>2005</u>	<u>2004</u>
Accrued clinical trial costs .....	\$ 8,289	\$ 5,901
Accrued interest .....	142	142
Payable to Eli Lilly .....	—	10,000
Royalties payable .....	7,061	4,421
Accrued sales and marketing .....	568	2,134
Other accrued liabilities .....	<u>3,139</u>	<u>1,915</u>
Total other accrued liabilities .....	<u>\$19,199</u>	<u>\$24,513</u>

**10. COMPREHENSIVE INCOME (LOSS)**

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss .....	\$(5,235)	\$(59,478)	\$(97,001)
Change in unrealized gain/(loss) on available-for-sale securities ..	173	(638)	(557)
Change in realized and unrealized gain on foreign currency hedge .....	<u>(1,005)</u>	<u>1,824</u>	<u>—</u>
Comprehensive loss .....	<u>\$(6,067)</u>	<u>\$(58,292)</u>	<u>\$(97,558)</u>

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

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Net unrealized gain/(loss) on available-for-sale securities .....	\$(65)	\$ (238)
Gain on foreign currency hedge .....	<u>819</u>	<u>1,824</u>
Accumulated other comprehensive income .....	<u>\$754</u>	<u>\$1,586</u>

**11. CONVERTIBLE SUBORDINATED NOTES**

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

**12. CONVERTIBLE SENIOR NOTES**

In February 2004, we issued 0.25% convertible senior notes due March 1, 2011 in an aggregate principal amount of \$170.0 million (the "Senior Notes"). The Senior Notes are convertible into our common stock at the option of the holder at a conversion price of approximately \$21.63 per share, subject to adjustment in certain

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

circumstances. Interest on the Senior Notes is payable semiannually in arrears on March 1 and September 1 of each year. The Senior Notes are unsecured and rank on parity with all of our other existing and future senior unsecured debt and prior to all subordinated indebtedness. In addition, the Senior Notes are effectively subordinated to any existing and future secured debt to the extent of the value of the collateral securing such debt. As of December 31, 2005, we had no secured debt and no senior obligations. Offering expenses of \$5.8 million related to the sale of the Senior Notes have been included in other assets and are being amortized to interest expense over the life of the Senior Notes, which is seven years from the date of issuance. Accumulated amortization at December 31, 2005 is \$1.6 million.

### 13. STOCKHOLDERS' EQUITY

#### *Restricted Stock Awards*

During the year ended December 31, 2005, we did not grant any restricted stock awards. During the years ended December 31, 2004, and 2003, respectively, we granted employees restricted stock awards for 525,600 shares and 25,000 shares of our common stock with a weighted-average fair value of \$15.35 per share and \$20.15 per share, respectively, that vest annually over a four-year period, thirty percent in each of the first three years and ten percent in the final year, through September 2008. Restricted stock awards are shares of common stock which are forfeited if the employee leaves InterMune prior to vesting. As a result of these awards, during the years ended December 31, 2005, 2004 and 2003, we recognized \$1.7 million, \$1.1 million and \$0.2 million in compensation expense, respectively. We reversed approximately \$2.3 million and \$1.1 million of deferred compensation in 2005 and 2004, respectively, due to employee terminations. As the restricted shares vest through 2008, we will continue to recognize stock based compensation expenses related to the grants of these restricted awards. These stock awards offer employees the opportunity to earn shares of our stock over time, rather than options that give the employee the right to purchase stock at a set price. If all of the remaining restricted stock awards that were granted in 2004 vest, we would recognize approximately \$2.1 million in compensation expense over the remaining period. However, no compensation expense will be recognized for stock awards that do not vest.

#### *Stock Compensation Plans*

In 1999, we adopted the 1999 Equity Incentive Plan ("1999 Plan"). The 1999 Plan provided for the granting of options to purchase common stock and the issuance of shares of common stock, subject to repurchase rights, to directors, employees and consultants. Certain options were immediately exercisable, at the discretion of our board of directors. Shares issued pursuant to the exercise of an unvested option are subject to the right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. In 2000, we terminated all remaining unissued shares under the 1999 Plan amounting to 121,584 shares. We repurchased 7,127 early exercised and unvested shares from certain terminated employees at a purchase price of \$0.125 per share in 2003 (none in 2005 or 2004). Under the 1999 Plan, 51,550 shares have been granted to employees that are subject to repurchase as of December 31, 2005.

