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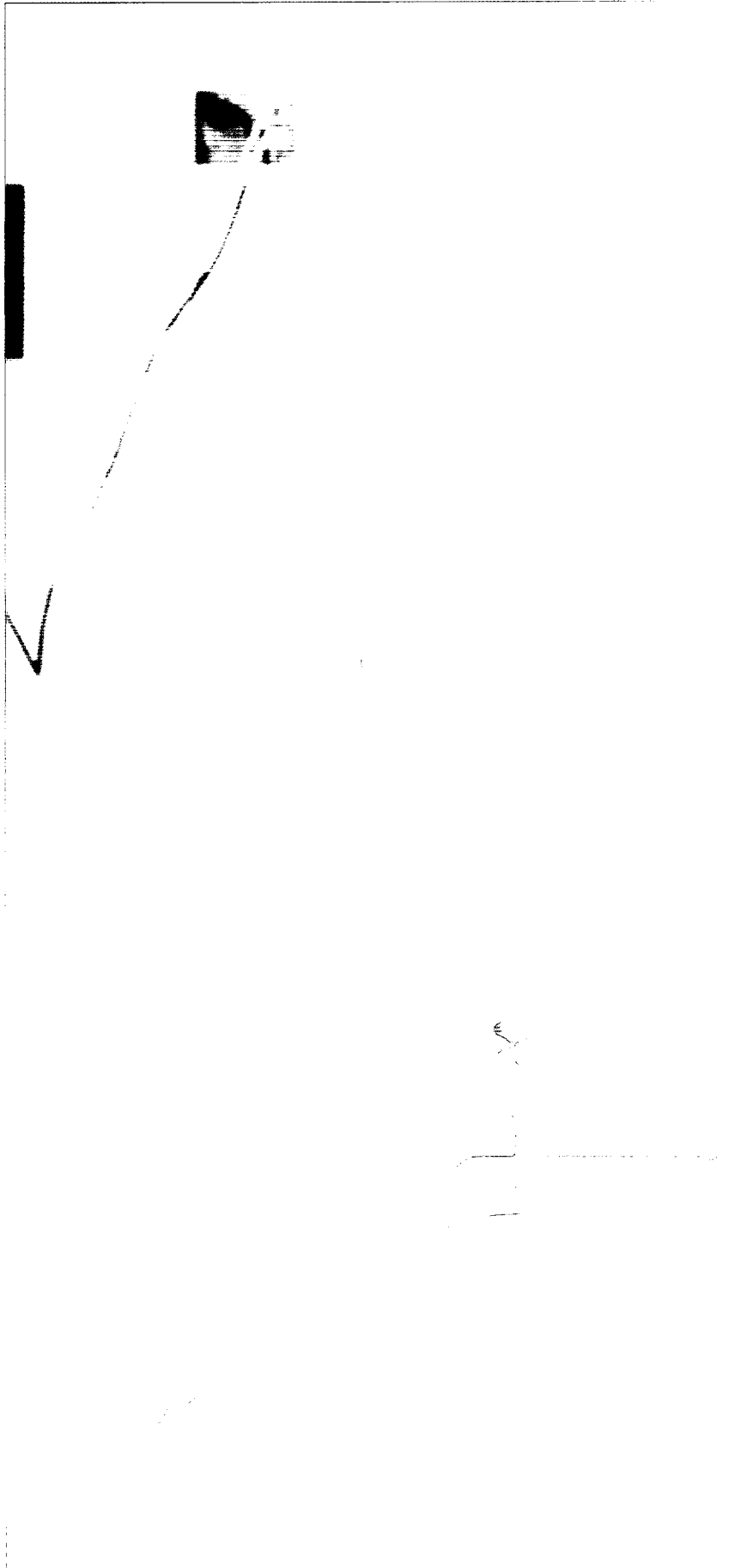
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FINANCIAL

# Commitment

InterMune  
2002 Annual Report

CRCM



# Perseverance

developing new  
treatment options





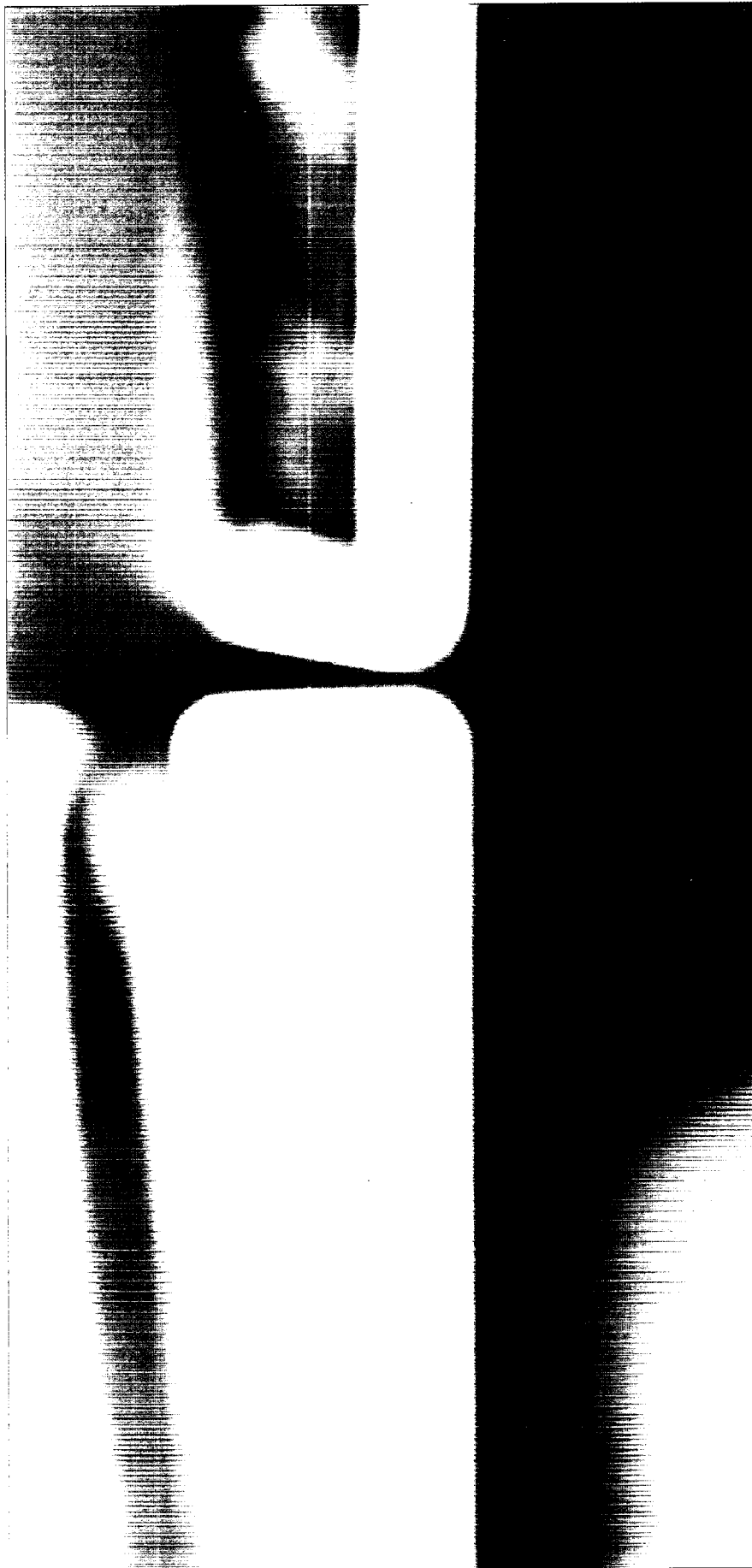




# Diligence

achieving profitability

Focus  
educating physicians







Moderate Profit



# Endurance

continuing our  
unprecedented track record

# InterMune

committed to maximizing the value  
of life-saving therapies

Commitment is the driving force behind InterMune's commercial, clinical and applied research programs.

Commitment unites our employees to a common vision: to maximize the value of therapies that help prolong and improve patients' lives.

Our progress thus far is unprecedented.

With substantial revenue growth and clinical momentum, InterMune is well positioned to help physicians treat patients and to build stockholder value for the long term.



W. Scott Harkonen,  
Chief Executive Officer and President



### **To Our Stockholders,**

InterMune enters 2003 in a formidable market position distinguished by strong financial results and tremendous progress made across the Company's commercial, clinical development and applied research programs. Our strength today reflects the unwavering commitment of our employees – to patients for whom we are developing new therapies and to investors for whom we are building a sustainable biopharmaceutical company.

During the past year, we exceeded our own expectations, extending our track record of greater than 100 percent annual revenue growth driven by sales of Actimmune®, Infergen® and Amphotec®. We solidified InterMune's leadership position in the idiopathic pulmonary fibrosis (IPF) market and established our presence in the field of hepatology. We successfully completed enrollment of our second global Phase III clinical trial of oritavancin, keeping us on track for an NDA filing for this novel antibiotic in 2004. We expanded our late-stage pipeline by in-licensing pirfenidone, a small molecule compound with broad therapeutic potential against multiple fibrotic diseases. We organized our applied research programs under new leadership, advancing a series of technology-based collaborations and initiatives focused on pulmonary, infectious and hepatic diseases. We also built our management team with new heads of finance, regulatory and medical affairs, and elected several new members to our Board of Directors – bringing a substantial level of biotechnology and pharmaceutical industry experience that further positions InterMune for long-term success.