In 2000, our board of directors adopted the 2000 Equity Incentive Plan, which was most recently amended in 2004 and re-named the Amended and Restated 2000 Equity Incentive Plan ("2000 Plan"). In 2000, a total of 2 million shares of common stock were initially reserved for issuance under the 2000 Plan. In 2004, an additional 1 million shares of common stock were reserved for issuance under the 2000 Plan. The 2000 Plan provides for the granting of options to purchase common stock and the issuance of shares of common stock, subject to repurchase rights, to directors, employees and consultants. Shares issued pursuant to the exercise of an unvested option are subject to our right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. Options not immediately exercisable generally vest up to a maximum of three years. Options granted under the 2000 Plan have a maximum term of 10 years.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In 2000, our board of directors adopted the 2000 Non-Employee Directors' Stock Option Plan, which was most recently amended in 2004 and re-named the Amended and Restated 2000 Non-Employee Directors' Stock Option Plan ("Directors' Plan"). In 2000, a total of 180,000 shares of common stock were initially reserved for issuance under the Directors' Plan. In 2004, an additional 550,000 shares of common stock were reserved for issuance under the Director's Plan. The Directors' Plan provides for the granting of options to purchase common stock and the issuance of shares of common stock, subject to repurchase rights, to directors of InterMune. 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 one year from the date of grant for annual grants and three years from the date of grant for initial grants made to new directors. Options not immediately exercisable generally vest over four years. Options granted under the Directors' Plan 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, 2002	2,528,733	4,490,704	\$32.46
Authorized	180,000	—	—
Shares terminated under 1999 plan and not available for future grants	(67,132)	—	—
Granted	(2,476,423)	2,476,423	\$19.78
Restricted shares granted	(25,000)	—	—
Cancelled	1,164,290	(1,164,290)	\$31.86
Exercised	—	(74,845)	\$ 5.51
Repurchased	7,217	—	\$0.125
Balance at December 31, 2003	1,311,685	5,727,992	\$27.52
Authorized	1,550,000	—	—
Shares terminated under 1999 plan and not available for future grants	(13,667)	—	—
Granted	(1,603,077)	1,603,077	\$13.79
Restricted shares granted	(525,600)	—	—
Cancelled	2,276,414	(2,276,414)	\$29.02
Restricted shares cancelled	74,620	—	—
Exercised	—	(109,203)	\$ 8.04
Balance at December 31, 2004	3,070,375	4,945,452	\$22.81
Granted	(2,317,724)	2,317,724	\$12.44
Cancelled	795,980	(795,980)	\$21.88
Restricted shares cancelled	152,275	—	—
Exercised	—	(18,166)	\$12.95
Balance at December 31, 2005	<u>1,700,906</u>	<u>6,449,030</u>	\$19.22

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table summarizes information about options outstanding at December 31, 2005:

<u>Options Outstanding</u>				<u>Options Exercisable</u>	
<u>Range of Exercise Prices</u>	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
\$ 4.50 — \$11.93	1,663,908	8.93	\$10.93	395,166	\$ 9.83
\$11.95 — \$16.96	1,718,244	9.00	\$13.62	496,214	\$14.36
\$17.04 — \$23.50	1,628,213	7.52	\$19.77	1,158,608	\$19.75
\$23.57 — \$53.00	<u>1,438,665</u>	6.17	\$34.89	<u>1,394,715</u>	\$35.12
	<u>6,449,030</u>	7.98	\$19.22	<u>3,444,703</u>	\$24.06

***2000 Employee Stock Purchase Plan***

To provide employees with an opportunity to purchase our common stock through payroll deductions, our board of directors adopted the 2000 Employee Stock Purchase Plan (the “ESPP”). Under the ESPP, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the date of eligibility for enrollment or the date of purchase, whichever is less. Purchases are limited to the lesser of 15% of each employee’s eligible annual compensation or \$25,000. Through the end of December 2005, we issued a cumulative total of 471,252 shares under the ESPP, and 1,121,490 shares remained available for future issuance at December 31, 2005.

***Stock Compensation***

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

***Stockholder Rights Agreement***

In July 2001, our board of directors approved the adoption of a stockholder Rights Agreement, which provided for the distribution of one preferred share purchase right (a “Right”) for each outstanding share of our common stock. The dividend was paid on August 3, 2001 to the stockholders of record on that date. Each Right entitles the registered holder to purchase one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the “Preferred Shares”), at a price of \$390.00 per one one-hundredth of a Preferred Share (the “Purchase Price”), subject to adjustment. The Rights will be exercisable upon the earlier of: (i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of the outstanding common shares (an “Acquiring Person”), or (ii) ten business days (or such later date as may be determined by action of the board of directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person. In October 2004, the Rights Agreement was amended to allow Warburg Pincus Equity Partners,

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

L.P. and certain of its affiliates (“Warburg Pincus”) to acquire ownership of up to 25% of our issued and outstanding common stock in open market purchases without becoming an Acquiring Person. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P.

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

***Reserved Shares***

At December 31, 2005, common stock subject to future issuance is as follows:

Common stock issuable upon conversion of convertible senior debt . . . . .	7,858,811
Outstanding common stock options . . . . .	6,449,030
Common stock available for grant under stock option plans . . . . .	1,700,906
Common stock available for grant under the 2000 Employee Stock Purchase Plan . . . . .	<u>1,121,490</u>
Total . . . . .	<u><u>17,130,237</u></u>

**14. 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):

	<u>2005</u>	<u>2004</u>
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 139,000	\$ 122,000
Research and development credits . . . . .	17,000	6,000
Capitalized research and development costs . . . . .	12,000	46,000
Other, net . . . . .	<u>26,000</u>	<u>12,000</u>
Total deferred tax assets . . . . .	194,000	186,000
Valuation allowance . . . . .	<u>(194,000)</u>	<u>(186,000)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

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

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

allowance increased by \$8.0 million, \$28.0 million, and \$43.0 million during the years ended December 31, 2005, 2004 and 2003, respectively.

Deferred tax assets related to carryforwards at December 31, 2005 include approximately \$5.1 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders equity.

As of December 31, 2005, we had net operating loss carryforwards for federal income tax purposes of approximately \$384.1 million, which expire in the years 2019 through 2025, and federal research and development credits of approximately \$13.4 million, which expire in the years 2018 through 2025. In addition, we have net operating loss carryforwards for state income tax purposes of approximately \$72.6 million, which expire in the years 2006 through 2015, and state research and development tax credits of approximately \$4.8 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.

15. COMMITMENTS AND CONTINGENCIES

*Leases*

We have a non-cancelable lease for facilities, which expires in 2011. Total rent expense was approximately \$4.1 million for the year ended December 31, 2005 and approximately \$3.7 million for each of the years ended December 31, 2004 and 2003.

The following is a schedule by year of future minimum lease payments of all leases at December 31, 2005 (in thousands):

<u>Year</u>	<u>Operating Leases</u>
2006 .....	\$ 4,245
2007 .....	4,024
2008 .....	4,101
2009 .....	4,151
2010 .....	4,302
Thereafter .....	<u>1,748</u>
	<u>\$22,571</u>

The operating lease for our facility requires a letter 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 the facility and is effective until we reach profitability. At December 31, 2005 and 2004, restricted cash under this letter of credit amounted to \$1.4 million and \$1.7 million, respectively.

*Purchase Commitments*

We have purchase commitments with BI for the manufacture and supply of Actimmune®. In 2000, we entered into an agreement with BI for the clinical and commercial supply of Actimmune®. The agreement with BI generally provides for the exclusive supply by BI and exclusive purchase by us of Actimmune®. We are required to purchase a minimum amount of Actimmune® per year, and BI is required to supply Actimmune® to us, subject to certain limits. On July 26, 2005, we amended the supply agreement with BI pursuant to which BI agreed to waive certain of our minimum purchase commitments for Actimmune® for 2005, and to reduce certain other minimum Actimmune®

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

purchase requirements for 2006. With regard to certain minimum purchase requirements for 2007 and thereafter, BI granted us the option of either taking delivery of Actimmune® or paying for the difference between the amount of product actually purchased and the minimum purchase requirement. At December 31, 2005, our minimum purchase obligations totaled \$99.1 million and are committed through the year 2012. Of these commitments, we have \$6.5 million and \$16.1 million of outstanding fixed purchase order commitments that become due and payable in 2006 and 2007, respectively. Our contractual obligation to BI is denominated in euros.

***Contingent Payments***

We will be required to make contingent milestone payments in accordance with our license, commercialization and collaboration agreements in the aggregate amount of \$136.4 million if all of the milestones per the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones.

***Legal Proceedings***

On June 25, 2003, a purported securities class action entitled *Johnson v. Harkonen and InterMune, Inc.*, No. C 03-2954-MEJ, was filed in the United States District Court for the Northern District of California. Three additional class action complaints entitled *Lombardi v. InterMune, Inc., Harkonen and Surrey-Barbari*, No. C 03 3068 MJJ (filed on July 1, 2003); *Mahoney Jr. v. InterMune Inc., Harkonen and Surrey-Barbari*, No. C 03-3273 SI (filed on July 14, 2003); and *Adler v. Harkonen and InterMune Inc.*, No. C 03-3710 MJJ (filed on August 3, 2003), were filed in the same court, each making identical or similar allegations against us, our former chief executive officer and our former chief financial officer. On November 6, 2003, the various complaints were consolidated into one case by order of the court, and on November 26, 2003, a lead plaintiff, Lance A. Johnson, was appointed. A consolidated complaint titled *In re InterMune Securities Litigation*, No. C 03-2954 SI, was filed on January 30, 2004. The consolidated amended complaint named us, and our former chief executive officer and our former chief financial officer, as defendants and alleges that the defendants made certain false and misleading statements in violation of the federal securities laws, specifically Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. The lead plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock during the period from January 7, 2003 through June 11, 2003. The parties settled this case in May 2005 and a final settlement was approved by the court in August 2005. The settlement was funded in large part by InterMune's insurance carrier. As part of the settlement we included approximately \$2.0 million of selling, general and administrative expense in our 2005 financial results to reflect costs of the settlement.

On July 30, 2003, a stockholder, Michael Adler, purporting to act on our behalf filed a derivative action entitled *Adler v. Harkonen, et al.*, No. CIV 433125, in the California Superior Court for the County of San Mateo against our directors, our former chief executive officer and our former chief financial officer. We were also named as a nominal defendant solely in a derivative capacity. The derivative action was based on the same factual allegations and circumstances as the securities class actions and alleged state law claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. The derivative action sought unspecified damages, injunctive relief and restitution. The parties settled this case in August 2005 and the amount was not material to the financial statements.

On March 19, 2004, plaintiff Joan Gallagher filed an action against us and other defendants in the United States District Court for the Eastern District of Pennsylvania. Ms. Gallagher alleged that during her employment with InterMune, we actively marketed, and required our sales force to market, Actimmune® for a purpose for which the drug was not approved by the FDA, specifically for the treatment of IPF, in violation of "public policy," including the purported public policies of the Food Drug and Cosmetic Act, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act and the Pennsylvania Unfair Trade Practice and Consumer Protection Law. Ms. Gallagher alleged that she was wrongfully terminated from InterMune in violation of public policy due to her refusal to engage

**InterMune, Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

in the alleged off-label marketing. The parties settled this case in July 2005. The settlement amount, which was not material, was included in our 2005 results of operations.