These accomplishments exemplify InterMune's commitment to performance, and set the stage for continued momentum in our commercial, clinical development and applied research organizations.

### **Commercial**

InterMune's sales and marketing team is building upon \$112 million in 2002 product sales, representing a revenue increase of 180 percent year-over-year. Driven primarily by sales of Actimmune (interferon gamma-1b) and Infergen (interferon alfacon-1), we believe that InterMune is well on its way to achieving its 2003 revenue target of \$170 million to \$195 million.

In 2002, InterMune reorganized its sales force for maximum efficiency, integrating our team of field specialists to target physicians with our products. We hired key marketing executives from leading biotechnology and pharmaceutical companies to provide strategic oversight to these programs, bringing expertise that is enhancing our efforts to educate physicians about the safe and appropriate use of Actimmune, Infergen and Amphotec.

With an abundance of recent data, we are seeing a strong interest from physicians who are considering using interferon gamma-1b. Currently, more than 1,400 pulmonologists are prescribing interferon gamma-1b, and 3,000 IPF patients are taking the drug as a result of growing awareness about the benefits of earlier diagnosis and treatment of this fatal disease.

We established InterMune's presence in the field of hepatology in 2002 with the re-launch of Infergen for the treatment of chronic hepatitis C virus (HCV) infections. Prescribing trends are increasing as hepatologists learn more about the clinical advantages of this important therapy. Our efforts to educate physicians are supported by presentations of positive clinical data at recent medical meetings. These data suggest that Infergen is the most biologically potent interferon, positioning us to expand InterMune's share of the multi-billion dollar market for interferon therapies for chronic hepatitis C.

Our commercial team is paving the way for expansion into the hospital-based infectious disease market by selling anti-fungal agent Amphotec (amphotericin B cholesteryl sulfate complex for injection), indicated for the treatment of invasive aspergillosis. We are also preparing for a launch of *oritavancin* for complicated skin and skin-structure infections (CSSIs), which has the potential to become the cornerstone of our hospital-based infectious disease franchise, and the second product InterMune promotes for infectious disease indications in the hospital setting.

#### **Clinical Development**

InterMune's industry-leading clinical and regulatory teams are championing our efforts to advance the Company's late-stage product development pipeline. Our business strategy focuses first on expanding disease indications for our currently marketed products and second on developing new products that build our emerging pulmonary, infectious and hepatic disease franchises.

InterMune is the clear market leader for IPF with two promising therapies in development for this fatal disease. In November, at the 2002 annual meeting of the American College of Chest Physicians, clinical investigators reported on key data from our randomized, controlled Phase III clinical trial evaluating interferon gamma-1b, our first product candidate for the treatment of IPF. We intend to publish and present our data in peer-reviewed forums during the year and will work with the FDA to refine our plans for a confirmatory Phase III registration study of interferon gamma-1b in this indication.

Our second potential product in development for IPF is pirfenidone, an orally available agent that became a strategic addition to our product portfolio in March 2002. We are excited about the potential of pirfenidone as a therapy for IPF and are working to complete, ahead of schedule, a proof-of-concept Phase II clinical trial in this patient population. Pending the preliminary results of safety and efficacy, we intend to design and implement a larger-scale IPF study that may support marketing registration.

Our clinical team also is making progress with InterMune's portfolio of drug candidates that advance our position in the hepatitis market. More than four million people have been exposed to HCV in the United States, which can lead to liver fibrosis or cirrhosis, putting patients at an increased risk of life-threatening complications, progressive liver failure and death. We are committed to the devel-

opment of new treatments to help HCV patients fight this disease. In January, we began a Phase I study of PEG-Infergen – our next-generation Infergen that may result in a better therapy for chronic hepatitis C infections due to the advantages of pegylation. We also are conducting Phase II clinical studies of interferon gamma-1b as well as pirfenidone, two potential treatments for liver fibrosis. We recently completed enrollment of 500 patients into our interferon gamma-1b liver fibrosis study and expect to complete the trial by the end of 2003.

InterMune's third area of significant clinical and commercial opportunity is in the hospital-based infectious disease market with oritavancin, our second-generation glycopeptide antibiotic. With a second Phase III clinical trial of oritavancin for CSSIs nearing completion, InterMune plans to analyze the data from this study for presentation at a medical meeting later this year. If the data confirm results from the first Phase III study, oritavancin may become the new standard for second-generation agents to treat gram-positive infections.

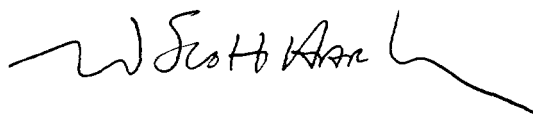
#### **Applied Research**

InterMune's applied research efforts gained traction in 2002 with the appointment of Dr. Lawrence Blatt, an expert in the fields of interferon biology, hepatology and biopharmacology, to head this important group. Under his leadership, our research teams are making great strides to advance our early stage pipeline by leveraging collaborative efforts and internal programs. Over the past year, we continued to innovate our existing products through new technology applications and combination-use studies, and are making progress identifying promising compounds that will fuel our pipeline with attractive product candidates for pulmonary, infectious and hepatic diseases.

#### **Future Growth**

InterMune is well positioned for continued financial, clinical and operational success. We boast a solid foundation of commercial products being promoted by our sales force and network of specialty pharmacy distributors. Our late-stage pipeline is poised to deliver a steady stream of clinical results over the next several years that will form the basis for regulatory discussions and product launches. And our management team brings the experience, track record and absolute commitment required to continue the growth and value creation of this world-class biopharmaceutical company.

Perseverance, diligence, focus and endurance – this is our motto for the year.



# Pipeline

late-stage programs for pulmonary,  
infectious and hepatic diseases

Product	Pre-clinical
Actimmune® (interferon gamma-1b) Chronic Granulomatous Disease Severe, Malignant Osteopetrosis	
Interferon Gamma-1b Idiopathic Pulmonary Fibrosis Ovarian Cancer Cryptococcal Meningitis Liver Fibrosis Non-Hodgkins Lymphoma Invasive Aspergillosis	
Infergen® (interferon alfacon-1) Hepatitis C	
PEG-Infergen (PEG-interferon alfacon-1) Hepatitis C	
Amphotec® (amphotericin B cholesterol sulfate) Invasive Aspergillosis	
Oritavancin Complicated Skin and Skin-structure Infections Nosocomial Pneumonia* Bacteremia	
Pirfenidone Pulmonary Fibrosis Liver Fibrosis Kidney Fibrosis	
Enhanced Gamma IFN	
	*planned

Phase 1

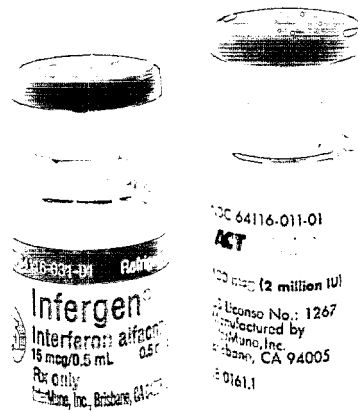
Phase 2

Phase 3

Marketed

# Products

foundation for future growth



#### Actimmune® (interferon gamma-1b)

InterMune's flagship product Actimmune, a biological response modifier marketed for two congenital disorders, has widespread potential as a breakthrough treatment for idiopathic pulmonary fibrosis (IPF), liver fibrosis and ovarian cancer. InterMune is actively developing interferon gamma-1b for these diseases to expand upon its FDA-approved indications for chronic granulomatous disease and severe, malignant osteopetrosis. InterMune's late-stage clinical programs for interferon gamma-1b include a recently completed Phase III clinical trial in IPF patients, a large-scale Phase III study in ovarian cancer and a Phase II study in liver fibrosis. The Company also is evaluating a second-generation interferon gamma that may allow for administration once weekly.

#### Infergen® (interferon alfacon-1)

Infergen, also known as consensus interferon, is marketed for the treatment of adults with chronic hepatitis C virus (HCV) infections. It is currently the only FDA approved, bio-optimized interferon developed through rational drug design and the only interferon with data in the label specifically for non-responding or refractory patients. InterMune's sales force re-launched Infergen during the past year with an active campaign to educate U.S. hepatologists about the safe and appropriate use of Infergen, which represents new hope for the more than 50 percent of HCV patients who fail other currently available therapies. InterMune has initiated development of PEG-Infergen (pegylated interferon alfacon-1), which may offer the benefits of less frequent dosing and reduced side effects.

#### Oritavancin

InterMune's oritavancin, a second-generation glycopeptide antibiotic, represents a novel advancement in the field of infectious disease. Oritavancin's mechanism of action allows it to kill harmful and resistant strains of gram-positive bacteria, unlike many other agents that merely suppress them. This advantage, coupled with a long half-life, positions oritavancin as a strong candidate to become a first-line therapy for serious gram-positive infections, even those resistant to current antibiotics. Based on the positive results of a Phase III clinical trial of oritavancin for complicated skin and skin-structure infections (CSSIs), InterMune is completing a second Phase III study of oritavancin in this indication, the results of which could lead to an NDA filing in 2004.