On November 9, 2004, we received a subpoena from the U.S. Department of Justice requiring us to provide the Department of Justice with certain information relating to Actimmune®, including information regarding the promotion and marketing of Actimmune®. We are cooperating with the Department of Justice in this inquiry. Although we cannot predict whether the outcome of this inquiry will have a material adverse effect on our business, it is possible that we will be required to pay a substantial civil fine in connection with the settlement of this matter. At this time we cannot predict the magnitude of such a fine or the impact the payment of such a fine may have on our future business operations.

**16. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION**

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. Prior to its divestiture in December 2005, we also marketed Infergen® in the United States and Canada for chronic HCV infections; and prior to its divestiture in May 2005, we also marketed Amphotec® worldwide for invasive aspergillosis. Total revenue for each of the years ended 2005, 2004 and 2003 has been adjusted to reflect the reclassification of Infergen® revenue into discontinued operations.

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Actimmune .....	\$107,633	\$124,980	\$141,402
Others .....	<u>2,863</u>	<u>3,700</u>	<u>3,460</u>
Totals .....	<u>\$110,496</u>	<u>\$128,680</u>	<u>\$144,862</u>

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
United States .....	\$110,017	\$126,288	\$142,109
Rest of world .....	<u>479</u>	<u>2,392</u>	<u>2,753</u>
Totals .....	<u>\$110,496</u>	<u>\$128,680</u>	<u>\$144,862</u>

Our revenue and trade receivables are concentrated with a few customers. We perform credit evaluations on our customers' financial condition and limit the amount of credit extended. However, we generally do not require collateral on accounts receivable. Concentrations of credit risk, with respect to accounts receivable, exist to the extent of amounts presented in the financial statements. Three customers represented 46%, 12% and 11%, respectively, of total accounts receivable at December 31, 2005, and three customers represented 47%, 14% and 12%, respectively, of total accounts receivable at December 31, 2004. No other customer represented more than 10% of accounts receivable at December 31, 2005 or December 31, 2004.

Revenue from customers representing 10% or more of total sales during the years ended December 31, 2005, 2004 and 2003 were as follows:

<u>Customer</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
CuraScript, Inc (formerly Priority Healthcare) .....	59%	61%	62%
Caremark .....	21%	14%	12%
Merck Medco .....	7%	11%	11%

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**17. RELATED PARTY TRANSACTIONS**

On October 29, 2004 we entered into an Amended and Restated Standstill Agreement with Warburg Pincus Equity Partners, L.P. and certain of its affiliates (“Warburg Pincus”) that permits Warburg Pincus to acquire up to 25% of our outstanding common stock in the open market. Under this agreement, Warburg Pincus may acquire up to 25% of our outstanding common stock and we have granted Warburg Pincus certain registration rights with respect to its holdings. In exchange for allowing Warburg Pincus to increase its ownership stake, Warburg Pincus has granted the independent members of our board of directors the right to vote the shares of InterMune common stock owned by Warburg Pincus in excess of 19.9%. In addition, Warburg Pincus has agreed to certain limitations on the manner in which it may dispose of its ownership interest in InterMune. In connection with this transaction, we have also amended our stockholder Rights Plan to allow Warburg Pincus to acquire up to 25% of our outstanding common stock in open market purchases. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus Equity Partners, L.P. As of December 31, 2005, Warburg Pincus held approximately 22% of our outstanding common stock.

**18. EMPLOYEE SAVINGS PLAN**

On May 1, 1999, we adopted a 401(k) defined contribution plan that covers all full time employees, as defined, who fulfill certain length-of-service requirements. Employees may contribute up to the maximum limit imposed by federal tax law. Beginning in 2005, we began matching employee contributions at a rate of 50% of the first \$6,000 per employee contributed each year. Our total matching contribution in 2005 was \$0.8 million. We did not make any matching contributions under the 401(k) defined contribution plan in 2004 or 2003.

**19. GUARANTEES AND INDEMNIFICATIONS**

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

As permitted under Delaware law and in accordance with our Bylaws, we indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. We terminate the indemnification agreements with our officers and directors upon the termination of their employment, but the termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, our director and officer insurance policy limits our exposure and may enable us to recover a portion of any future amounts paid. Accordingly, we believe the fair value of these indemnification agreements is minimal. Therefore, we have not recorded any liabilities for these agreements as of December 31, 2005.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

20. QUARTERLY FINANCIAL DATA (Unaudited)

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total Year</u>
	(In thousands, except per share amounts)				
<b>2005</b>					
Revenue, net					
Actimmune . . . . .	\$ 27,705	\$ 25,892	\$ 25,793	\$ 28,243	\$107,633
Others . . . . .	<u>642</u>	<u>782</u>	<u>667</u>	<u>772</u>	<u>2,863</u>
Total revenue, net . . . . .	<u>\$ 28,347</u>	<u>\$ 26,674</u>	<u>\$ 26,460</u>	<u>\$ 29,015</u>	<u>\$110,496</u>
Cost of goods sold . . . . .	\$ 6,585	\$ 7,535	\$ 12,487	\$ 7,235	\$ 33,842
Amortization and impairment of acquired product rights . . . . .	786	144	125	125	1,180
Loss from operations . . . . .	(11,623)	(15,068)	(19,770)	(15,204)	(61,665)
Loss from continuing operations . .	(10,227)	(14,566)	(18,741)	(14,114)	(57,648)
Income (loss) from discontinued operations . . . . .	(7,179)	(9,162)	(5,027)	73,781	52,413
Net income (loss) . . . . .	(17,406)	(23,728)	(23,768)	59,667	(5,235)
Basic and diluted net loss per common share:					
Continuing operations . . . . .	\$ (0.32)	\$ (0.45)	\$ (0.58)	\$ (0.44)	\$ (1.79)
Discontinued operations . . . . .	<u>(0.22)</u>	<u>(0.29)</u>	<u>(0.16)</u>	<u>2.28</u>	<u>1.63</u>
Net loss per common share . . . . .	<u>\$ (0.54)</u>	<u>\$ (0.74)</u>	<u>\$ (0.74)</u>	<u>\$ 1.84</u>	<u>\$ (0.16)</u>
<b>2004</b>					
Revenue, net					
Actimmune . . . . .	\$ 32,921	\$ 31,349	\$ 30,063	\$ 30,647	\$124,980
Others . . . . .	<u>1,208</u>	<u>616</u>	<u>1,218</u>	<u>658</u>	<u>3,700</u>
Total revenue, net . . . . .	<u>\$ 34,129</u>	<u>\$ 31,965</u>	<u>\$ 31,281</u>	<u>\$ 31,305</u>	<u>\$128,680</u>
Cost of goods sold . . . . .	\$ 8,658	\$ 7,460	\$ 9,928	\$ 7,093	\$ 33,139
Amortization of acquired product rights . . . . .	187	186	184	186	743
Loss from operations . . . . .	(4,546)	(7,009)	(6,353)	(18,109)	(36,017)
Loss from continuing operations . .	(8,967)	(7,967)	(10,265)	(17,844)	(45,043)
Loss from discontinued operations . . . . .	(2,744)	(5,100)	(2,595)	(3,996)	(14,435)
Net loss . . . . .	(11,711)	(13,067)	(12,860)	(21,840)	(59,478)
Basic and diluted net loss per common share:					
Continuing operations . . . . .	\$ (0.28)	\$ (0.25)	\$ (0.32)	\$ (0.57)	\$ (1.42)
Discontinued operations . . . . .	<u>(0.09)</u>	<u>(0.16)</u>	<u>(0.08)</u>	<u>(0.12)</u>	<u>(0.45)</u>
Net loss per common share . . . . .	<u>\$ (0.37)</u>	<u>\$ (0.41)</u>	<u>\$ (0.40)</u>	<u>\$ (0.69)</u>	<u>\$ (1.87)</u>

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* Under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures. Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

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

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we have assessed the effectiveness of our internal control over financial reporting as of December 31, 2005, and as a result of this assessment, we have concluded that our internal control over financial reporting was effective as of December 31, 2005. In making our assessment of internal control over financial reporting, we used the criteria issued in the report Internal Control-Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission.

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

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

The Board of Directors and Stockholders  
InterMune, Inc.

We have audited management's assessment, included in "Management's Report on Internal Control Over Financial Reporting" in Item 9A of this Form 10-K, that InterMune, Inc. (the "Company") maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO criteria"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that InterMune, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, InterMune, Inc. has maintained effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of InterMune, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 and our report dated March 10, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

San Jose, California  
March 10, 2006

*Changes in Internal Control over Financial Reporting.* There have been no changes to our internal controls over financial reporting during the three months ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

**ITEM 9B. OTHER INFORMATION.**

None.

### **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant expect to file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for our Annual Meeting of Stockholders to be held at 10:00 a.m. on May 24, 2006 (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

#### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

##### *Identification of Directors and Executive Officers*

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

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

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

##### *Code of Business Conduct and Ethics*

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

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

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

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

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

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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

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

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

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

**(1) Financial Statements**

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

**(2) Financial Statement Schedules**

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

Schedule II

InterMune, Inc.

Valuation and Qualifying Accounts and Reserves  
Years ended December 31, 2005, 2004 and 2003

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Charged to Revenue or Expense</u>	<u>Utilizations</u>	<u>Balance at End of Year</u>
	(In thousands)			
Allowance for doubtful accounts, product returns, chargebacks, and rebates:				
Year ended December 31, 2005 .....	\$3,403	\$18,023	\$(17,192)	\$ 4,234
Year ended December 31, 2004 .....	2,977	12,465	(12,039)	3,403
Year ended December 31, 2003 .....	3,415	12,495	(12,933)	2,977
Reserves of excess inventory and non-cancelable purchase obligations:				
Year ended December 31, 2005 .....	\$3,954	\$ 9,082	\$ (666)	\$12,370
Year ended December 31, 2004 .....	580	4,126	(752)	3,954
Year ended December 31, 2003 .....	—	900	(320)	580