# Actimmune

interferon gamma-1b



Approved Indications

Chronic granulomatous disease

Severe, malignant osteopetrosis

Highlights

12-year track record of safety  
and efficacy

Broad therapeutic activity against  
life-threatening diseases

Multiple mechanisms of action

New Disease Targets

Idiopathic pulmonary fibrosis (IPF)

Liver fibrosis

Ovarian cancer

Advances in Development

Once-weekly administration



### **Idiopathic Pulmonary Fibrosis (IPF)**

Approximately 75,000 patients in the United States suffer from IPF, a universally fatal disease with no FDA approved therapies that is characterized by the chronic, progressive scarring of the lungs. Since 1999, InterMune has been working to develop interferon gamma-1b as the first potential effective treatment for patients afflicted with this disease. The results of our Phase III clinical trial of interferon gamma-1b offer IPF patients hope for improved survival. A survival benefit has now been observed in two out of two clinical trials and, as expected, the survival benefit was strengthened in patients with mild to moderate disease and patients who complied with the treatment regimen.

### **Liver Fibrosis**

Interferon gamma-1b also has the potential to treat patients with severe liver fibrosis, or cirrhosis, caused by viral or chemical injury. Based on preclinical data showing that interferon gamma-1b may prevent or reverse the development of cirrhosis, InterMune is conducting a Phase II clinical study to evaluate the safety and anti-fibrotic activity of interferon gamma-1b in patients with HCV-induced liver fibrosis who have failed standard antiviral therapy.

### **Ovarian Cancer**

Ovarian cancer affects approximately 105,000 women in the United States and is a leading cause of death from cancer among women. Women diagnosed with the disease have a poor prognosis and limited treatment options. Based on compelling findings from a Phase II study, InterMune is evaluating interferon gamma-1b as an adjunctive first-line therapy for ovarian cancer. The Company is conducting an international Phase III study in 800 women with the goal of showing improved survival in patients treated with interferon gamma-1b in combination with standard chemotherapy.

# Infergen

interferon alfacon-1

Approved Indications

Chronic hepatitis C infections

Highlights

Only bio-optimized  
interferon on market

Only interferon with label  
information for refractory  
HCV patients

Advances in Development

PEG-Infergen

New delivery methods

Phase IV comparison studies





## Hepatitis C

Known as the "silent epidemic," approximately four million people in the United States have been exposed to the hepatitis C virus, the cause of a blood-borne infection that can lead to chronic liver inflammation, cirrhosis and liver cancer.

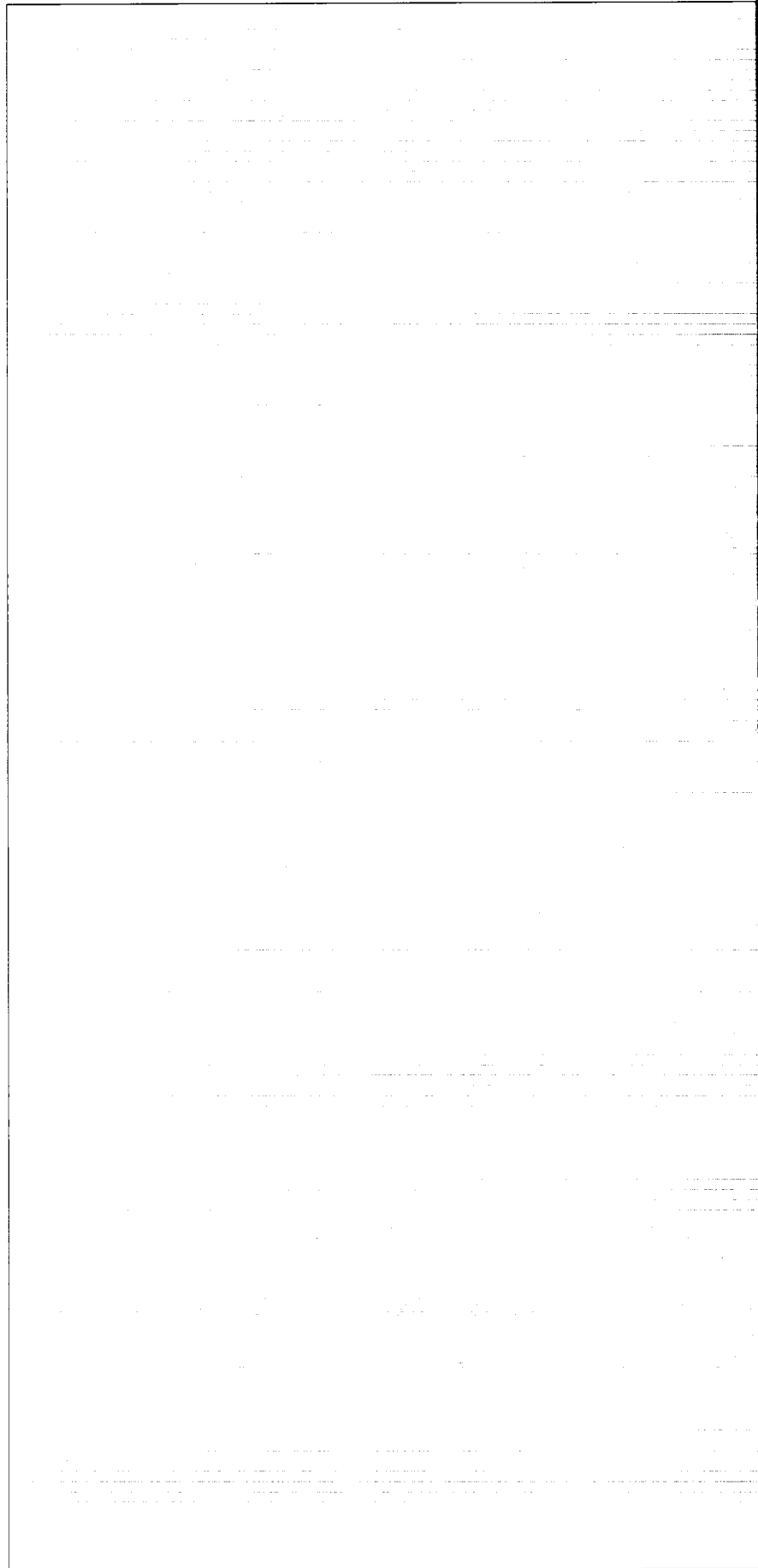
InterMune is at the forefront of the next generation of HCV therapies with PEG-Infergen, a pegylated version of its FDA-approved Infergen, in clinical development. Infergen is indicated for the treatment of patients 18 years of age or older with chronic hepatitis C infections. As the only bio-optimized interferon therapy available for patients, Infergen provides physicians with another treatment option for the nearly 50 percent of HCV patients who will either fail or relapse from initial therapy.

Recent studies further support the clinical advantages of Infergen therapy. In November, InterMune reported data from a clinical study of Infergen plus ribavirin, compared to interferon alfa-2b plus ribavirin, which demonstrated that patients treated with the Infergen combination therapy achieved a higher sustained virologic response (SVR) than those patients treated in the comparison group. These findings confirm the benefit of Infergen's biologic potency and suggest that Infergen in combination with ribavirin may set a new treatment threshold for this difficult-to-treat patient population.

To further advance the treatment of HCV, InterMune has initiated the development of its PEG-Infergen, which may have even higher response rates. The Company is conducting a Phase I clinical trial of PEG-Infergen to determine dosing and evaluate safety, and expects to begin Phase II clinical development later this year. The introduction of PEG-Infergen may mark the beginning of a new era of HCV therapeutics where more potent bioengineered compounds are used to combat this disease.

# Oritavancin

glycopeptide antibiotic





Status

Phase III clinical development

Disease Targets

Gram-positive infections:

Complicated skin and skin-structure  
infections (CSSIs)

Bacteremia (blood infections)

Hospital-acquired pneumonia

Highlights from the first Phase III clinical study suggest:

Effective against resistant strains of  
gram-positive bacteria

Reduces total treatment time of CSSIs

Eliminates need for oral  
follow-up therapy

First antibiotic to treat  
CSSIs in 7 days or less





### Gram-positive infections

The rising incidence of hospital-based gram-positive infections and the soaring cost of in-patient treatment creates a pressing need for new antibiotics that can overcome bacterial resistance. InterMune's oritavancin, a second-generation glycopeptide antibiotic with novel properties, is providing new hope against bacterial pathogens resistant to many of today's antibiotics.

InterMune is actively developing oritavancin as a treatment for complicated skin and skin-structure infections (CSSIs), a common infection found in the hospital and community settings caused by gram-positive pathogens. Data reported last year from a Phase III clinical study of 517 patients with CSSIs demonstrated that oritavancin intravenous therapy can reduce treatment times by one-half of the current standard of care – intravenous therapy with vancomycin followed by oral therapy with cephalexin administered for a longer period. Thus, oritavancin eliminates the need for follow-up therapy with oral antibiotics. These benefits could translate into reduced health care costs associated with CSSIs.

Based on these compelling findings, InterMune is conducting a second global, randomized, controlled Phase III clinical study evaluating oritavancin in CSSIs. With enrollment of patients recently completed, the Company is on track to report data from the study later this year. If data from this study confirm the results of the first Phase III study, InterMune intends to file for regulatory approval of oritavancin in 2004.

As demonstrated by the first Phase III clinical trial, oritavancin could be the first antibiotic ever to treat serious infections in seven days or less. This positions oritavancin to become the new standard of second-generation agents to treat hospital-based gram-positive infections.

# Growth

revenues continue  
to increase

\$111,965,000

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2002

\$39,951,000

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2001

\$11,201,000

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2000

\$556,000

---

1999

# InterMune

officers and directors  
corporate information

## Board of Directors

W. Scott Harkonen, M.D.  
President, CEO and Chairman of the Board of Directors

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

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

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

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

Jonathan S. Leff  
Partner,  
Warburg Pincus LLC

William R. Ringo, Jr.  
Former President, Oncology and Critical Care Products,  
Eli Lilly

## Senior Management

W. Scott Harkonen, M.D.  
President, CEO and Chairman of the Board of Directors

James E. Pennington, M.D.  
Executive Vice President of Medical and Scientific Affairs

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

Marianne T. Armstrong, Ph.D.  
Senior Vice President of Global Regulatory Operations and  
Corporate Compliance

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

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

John J. Wulf  
Senior Vice President of Corporate Development

Lawrence M. Blatt, Ph.D.  
Vice President of Biopharmacology Research

Henry H. Hsu, M.D.  
Vice President of Clinical Research

Keith A. Katkin  
Vice President of Pulmonary Marketing

Randall E. Kaye, M.D.  
Vice President of Medical Affairs

Brian S. Murphy, M.D.  
Vice President of Hepatology Marketing

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

Curtis L. Ruegg, Ph.D.  
Vice President of Process Development

Bradley R. Scates  
Vice President of Finance

Vida Shafiq  
Vice President of International Business Operations

**Annual Meeting**  
The annual stockholders meeting will be held on May 29, 2003, at 9:15 a.m. at InterMune, Inc., 3280 Bayshore Boulevard, Brisbane, CA.

**Legal Counsel**  
Cooley Godward LLP  
Palo Alto, CA

**Corporate Secretary**  
Stephen N. Rosenfield  
Executive Vice President of Legal Affairs,  
General Counsel and Secretary

**Independent Auditors**  
Ernst & Young LLP  
Palo Alto, CA

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

**Stock Listing**  
Symbol: ITMN  
Stock exchange: NASDAQ

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

**Websites**  
www.intermune.com www.infergen.com  
www.actimmune.com www.amphotec.com

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#### Investor Services

A copy of the Company's Annual Report to the Securities and Exchange Commission on Form 10-K is available without charge upon request to:

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

#### Stockholder Information

Since our initial public offering of common stock, \$0.001 par value, on March 24, 2000, our common stock has been traded on the NASDAQ National Market under the symbol ITMN. As of March 11, 2003, there were 180 stockholders of record. No cash dividends have been paid to date by us, and we do not anticipate the payment of dividends in the foreseeable future.

The following table sets forth the high and low closing prices of our common stock, as reported by NASDAQ for the fiscal periods indicated.

Fiscal Year	High	Low
2002		
First Quarter	\$ 51.19	\$ 27.86
Second Quarter	32.48	20.37
Third Quarter	33.44	15.76
Fourth Quarter	38.25	24.90
2001		
First Quarter	\$ 44.88	\$ 12.50
Second Quarter	42.07	15.62
Third Quarter	46.53	26.76
Fourth Quarter	52.96	35.75

#### Forward-Looking Statements/Risk Factors

Except for the historical information contained herein, this Annual Report contains certain forward-looking statements that involve risks and uncertainties concerning certain of InterMune's financial projections and projected business, commercial, product and clinical development activities, timelines and goals. All forward-looking statements and other information included in this Annual Report are based on information available to InterMune as of March 31, 2003, and InterMune assumes no obligation to update any such forward-looking statements or information. InterMune's actual results could differ materially from those described in InterMune's forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in detail under the heading "Risk Factors" and the other risks and factors discussed in InterMune's 10-K report filed with the SEC on March 31, 2003, which are incorporated herein by reference. Although a summary of certain of the risks and other factors concerning certain of the forward-looking statements in this Annual Report follow, these risks and factors should be considered only in connection with the fully discussed risks and other factors discussed in detail in the 10-K report and InterMune's other periodic reports filed with the SEC. InterMune's financial projections are subject to the uncertainties and risks of a continuing increase in sales of Actimmune for IP1, an indication for which Actimmune has not been approved by the FDA, and limitations imposed by the U.S. FDA with respect to InterMune's communications with physicians concerning Actimmune and Infergen. InterMune's projected business, commercial, product and clinical development activities, timelines and goals are subject to the uncertainties and risks of significant regulatory, supply, intellectual property and competitive barriers to entry; the uncertain, lengthy and expensive drug research and clinical development and regulatory process; budget constraints; competition; and InterMune's ability to obtain, maintain and enforce patents and other intellectual property.

# InterMune

3280 Bayshore Boulevard

Brisbane, CA 94005

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



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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2002

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

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

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

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

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

Common Stock, \$0.001 par value  
(Title of class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

As of June 28, 2002, the aggregate market value (based upon the closing sales price of such stock as reported in the Nasdaq Stock Market on such date) of the voting stock held by non-affiliates of the registrant was \$441,045,008. Excludes an aggregate of 10,568,495 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 28, 2002. 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.

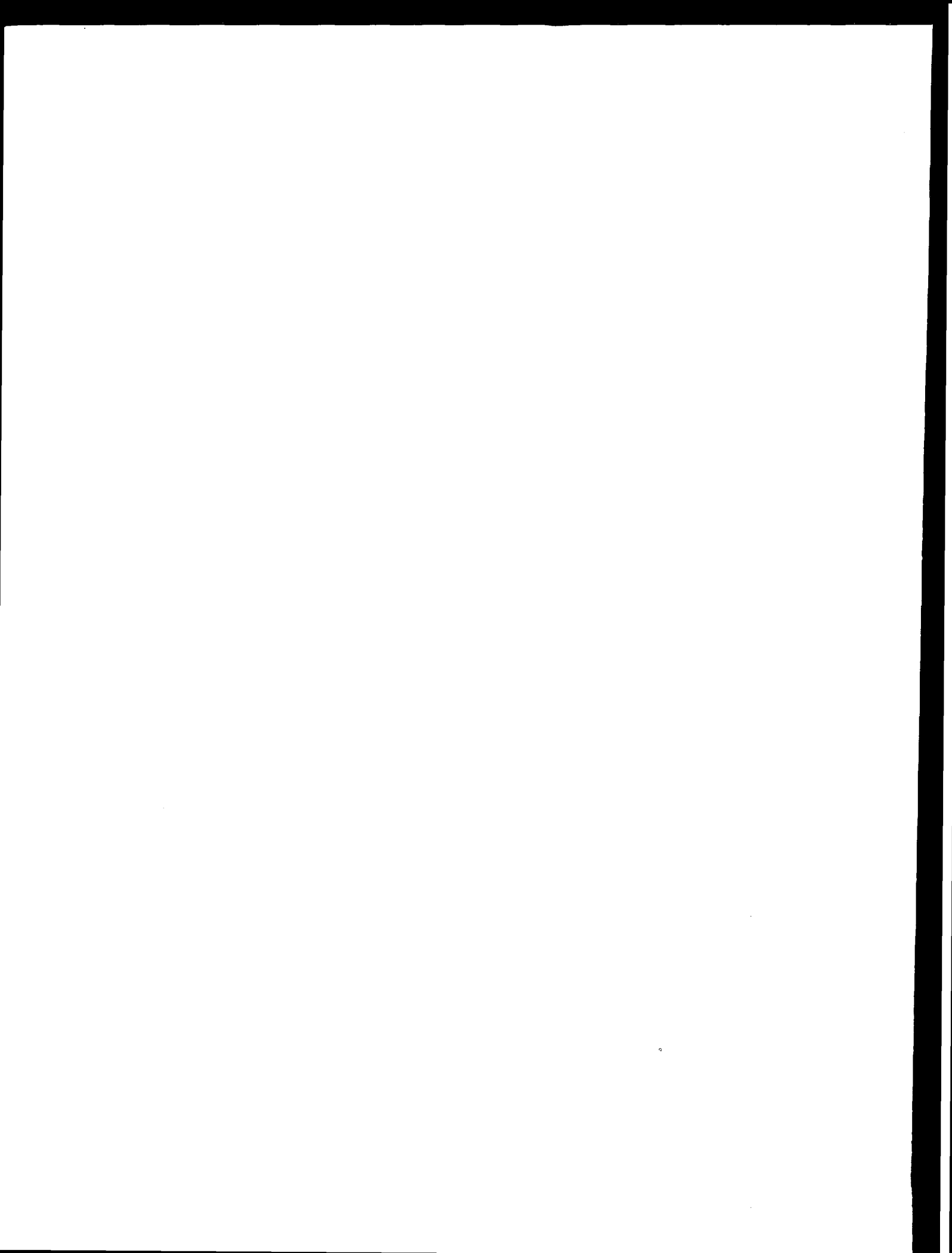
As of March 11, 2003, the number of outstanding shares of the registrant's Common Stock was 31,706,855 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2003 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 10-13 of this Form 10-K.