### (3) Exhibits

<u>Number</u>	<u>Description of Document</u>
3.1	Certificate of Incorporation of Registrant.(1)
3.2	Certificate of Ownership and Merger, dated April 26, 2001.(10)
3.3	Bylaws of Registrant.(1)
3.4	Certificate of Amendment of Certificate of Incorporation of Registrant.(16)
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Registrant.(24)
3.6	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock.(8)
4.1	Specimen Common Stock Certificate.(1)
4.6	Indenture, dated as of February 17, 2004, between Registrant and The Bank of New York.(20)
4.7	Registration Rights Agreement, dated as of February 17, 2004, among Registrant, Morgan Stanley & Co. Incorporated, Banc of America Securities LLC, Credit Suisse First Boston LLC, Harris Nesbitt Corp. and RBC Capital Markets Corporation.(20)
10.1+	Form of Indemnity Agreement.(1)
10.2+	1999 Equity Incentive Plan and related documents.(1)
10.3+	Stock option grant notice, stock option agreement and notice of exercise for Amended and Restated 2000 Equity Incentive Plan.(2)
10.4+	2000 Employee Stock Purchase Plan and related documents.(1)
10.5+	Annual stock option grant notice and initial stock option grant notice for Amended and Restated 2000 Non-Employee Directors' Stock Option Plan.(14)
10.6	Amended and Restated Investor Rights Agreement, dated January 7, 2000, between Registrant and certain holders of the common stock.(1)
10.7	Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(8)
10.8	Preliminary Stipulation of Settlement Agreement, dated May 6, 2005.(27)
10.19*	Data Transfer, Clinical Trial, and Market Supply Agreement, dated January 27, 1999, between the Registrant and Boehringer Ingelheim.(1)
10.20+	Form of Change of Control Provisions for Officers.(3)
10.24	Assignment and Option Agreement, dated June 23, 2000, between Registrant and Connetics Corporation.(4)
10.25	Consent to Assignment Agreement, dated June 23, 2000, between Registrant, Connetics Corporation and Genentech, Inc.(4)
10.27	Notice re: Return of Rights to Gamma Interferon for Treatment of Infectious Diseases in Japan, dated July 25, 2000, between Registrant and Genentech, Inc.(4)
10.29	Form of Common Stock Purchase Agreement, dated August 11, 2000, between the Company and Investors.(5)
10.31	Lease Agreement, dated December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.32	First Amendment to Brisbane Technology Park Lease, effective as of December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.34	Product Acquisition Agreement, dated January 2, 2001, between Registrant and ALZA Corporation.(7)
10.35	Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(7)
10.38	Amendment No. 5, dated January 25, 2001, to License Agreement, dated May 5, 1998, between Registrant and Genentech, Inc.(7)
10.39*	License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen, Inc.(9)
10.40	Letter Amendment, dated August 1, 2001, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(10)

<u>Number</u>	<u>Description of Document</u>
10.41*	Agreement for Consulting Services, dated August 1, 2001, between Registrant and The SGO Group LLC.(10)
10.42*	Asset Purchase and License Agreement, dated September 19, 2001, between Registrant and Eli Lilly and Company.(10)
10.43*	Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(11)
10.47+	Employment Offer Letter, dated April 5, 2002, between Registrant and Marianne Armstrong, Ph.D.(12)
10.48+	Bonus Plan Memorandum, dated April 18, 2002, from Registrant to Marianne Armstrong, Ph.D.(12)
10.49+	Secured Promissory Note, dated May 1, 2002, between Registrant and Marianne Armstrong, Ph.D.(12)
10.50*	Amendment No. 1, dated April 26, 2002, to the Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(12)
10.51*	Amendment No. 1, dated April 25, 2002, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc.(12)
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.(12)
10.53	Letter Amendment, dated May 28, 2002, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(12)
10.54	Letter Amendment, dated July 1, 2002, to Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(12)
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.(14)
10.58+	Employment Offer Letter, dated April 30, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(15)
10.59+	Bonus Plan Memorandum, dated May 22, 2002, from Registrant to Lawrence M. Blatt, Ph.D.(15)
10.60+	Promissory Note, dated May 22, 2002, between Registrant and Lawrence M. Blatt, Ph.D.(15)
10.62+	Employment Offer Letter, dated July 2, 2003, between Registrant and Roger L. Hawley.(15)
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.(17)
10.65+	Employment Offer Letter, dated September 24, 2003, between Registrant and Daniel G. Welch.(16)
10.68*	License Agreement, dated March 29, 2002, among Registrant, Marnac, Inc., KDL, Inc., KDL GmbH, Dr. Solomon Margolin and Dr. Shitotomo Yamauchi.(20)
10.69+	Stock Bonus Award Agreement, dated November 5, 2003, between Registrant and William R. Ringo, Jr.(18)
10.74	Aralast Promotion Agreement, dated as of March 26, 2004, by and between Registrant and Baxter Healthcare Corporation.(22)
10.77+	Employment Offer Letter Agreement, dated October 19, 2004, between Registrant and Norman L. Halleen.(25)
10.79	Amended and Restated Standstill Agreement, dated October 29, 2004, among Registrant, Warburg Pincus & Co. and certain affiliates of Warburg Pincus & Co.(26)
10.80	Registration Rights Agreement, dated October 29, 2004, among Registrant, Warburg Pincus & Co. and certain affiliates of Warburg Pincus & Co.(26)
10.81	Amendment, dated October 29, 2004 to Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(26)
10.82+	Employment Offer Letter Agreement, dated October 29, 2004 and effective as of November 1, 2004, between Registrant and Cynthia Robinson.(26)
10.83+	Employment Offer Letter Agreement, dated June 13, 2001, between Registrant and Williamson Bradford, M.D., Ph.D.(28)