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INTERMUNE, INC.

ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002

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## PART 1

### ITEM 1. BUSINESS

#### Forward Looking Statements and Risk Factors

This Annual Report on Form 10-K contains forward-looking statements concerning our operations, economic performance and financial condition. Forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, are included, for example, in the discussions about:

- our strategy;
- sufficiency of our cash resources;
- revenues from product sales and existing and new collaborations;
- product development;
- our research and development expenses and other expenses; and
- our operational and legal risks.

These statements reflect our current views with respect to future events, are based on assumptions and involve risks and uncertainties. Actual results may differ materially from those expressed or implied in those statements. Factors that could cause these differences include, but are not limited to, those discussed under "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Given these uncertainties, you should not place undue reliance on these forward-looking statements.

#### Overview

We are developing and commercializing innovative products for the treatment of serious pulmonary, infectious and hepatic diseases. We have three marketed products, growing product revenues and advanced-stage clinical programs addressing a range of unmet medical needs with attractive commercial markets.

Our track record of annual revenue growth is fueled by sales of our three marketed products:

- Actimmune® (interferon gamma-1b), approved for the treatment of severe, malignant osteopetrosis and chronic granulomatous disease (CGD);
- Infergen® (interferon alfacon-1), approved for the treatment of chronic hepatitis C infections; and
- Amphotec® (amphotericin B cholesteryl sulfate complex for injection), approved for the treatment of invasive aspergillosis.

We have a late-stage development pipeline including lead clinical programs focused on the development of interferon gamma-1b for the treatment of fibrotic diseases, cancer and infectious diseases; oritavancin for the treatment of serious gram-positive infections; and a pegylated form of interferon alfacon-1 (PEG-Infergen) for the treatment of chronic hepatitis C infections.

In parallel with our commercial and clinical programs, our applied research efforts focus on exploring new uses of our lead products and identifying promising drug candidates to build our pulmonary disease, infectious disease and hepatology franchises.

We are pursuing the following product development programs:

<u>Program</u>	<u>Clinical Status as of March 1, 2003</u>
<b><i>INTERFERON GAMMA-1b</i></b>	
<i>Idiopathic pulmonary fibrosis</i>	<i>Phase III</i>
<i>Ovarian cancer</i>	<i>Phase III</i>
<i>Cryptococcal meningitis</i>	<i>Phase III</i>
<i>Non-Hodgkin's lymphoma</i>	<i>Phase II</i>
<i>Liver fibrosis</i>	<i>Phase II</i>
<i>Invasive aspergillosis</i>	<i>Phase II*</i>
<b><i>NEXT-GENERATION INTERFERON GAMMA</i></b>	<i>Preclinical studies</i>
<b><i>ORITAVANCIN</i></b>	
<i>Complicated skin and skin-structure infections</i>	<i>Phase III</i>
<i>Bacteremia</i>	<i>Phase II*</i>
<i>Nosocomial pneumonia</i>	<i>Phase II/III (planned)</i>
<b><i>INFERGEN</i></b>	
<i>Chronic hepatitis C infections</i>	<i>Phase IV*</i>
<b><i>PEG-INFERGEN</i></b>	
<i>Chronic hepatitis C infections</i>	<i>Phase I</i>
<b><i>PIRFENIDONE</i></b>	
<i>Pulmonary fibrosis</i>	<i>Phase II*</i>
<i>Renal fibrosis</i>	<i>Phase II*</i>
<i>Hypertrophic cardiomyopathy</i>	<i>Phase II*</i>
<i>Hepatic cirrhosis</i>	<i>Phase II*</i>
<i>Radiation-induced fibrosis</i>	<i>Phase II*</i>

\* These clinical trials were initiated under investigational new drug applications held by a party other than InterMune.

#### Our Strategy

Our objective is to become a leading global biopharmaceutical company. We intend to grow our product revenues by capitalizing on the opportunities presented by our marketed products and by developing and commercializing new products. The key elements of our strategy for achieving these objectives include:

*Expand the number of diseases for which the FDA approves Actimmune and Infergen for treatment, and obtain FDA approval of oritavancin, PEG-Infergen and pիրfenidone. We plan to develop Actimmune, Infergen, oritavancin and pիրfenidone for a number of diseases where preclinical studies and clinical trials have shown evidence that they are potentially effective treatments. Some of the diseases for which Actimmune may demonstrate therapeutic activity include idiopathic pulmonary fibrosis, ovarian cancer, cryptococcal meningitis, non-Hodgkin's lymphoma, liver fibrosis and invasive aspergillosis. We believe that the risks and time required to obtain FDA approval of Actimmune for new diseases may be reduced because of its established safety profile. We also believe that the life-threatening nature of some of the diseases that we intend to treat may help us obtain accelerated, or fast track, designation for Actimmune for some of these diseases. We have obtained fast track designation from the FDA for Actimmune in the treatment of idiopathic pulmonary fibrosis. Infergen*

has development potential in additional therapies for hepatitis C infections and additional diseases, such as hepatitis B infections and cancer. We believe that PEG-Infergen has significant potential to compete with other pegylated treatments for chronic hepatitis C infections. Oritavancin has development potential for gram-positive bacterial infections, including strains resistant to many antibiotics. Pirfenidone has development potential for fibrotic diseases, including in the lung, kidney, liver and heart.

*Partner key programs and continue to in-license or acquire preclinical and development-stage programs and FDA approved products.* We are seeking development and commercialization partners for certain programs, such as oritavancin, in order to accelerate our development and commercialization efforts, offset our expenses and maximize the value of our products in markets in which we do not currently have an established sales and marketing organization, such as in Asia. We also plan to continue to in-license and acquire rights to additional programs and products, especially those for the treatment of life-threatening pulmonary and infectious diseases. To date, we have in-licensed or acquired rights to Actimmune, Infergen, Amphotec, oritavancin and pirfenidone. We believe that our development expertise and focus, as well as our financial and commercial resources, will provide us with significant opportunities to attract development and commercialization partners.

*Develop our sales and marketing organization to serve pulmonologists, gastroenterologists and hepatologists.* We are developing a sales and marketing organization to support the approximately 8,000 pulmonologists and 10,000 gastroenterologists and hepatologists practicing in the United States. Pulmonologists are physicians who treat diseases of the lung, and gastroenterologists and hepatologists are physicians who treat diseases of the liver. We believe that a focused marketing organization and a specialized sales force can effectively serve these physicians, who are both hospital and community based, and are concentrated in major metropolitan areas.

*Increase sales of marketed products.* Actimmune is approved by the FDA for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. We believe that our strategic partnership with Boehringer Ingelheim International GmbH to develop and commercialize Imukin, Boehringer Ingelheim International's tradename for interferon gamma-1b, outside the United States, Canada and Japan, has the potential to provide us with royalty revenues. In January 2002, we announced the relaunch of Infergen for the treatment of chronic hepatitis C infections. We believe that the unmet need for effective, chronic hepatitis C infection treatments provides a significant opportunity for revenue growth.

*Invest in applied research to develop new products and bring them to market.* In 2002, we established, and are continuing to develop, an internal applied research group focused on the preclinical development of compounds that are 6 to 24 months from human testing. The applied research group seeks to validate early stage product candidates, characterize and optimize compounds and advance them to clinical development. In addition, this group will explore additional formulations and mechanisms of action to enable us to further develop our marketed and late-stage products. We are building basic biology and chemistry labs, forming a scientific advisory board and continuing to add significant personnel with research expertise.

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

Our lead product, Actimmune, is approved by the FDA for the treatment of two rare congenital disorders: chronic granulomatous disease and severe, malignant osteopetrosis. We believe that our most significant near-term opportunity is for Actimmune in the treatment of idiopathic pulmonary fibrosis, which we estimate to afflict approximately 75,000 persons in the United States. We recently reported data from our Phase III clinical trial of Actimmune for the treatment of this disease. We are also conducting or planning additional clinical trials of Actimmune for the treatment of ovarian cancer, non-Hodgkin's lymphoma, liver fibrosis, cryptococcal meningitis and invasive aspergillosis. We have rights

to develop and commercialize Actimmune for a broad range of diseases in the United States, Canada and Japan, and we are collaborating with Boehringer Ingelheim, which has similar rights in Europe and the rest of the world, to develop and commercialize interferon gamma-1b under the trade name Imukin. See "License and Other Agreements."

The active ingredient in Actimmune is interferon gamma-1b. Interferons, such as interferon gamma-1b, are human proteins that are produced in response to a variety of disease conditions. Interferon gamma is a unique human protein that has pleiotropic effects, meaning that it acts by multiple mechanisms. Because the molecule functions by multiple mechanisms, it has multiple therapeutic activities. Some of the effects of interferon gamma include stimulation of the immune system, interfering with the process of fibrosis and blocking the replication of viruses. Interferon gamma also has demonstrated an excellent safety profile.

Actimmune performs several important activities in the human body. For example, Actimmune regulates the activity of the body's scar-forming cells, called fibroblasts. Actimmune directly blocks the multiplication of fibroblasts and also inhibits the production and action of TGF-beta, a potent scar-inducing molecule. The result of these actions is the prevention of excessive scarring, which is known as anti-fibrotic activity. The anti-fibrotic activity of Actimmune has been demonstrated in both preclinical studies and in clinical trials.

Another of Actimmune's important activities in the body is to activate the immune system by stimulating a class of immune cells known as macrophages. This action results in increased killing and removal of infectious organisms, such as bacteria and fungi. We believe that interferon gamma-1b may have the broadest range of therapeutic activity in bacterial and fungal diseases of any protein yet identified.

*Chronic granulomatous disease.* Actimmune is currently approved for the treatment of chronic granulomatous disease (CGD), 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 the treatment of CGD based on its ability to reduce the frequency and severity of serious infections associated with this disease. In clinical trials, patients treated with Actimmune had 67% fewer disease-related infections and hospitalizations compared to the placebo group. There are approximately 400 patients with CGD in the United States, and Actimmune is the only FDA approved drug for the disease.

*Severe, malignant osteopetrosis.* Actimmune is approved for the treatment of severe, malignant osteopetrosis, a life-threatening, congenital disorder that results in increased susceptibility to infection and an overgrowth of bony structures that may lead to blindness and/or deafness. The FDA approved Actimmune for the treatment of this disease in February 2002. Severe, malignant osteopetrosis primarily affects children, and Actimmune is the only FDA approved drug for this disease. We estimate that there are approximately 400 patients with severe, malignant osteopetrosis in the United States for whom treatment with Actimmune may be appropriate.

*Idiopathic pulmonary fibrosis.* Idiopathic pulmonary fibrosis is a disease characterized by progressive scarring, or fibrosis, of the lungs, which leads to their deterioration and destruction. The cause of idiopathic pulmonary fibrosis is unknown, and currently there is no FDA approved effective treatment. The prognosis is poor for patients with idiopathic pulmonary fibrosis, which occurs primarily in persons 40 to 70 years old. Most patients die from progressive loss of lung function. The median life span for patients suffering from idiopathic pulmonary fibrosis is approximately 2.8 years from the time of diagnosis.

Treatment options for idiopathic pulmonary fibrosis are limited and only minimally, if at all, effective. Attempted drug therapies include high dose corticosteroids and immunosuppressant



anti-cancer drugs, both of which are minimally effective and may result in significant adverse side effects. For these reasons, treatment with corticosteroids and immunosuppressant anti-cancer drugs is not recommended for patients with idiopathic pulmonary fibrosis. As a last resort, a small percentage of patients undergo lung transplantation, but donors are limited, and many patients die while awaiting a transplant.

*Our Phase III clinical trial.* In August 2002, we reported data from our Phase III clinical trial of Actimmune for the treatment of patients with documented idiopathic pulmonary fibrosis who have not responded to previous treatment with corticosteroids and who have evidence of deteriorating lung function. A total of 330 patients were randomized into this double-blind, placebo-controlled trial conducted at 58 centers around the United States and Europe. Patients received either placebo or 200 micrograms of Actimmune injected subcutaneously 3 times per week. Patients were to remain in the trial until 48 weeks after the 306<sup>th</sup> patient was enrolled. Median treatment duration was 60 weeks. The primary endpoint of the clinical trial was progression-free survival time defined as any one of the following: (i) a decrease in percent predicted forced vital capacity (FVC) of greater than or equal to 10%, (ii) an increase in A-a gradient of greater than or equal to 5 mmHg or (iii) death. Secondary endpoints of the trial included dyspnea, individual measures of pulmonary function and gas exchange, oxygen use and survival.

Final results from the trial 48 weeks after the 306<sup>th</sup> patient was enrolled (representing a 60 week median observation period as of June 26, 2002) showed that Actimmune did not demonstrate statistically significant efficacy with respect to the primary or secondary endpoints of the trial. The analysis of survival, a secondary endpoint in this trial, suggested that although Actimmune did not demonstrate a statistically significant increase in survival in the overall patient group, it may provide a survival benefit for patients with mild-to-moderate impairment in lung function.

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% decrease in mortality in favor of Actimmune versus placebo ( $p = 0.084$ ). In an exploratory analysis of the 254 patients with mild-to-moderate disease ( $FVC \geq 55$  percent), there were 6/126 deaths in the Actimmune-treated group (4.8%) and 21/128 deaths in the placebo group (16.4%), representing a 70% decrease in mortality in favor of Actimmune versus placebo ( $p = 0.004$ ).

An exploratory analysis of survival was conducted in the pre-specified cohort of idiopathic pulmonary fibrosis patients who received greater than or equal to 80% of their scheduled doses at the earliest time of death, or by June 26, 2002. Among these patients, which constituted over 80% of randomized patients in the Phase III clinical trial, there were 6/126 deaths in the Actimmune-treated group (4.8%) compared to 20/143 deaths in the placebo group (14.0%), representing a 66% relative reduction in mortality in favor of Actimmune ( $p=0.017$ ).

We continued to follow patients in the study for three to five additional months beyond the pre-specified analysis of the Phase III clinical trial in June 2002. In the overall intent-to-treat patient population through the follow-up period, there were 26/162 deaths in the Actimmune-treated group (16.0%) compared to 36/168 deaths in the placebo group (21.4%), representing a 25% relative reduction in mortality in favor of Actimmune ( $p = 0.17$ ).

Exploratory subgroup analyses from this follow-up period continue to suggest that Actimmune may have a more favorable effect in patients with mild-to-moderate idiopathic pulmonary fibrosis. In those patients with  $FVC \geq 55$  percent at study entry, there were 13/126 deaths in the Actimmune-treated group (10.3%) versus 26/128 deaths in the placebo group (20.3%), representing a 49% relative reduction in mortality in favor of Actimmune ( $p = 0.02$ ). In those patients with  $FVC \geq 60\%$  at study entry, there were 10/90 deaths in the Actimmune-treated group (11.1%) versus 16/92 deaths in the placebo group (17.4%), representing a 36% relative reduction in mortality in favor of Actimmune

( $p=0.15$ ). For the  $FVC \leq 55\%$  and  $FVC \leq 60\%$  subgroups, the  $p$  values were 0.45 and 0.61, respectively.

We believe these data continue to support the suggestion of a mortality benefit in mild-to-moderate idiopathic pulmonary fibrosis patients. Generally, before granting a marketing approval of a drug for the treatment of a disease, the FDA requires that the drug demonstrate safety and statistically significant efficacy with respect to the primary and/or secondary endpoints of the clinical trial. We therefore believe that the FDA will require us to conduct an additional Phase III clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis prior to approving Actimmune for the treatment of idiopathic pulmonary fibrosis.

In the Phase III clinical trial, Actimmune was generally well-tolerated with few discontinuations due to adverse events; however, there were a greater number of non-fatal pneumonias in the Actimmune-treated group versus the placebo group. A majority of patients involved in the trial elected to roll over to the optional open-label extension study to be followed for at least 12 months.

*Idiopathic pulmonary fibrosis market.* We believe that there are approximately 75,000 patients with idiopathic pulmonary fibrosis in the United States, approximately two-thirds of which have the mild-to-moderate form of the disease. In addition, if Actimmune is determined to be a safe and effective treatment for the treatment of idiopathic pulmonary fibrosis, it may also have potential to treat some other forms of pulmonary fibrosis, including fibrosis caused by sarcoidosis, radiation, some environmental exposures and connective tissue diseases such as scleroderma.

*Ovarian cancer.* Ovarian cancer is the third most common cancer in women, afflicting approximately 105,000 women and causing approximately 14,000 deaths in the United States per year. We believe that approximately 25,000 new cases are diagnosed annually in the United States. Current treatment with chemotherapy is suboptimal, with a five-year survival rate of only 44%. In preclinical *in vitro* and *in vivo* studies, interferon gamma-1b has been shown to be directly toxic to ovarian cancer cells and to stimulate the body's immune system to enhance the removal of cancer cells. A European study of 148 women published in the March 2000 issue of *The British Journal of Cancer* showed that the addition of interferon gamma-1b to chemotherapy delayed the time to disease progression from an average of 17 months to 48 months. We are currently conducting a Phase III clinical trial of interferon gamma-1b in combination with carboplatin and paclitaxel for the first-line treatment of ovarian cancer in women who have undergone surgical resection.

*Cryptococcal meningitis.* See "Systemic fungal infections" below.