<u>Number</u>	<u>Description of Document</u>
10.84+	Employment Offer Letter Agreement, dated May 14, 2004, between Registrant and Thomas Kassberg.(28)
10.85+	Employment Offer Letter Agreement, dated June 1, 2001, between Registrant and Steven Porter, M.D., Ph.D. (28)
10.86+	Employment Offer Letter Agreement, dated August 9, 2004, between Registrant and Robin Steele. (28)
10.87+	Salary Information for Executive Officers. (28)
10.88+	Compensation Arrangements with Non-Employee Directors. (28)
10.89+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 18, 2004, between Registrant and Marianne Armstrong, Ph.D. (28)
10.90+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 18, 2004, between Registrant and Lawrence M. Blatt, Ph.D. (28)
10.91+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 27, 2004, between Registrant and Williamson Bradford, M.D., Ph.D. (28)
10.92+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 26, 2004, between Registrant and Roger L. Hawley. (28)
10.93+	Amendment to Offer Letter re Severance Pay and Change in Control, dated August 10, 2004, between Registrant and Thomas Kassberg. (28)
10.94+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 26, 2004, between Registrant and Steven Porter, M.D., Ph.D. (28)
10.95+	Amendment to Offer Letter re Severance Pay and Change in Control, dated July 27, 2004, between Registrant and Howard A. Simon, Esq. (28)
10.96*	Amendment No. 2, dated December 31, 2004, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc. (28)
10.97*	Amendment No. 3, dated December 31, 2004, to the License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc. (28)
10.98**	Amendment No. 3, dated July 26, 2005, to Data Transfer, Clinical Trial and Market Supply Agreement, dated January 27, 2000, between Registrant and Boehringer Ingelheim Austria, GmbH.(29)
10.99**	Data Transfer, Clinical Trial and Market Supply Agreement, dated November 3, 2005, between Registrant and Boehringer Ingelheim Austria, GmbH.(31)
10.100**	Product Acquisition Agreement, dated November 28, 2005, between Registrant and Valeant Pharmaceuticals North America.(30)
10.101**	Amendment Number 3, dated December 22, 2005, to Development and Supply Agreement dated December 28, 2001, between Registrant and Abbott Laboratories.(31)
10.102**	Amendment Number 4, dated December 22, 2005, to License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen Inc.(31)
10.103**	Asset Purchase Agreement dated December 23, 2005, between Registrant and Targanta Therapeutics Corporation.(31)
10.104**	License Agreement, dated December 23, 2005, between Registrant and Eli Lilly & Company.(31)
10.105+	Severance Agreement and General Release, dated January 6, 2006, between Registrant and Roger L. Hawley.(31)
10.106**	Amendment No. 6, dated February 27, 2006, to License Agreement dated May 5, 1998, between Registrant and Genentech, Inc.(31)
10.107+	Amended and Restated 2000 Equity Incentive Plan.(31)
10.108+	Amended and Restated 2000 Non-Employee Directors' Stock Option Plan.(31)
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)

<u>Number</u>	<u>Description of Document</u>
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) Incorporated by reference to pages 16 through 26 of Exhibit 10.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 18, 2000 (No. 333-45460).
- (3) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (4) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
- (5) Filed as an exhibit to the Registrant's Current Report on Form 8-K on August 23, 2000.
- (6) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
- (7) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- (8) Filed as an exhibit to the Registrant's Current Report on Form 8-K on July 18, 2001.
- (9) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (10) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (11) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (12) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2002.
- (13) Incorporated by reference to pages following page 10 of Exhibit 10.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 18, 2000 (No. 333-45460).
- (14) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2003.
- (15) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2003.
- (16) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2003.
- (17) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended September 30, 2003.
- (18) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

- (19) Filed as an exhibit to the Registrant's amended Annual Report on Form 10-K/A (Amendment No. 1) for the year ended December 31, 2003.
- (20) Filed as an exhibit to the Registrant's amended Annual Report on Form 10-K/A (Amendment No. 2) for the year ended December 31, 2003.
- (21) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2004.
- (22) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended March 31, 2004.
- (23) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2004.
- (24) Filed as an exhibit to the Registrant's amended Quarterly Report on Form 10-Q/A (Amendment No. 1) filed for the quarter ended June 30, 2004.
- (25) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2004.
- (26) Filed as an exhibit to the Registrant's Current Report on Form 8-K on November 4, 2004.
- (27) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2005.
- (28) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004.
- (29) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2005.
- (30) Incorporated by reference to Exhibit 2.1 of Form 8-K (File No. 001-11397) filed by Valeant Pharmaceuticals International, the parent company of Valeant Pharmaceuticals North America on January 5, 2006.
- (31) Filed herewith.

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(c) **Exhibits**

See Item 15(a) above.

(d) **Financial Statement Schedules**

See Item 15(a) above.

## SIGNATURES

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

INTERMUNE, INC.