*Non-Hodgkin's lymphoma.* Non-Hodgkin's lymphoma, a group of cancers that affect the lymph system, afflicts approximately 285,000 patients in the United States and is the sixth most common cancer and the fifth most common cause of cancer death in the United States. Treatment with standard anti-cancer drugs is often ineffective and results in a high percentage of patients with relapsed or refractory disease. Rituximab, a drug developed and co-promoted by Genentech, Inc. and IDEC Pharmaceuticals Corporation, is the current standard of care for the treatment of relapsed or refractory, low-grade or follicular, B-cell non-Hodgkin's lymphoma, which affects approximately 75,000 patients in the United States. Rituximab works by binding to CD20 receptors, which are over-abundant on non-Hodgkin's lymphoma cells, and by attracting immune-effector cells that kill the cancer cells by a process called antibody dependent cellular cytotoxicity. Several preclinical studies have found that interferon gamma-1b increases the number of CD20 receptors on cancer cells and increases the activity of the antibody dependent cellular cytotoxicity process. Based on these studies, we believe that the addition of Actimmune to rituximab therapy may enhance the elimination of cancer cells. We have initiated a Phase II clinical trial of interferon gamma-1b in combination with rituximab for the treatment of relapsed or refractory, low-grade or follicular, B-cell non-Hodgkin's lymphoma.

**Liver fibrosis.** Liver fibrosis is a life-threatening disease characterized by excessive scarring of the liver, typically caused by chronic hepatitis C infections or alcoholism. Excessive scarring of the liver results in compromised liver function and can cause death. There are almost four million people in the United States who have the antibody to the hepatitis C virus, indicating ongoing or previous infection with the virus. Standard treatment for these patients typically attempts to address only the hepatitis C infection and not the fibrosis caused by hepatitis C infections. Several preclinical studies have demonstrated that interferon gamma-1b may prevent and even reverse the fibrosis that forms in the liver as a result of infections or liver toxins. We are conducting a 500-patient, multi-center, randomized, placebo-controlled Phase II clinical trial of interferon gamma-1b for the treatment of liver fibrosis in patients with chronic hepatitis C infections who have failed prior anti-viral treatment.

**Systemic fungal infections.** Systemic fungal infections are life-threatening diseases caused by various fungi that attack patients with weakened immune systems. Two systemic fungal infections that we are targeting are cryptococcal meningitis, an infection of the lining of the brain, and invasive aspergillosis, an infection that occurs in people with suppressed or deficient immune function. Currently available therapies for these infections are often ineffective and may result in serious adverse side effects. Mortality from systemic fungal infections remains high. There are approximately 200,000 patients diagnosed with systemic fungal infections in the United States each year. There is a clear need for new, effective and less toxic drugs to treat them. Recent research results support the potential benefit of combining interferon gamma-1b with conventional antifungal therapy, such as amphotericin B, in the treatment of several of the most prevalent types of systemic fungal infections. Because interferon gamma-1b works by acting directly on the immune system, we believe that new antifungal agents will also have greater efficacy when combined with interferon gamma-1b.

**Cryptococcal meningitis.** We conducted a Phase II clinical trial designed to determine dose and efficacy of interferon gamma-1b in combination with amphotericin B for the treatment of cryptococcal meningitis. The current standard of care is treatment with amphotericin B followed by fluconazole. In December 2001, we announced positive results from this clinical trial. The addition of interferon gamma-1b to the standard regimen showed a strong trend toward more rapid clearance of cryptococcus fungus from cerebral spinal fluid, when compared with conventional anti-fungal therapy alone. After two weeks of treatment, fungal cultures in the cerebral spinal fluid were negative in 38% of patients who received interferon gamma-1b as adjunctive therapy as compared to 18% of placebo recipients. We initiated a Phase III clinical trial of interferon gamma-1b for the treatment of cryptococcal meningitis in 2002.

**Invasive aspergillosis.** The National Institute of Health is currently conducting a Phase II clinical study of interferon gamma-1b for the treatment of invasive aspergillosis.

#### **Next-generation interferon gamma**

We have a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc., to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than interferon gamma-1b. We plan to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. See "License and other Agreements—Maxygen (next-generation interferon gamma)."

#### **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 demonstrates the ability to kill most strains of bacteria, while other glycopeptides and many

other agents merely suppress them. Oritavancin may be effective in the treatment of a range of infections caused by gram-positive bacteria.

We are currently completing a second Phase III clinical trial with oritavancin for the treatment of complicated skin and skin-structure infections. If this clinical trial is successful, we intend to file a new drug application with the FDA in the first quarter of 2004. We are also considering clinical trials with oritavancin for the treatment of other gram-positive bacterial infections, including those resistant to conventional antibiotics, for which oritavancin may also be effective.

We have worldwide rights to oritavancin.

*Complicated skin and skin-structure infections.* Each year, there are nearly 2.5 million cases of skin and skin-structure infections in the United States and approximately 400,000 patients with complicated skin and skin-structure infections who require hospitalization. As drug resistance in hospitals and the community increases, we believe that skin and skin-structure infections will more frequently develop into complicated skin and skin-structure infections that require hospitalization. Complicated skin and skin-structure infections are often treated by vancomycin followed by oral cephalexin.

In December 2001, we announced results of a Phase III clinical trial demonstrating that oritavancin reduced the treatment time by half for complicated skin and skin-structure infections as compared to the current standard of care by eliminating the need for follow-up therapy with oral antibiotics. In the Phase III clinical trial, oritavancin was shown to be safe, well-tolerated and as effective as the standard therapy of vancomycin followed by cephalexin.

*Bacteremia.* Bacteremia is a disease characterized by the presence of bacteria in the blood. Short-term bacteremia follows dental or surgical procedures, especially if local infection or very high-risk surgery releases bacteria from isolated sites. In some cases, prior antibiotic therapy can prevent this. Bacteremia causes little problem to a healthy immune system, but can be serious for those with prostheses or high susceptibility to bacterial invasion. Extensive bacteremia can release toxins into the blood (septicemia), leading to shock and vascular collapse. Antibiotic-resistant bacteria have increased the rate of severe bacteremia. There are approximately 500,000 cases of bacteremia each year. In July 2000, Eli Lilly initiated a Phase II clinical trial of oritavancin for the treatment of bacteremia. We do not plan to seek FDA approval of oritavancin specifically for the treatment of bacteremia. However, we plan to complete this clinical trial and include the results in future FDA filings related to oritavancin.

*Nosocomial pneumonia.* Nosocomial, or hospital-acquired, pneumonia is the second most common hospital-acquired infection in the United States. Nosocomial pneumonia typically develops in debilitated patients who have been exposed to an array of increasingly difficult to treat pathogens while hospitalized for moderate-to-severe medical or surgical conditions that compromise respiratory tract function and normal host defenses. There are approximately 1.2 million cases of nosocomial pneumonia each year in the United States. Nosocomial pneumonia has the highest mortality rate of all hospital-acquired infections and increases the length of hospital stay from 6 to 30 days. We intend to initiate a Phase II/III clinical trial for oritavancin for the treatment of nosocomial pneumonia in 2004.

In addition to the diseases listed above, we believe that, due to its bactericidal characteristics, resistance profile and safety profile, oritavancin may have the potential to treat additional diseases, including:

- endocarditis, an inflammation of the inside lining of the heart chambers and heart valves;
- osteomyelitis, an infection in the bones;
- meningitis, an inflammation of the membranes covering the brain and spinal cord;
- septic arthritis, an inflammation of the joints; and
- febrile neutropenia, an infection characterized by abnormally low levels of infection-fighting white blood cells and fever.

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

Infergen is FDA approved for the treatment of adult patients with chronic hepatitis C infections, including those patients who have never been treated with interferons, who relapse or who do not respond to previous hepatitis C infection treatments. Almost four million Americans have the antibody to the hepatitis C virus, indicating ongoing or previous infection with the virus. If undetected and untreated, hepatitis C infections can lead to chronic liver disease, including liver cancer and liver fibrosis. Hepatitis C infections are the second leading cause of liver cirrhosis and the leading indication for liver transplantation in the United States. As a result of persistent infection and progressive liver damage, an estimated 8,000 deaths are attributable to chronic hepatitis C infections in the United States annually. Infergen is the only interferon with data in the label for treatment of patients who have failed other hepatitis C infection treatments.

*In vitro* data have shown that interferon alfacon-1 has cytopathic activities superior to other interferon alpha agents. Infergen has demonstrated anti-viral, anti-proliferative and natural killer cell and interferon-gene induction activities. In November 2002, we announced preliminary results from a head-to-head Phase IV clinical trial that show Infergen plus ribavirin to be more effective than Rebetron® (interferon alfa-2b plus ribavirin) for the treatment of patients with chronic hepatitis C infections. The side effects associated with Infergen plus ribavirin in this trial were similar to those seen with Rebetron and included flu-like symptoms, fatigue, headache, nausea, cough and mood disorders such as depressed mood, anxiety, irritability and insomnia. We believe that Infergen's characteristics and the Phase IV clinical data provide evidence that Infergen could be superior to other interferon alpha products.

In January 2002, we relaunched Infergen through our sales force. We have the exclusive rights to market Infergen in the United States and Canada.