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

Dated: March 9, 2006

## POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the registrant and in the capacities and on the dates indicated have signed this Report below:

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ WILLIAM R. RINGO, JR.          </u> William R. Ringo, Jr.	Chairman of the Board of Directors	March 9, 2006
<u>          /s/ DANIEL G. WELCH          </u> Daniel G. Welch	President and Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2006
<u>          /s/ NORMAN L. HALLEEN          </u> Norman L. Halleen	Senior Vice President of Finance Administration and Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2006
<u>          /s/ WILLIAM A. HALTER          </u> William A. Halter	Director	March 9, 2006
<u>          /s/ JAMES I. HEALY          </u> James I. Healy	Director	March 9, 2006

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ THOMAS R. HODGSON</u> Thomas R. Hodgson	Director	March 9, 2006
<u>/s/ DAVID S. KABAKOFF</u> David S. Kabakoff	Director	March 9, 2006
<u>/s/ JONATHAN S. LEFF</u> Jonathan S. Leff	Director	March 9, 2006
<u>/s/ MICHAEL L. SMITH</u> Michael L. Smith	Director	March 9, 2006

# corporate directory

## executive management

Daniel G. Welch  
President and Chief Executive Officer

Marianne T. Armstrong, Ph.D.  
Chief Medical Affairs and Regulatory Officer

Lawrence M. Blatt, Ph.D.  
Chief Scientific Officer

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

Thomas R. Kassberg  
Senior Vice President of Corporate  
Development and Commercial Operations

Steven B. Porter, M.D., Ph.D.  
Chief Medical Officer

Cynthia Y. Robinson, Ph.D.  
Senior Vice President of  
Development Operations

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

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

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

## board of directors

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

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

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

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

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

## board of directors (cont'd)

David S. Kabakoff, Ph.D.  
President  
Strategy Advisors, LLC

Jonathan S. Leff  
Partner  
Warburg Pincus LLC

Michael L. Smith  
Former Executive Vice President and  
Chief Financial Officer  
Anthem, Inc.

## annual meeting

The annual stockholders meeting will  
be held on May 24, 2006 at 10:00 a.m.  
at InterMune, Inc., 3280 Bayshore  
Boulevard, Brisbane, CA 94005

## corporate secretary

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

## independent registered public accounting firm

Ernst & Young LLP  
San Jose, CA

## transfer agent

Mellon Investor Services LLC  
235 Montgomery Street, 23rd Floor  
San Francisco, CA 94104  
(415) 951-4180

## stock listing

Symbol: ITMN  
Stock Exchange: NASDAQ

## corporate headquarters

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

## website

[www.intermune.com](http://www.intermune.com)

## investor services

A copy of the Company's 2005 Form  
10-K, which is filed with the Securities and  
Exchange Commission, is available for  
download at [www.intermune.com](http://www.intermune.com) or upon  
request to:

Investor Relations  
InterMune, Inc.  
3280 Bayshore Boulevard  
Brisbane, CA 94005  
Phone: (415) 466-2200  
[www.intermune.com](http://www.intermune.com)  
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## 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 System under the  
symbol ITMN. As of January 31, 2006, there were 109  
stockholders of record. No cash dividends have been paid  
to date by us, and we do not anticipate the payment of any  
dividends in the foreseeable future.

## Forward-Looking Statements/Risk Factors

Except for the historical information contained herein, this  
letter contains certain forward-looking statements that  
involve risks and uncertainties, including without limitation,  
the statements indicating that InterMune: (i) has several  
development programs with potential to address unmet  
medical needs in hepatology and pulmonology; (ii) believes  
that the corporate actions taken by it in 2005 put it in a  
position to more rapidly advance these development pro-  
grams; (iii) believes that patients diagnosed with idiopathic  
pulmonary fibrosis represent a seriously underserved  
patient population and a major unmet medical need, and  
that it is well positioned to be a leader in delivering a therapy  
for such unmet medical need; (iv) believes that the chosen  
endpoint for its pifrenidone CAPACITY trial is supported by  
data from earlier clinical studies of pifrenidone; (v) believes  
that hepatitis C protease inhibitors may inhibit replication of  
the hepatitis C virus and could provide an important com-  
ponent of first-line treatment for patients with the hepatitis  
C virus; (vi) expects meaningful progress in its late-stage  
clinical development programs; (vii) expects to complete  
enrollment of any particular clinical trial and to report data  
relating to any such trial by a specified date; and (viii)  
expects to submit a European Clinical Trial Authorisation for  
its hepatitis C virus protease inhibitor in 2006. Factors that  
could cause actual results or outcomes to differ materially  
from those expressed in any forward-looking statement  
include, but are not limited to, those discussed in our Form  
10-K filed with the Securities and Exchange Commission  
on March 13, 2006 and enclosed herewith, including the  
factors discussed in detail under the heading "Risk Factors"  
in Item 1A of our Form 10-K. Further, any forward-looking  
statement speaks only as of the date on which it is made,  
and we undertake no obligation to update any forward-look-  
ing statement to reflect events or circumstances after the date  
of this letter to reflect the occurrence of unanticipated events.

corporate headquarters

intermune, inc. 3280 bayshore blvd. brisbane, ca 94005

phone 415.466.2200 / fax 415.466.2300 / [www.intermune.com](http://www.intermune.com)

**INTERMUNE**