### **PEG-Infergen**

To further expand upon the limited treatments for hepatitis C infections, we are developing of a pegylated form of Infergen, PEG-Infergen, which is being designed to offer patients an alternative therapy with less frequent dosing. In January 2003, we initiated a Phase I clinical trial to evaluate PEG-Infergen as a potential treatment for chronic hepatitis C infections.

Pegylated interferon alpha products may offer advantages over non-pegylated products because they circulate longer in the body. We believe that increasing Infergen's circulation time in the body will permit a less frequent dosing schedule and will enhance its anti-viral effects by maintaining therapeutic concentrations in the body for a longer period of time. We are using an optimized pegylation technique based upon technological advances learned from the pegylation of other interferon alpha products. We believe that PEG-Infergen may be superior to other pegylated interferon alpha products based upon the pegylation technology and Infergen's demonstrated greater anti-viral activity when compared to other interferon alpha products.

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

Amphotec is an FDA approved lipid-form of amphotericin B indicated for the treatment of invasive aspergillosis in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate in effective doses, and in patients with invasive aspergillosis where prior amphotericin B deoxycholate has failed. Systemic fungal infections that do not respond to initial treatment with standard antifungal treatment regimens are typically treated with amphotericin B, the active ingredient in Amphotec. We estimate that there are approximately 200,000 cases of systemic fungal infections each year in the United States. Worldwide sales of all amphotericin B-based products are approximately \$350 million per year. This product is approved in the United States under the name

Amphotec and under the name Amphotec® in more than 40 other countries. Amphotec was not actively marketed to physicians in the United States for the three years prior to our relaunch in January 2002.

### **Pirfenidone**

Pirfenidone is an orally active small molecule drug that appears to inhibit collagen synthesis, down-regulate production of multiple cytokines and block fibroblast proliferation and stimulation in response to cytokines. Pirfenidone, which may have activity in multiple fibrotic indications, is currently in Phase II clinical development for the treatment of pulmonary fibrosis, renal fibrosis, hypertrophic cardiomyopathy, hepatic cirrhosis and radiation-induced fibrosis. These clinical trials were initiated by parties other than InterMune and were underway at the time we acquired rights to pirfenidone, although we are now responsible for conducting them. We will be required to file our own investigational new drug application (IND) prior to commencing further clinical trials for pirfenidone. We are in the process of completing the 55-patient proof-of-concept Phase II clinical trial of pirfenidone in pulmonary fibrosis to collect preliminary safety and efficacy data. If these data are positive, we plan to accelerate the design and implementation of a larger-scale registrational program.

We have worldwide rights to pirfenidone, excluding Japan, Korea and Taiwan.

### **License and Other Agreements**

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

In 1998, we obtained a license under Genentech's patents relating to interferon gamma-1b. The license from Genentech terminates on the later of May 5, 2018 and the date that the last of the patents licensed under the agreement expires. Our licensed Actimmune rights include exclusive and non-exclusive rights under Genentech's patents. 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 rights include a license 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 chronic granulomatous disease 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 Boehringer Ingelheim International agreement discussed below. Under the Genentech license, we pay Genentech royalties on the sales of Actimmune, and make one-time payments to Genentech upon the occurrence of specified milestone events. We must satisfy specified obligations under the agreement with Genentech to maintain our license from Genentech. We are obligated under the agreement to develop and commercialize Actimmune for a number of diseases. Our rights to interferon gamma-1b under this agreement could revert to Genentech if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

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

In 2001, we formed an international strategic collaboration with Boehringer Ingelheim International (BI International) to clinically develop and seek regulatory approval for interferon gamma-1b in certain diseases and to commercialize a liquid formulation of interferon gamma-1b under one or more of BI International's trade names, including Imukin, in Europe and other major markets of the world (other than the United States, Canada and Japan). Under the agreement, the parties will seek to develop and obtain regulatory approval for the use of Imukin in the treatment of a variety of

diseases, including idiopathic pulmonary fibrosis, non-Hodgkin's lymphoma, liver fibrosis, ovarian cancer, tuberculosis, systemic fungal infections, chronic granulomatous disease and osteopetrosis. The agreement provides that we will fund and manage clinical and regulatory development of interferon gamma-1b for these diseases in the countries covered by the agreement. BI International has an option to exclusively promote Imukin in all of the major market countries covered by the agreement, and we may opt to promote the product in those countries and for those new diseases for which BI International does not do so. Both companies will receive royalties on sales of the product the other party makes in its own territory, on a specified royalty schedule.

*Eli Lilly and Company (oritavancin)*

In 2001, we entered into an asset purchase and license agreement with Eli Lilly pursuant to which we acquired worldwide rights to oritavancin from Eli Lilly. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. If we wish to enter into a relationship with a third party to commercialize oritavancin in any country, however, we must first offer Eli Lilly the opportunity to enter into such a commercialization relationship with us. After we negotiate with Eli Lilly, the agreement prohibits us from entering into an agreement with a third party on more favorable terms than those we offered to Eli Lilly. Pursuant to the agreement, we paid Eli Lilly \$50.0 million and will be obligated to pay Eli Lilly significant milestone and royalty payments upon our successful development and commercialization of oritavancin. In September 2002, Eli Lilly exercised its option under the agreement to reduce the agreed percentage of royalty payable by us to Eli Lilly upon successful commercialization of oritavancin. The exercise of this option required us to pay \$15.0 million to Eli Lilly. Our rights to oritavancin could revert to Eli Lilly if we do not meet our diligence obligations under the agreement or otherwise commit a material breach of the agreement. Additionally, if we are acquired by a company with a certain type of competing program and Eli Lilly has notified us prior to the acquisition that it believes in good faith that its economic interests in oritavancin under the agreement will be harmed in light of the acquisition, Eli Lilly may terminate the agreement and our rights to oritavancin would revert to Eli Lilly. In any event, we may not assign the agreement to a potential acquirer without the advance, written consent of Eli Lilly.

*Amgen Inc. (Infergen and PEG-Infergen)*

In 2001, we entered into a licensing and commercialization agreement with Amgen Inc. to obtain an exclusive license in the United States and Canada to Infergen (interferon alfacon-1), an interferon alpha product, and the rights to an early stage program to develop a pegylated form of Infergen (PEG-Infergen). Infergen is currently approved in both the United States and Canada to treat chronic hepatitis C infections. Under the agreement, we will have the exclusive right to market Infergen and clinically develop it for other indications in the United States and Canada. We have paid Amgen total consideration of \$29.0 million (including up-front license and other fees and milestones) and are obligated to pay royalties on sales of Infergen. We are also required to pay Amgen other milestone payments on our PEG-Infergen program and royalties on sales of the resulting product, if any. Our rights to Infergen could revert to Amgen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

*ALZA Corporation (Amphotec)*

In 2001, we acquired worldwide rights from ALZA to Amphotec (sold under the tradename Amphocil in certain countries outside the United States). The transaction terms included an up-front product acquisition fee of \$9.0 million, milestone payments based upon sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune, and royalties payable upon net sales of Amphotec. Under the agreement, we obtained access to certain existing distributorships for Amphotec and assumed ALZA's obligations under

agreements with its existing Amphotec distributors and service providers. We have diligence obligations under the agreement to set up additional distributorships for Amphotec or establish a sales force and begin to promote Amphotec in specified countries at specified times. Our rights to Amphotec could revert to ALZA if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. We are also subject to certain royalty obligations to the University of California under this agreement.

*Connetics Corporation (Actimmune)*

Through an assignment and option agreement with Connetics, we are obligated to pay to Connetics a royalty of 0.25% of our net U.S. sales for Actimmune until our net U.S. sales cumulatively surpass \$1.0 billion. Above \$1.0 billion, we are obligated to pay a royalty of 0.5% of our net U.S. sales of Actimmune.

Through a separate purchase agreement, we are obligated to pay Connetics a royalty of 4.0% on our net sales of Actimmune for the treatment of scleroderma.

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

In March 2002, we licensed from Marnac, a privately held biopharmaceutical company, 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 terms of the license agreement, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of \$18.8 million and future milestone and royalty payments. Our rights to the licensed products under the agreement could revert to Marnac if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

*Maxygen Holdings Ltd. (next-generation interferon gamma)*

We have a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc., to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens than interferon gamma-1b. We plan to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. We are funding Maxygen's optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. The terms of the agreement include up-front license fees, full research funding and development and commercialization milestone payments. In addition, Maxygen will receive royalties on product sales. Our rights to the licensed products under the agreement could revert to Maxygen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

**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 Supply Agreement (Actimmune)*

In 2000, we entered into an agreement with Boehringer Ingelheim Austria (BI Austria) for the clinical and commercial supply of Actimmune. The supply agreement with BI Austria generally provides for the exclusive supply by BI Austria and exclusive purchase by us of interferon gamma-1b. We are required to purchase a minimum amount of Actimmune per year, and BI Austria is required to supply



Actimmune to us, subject to certain limits. If BI Austria is not able to supply all of our requirements for interferon gamma-1b, we may choose an additional manufacturer. However, we are not entitled to seek such a secondary source until BI Austria has informed us of its unwillingness or inability to meet our requirements.

*Abbott Laboratories, Inc. Development and Supply Agreement (oritavancin)*

In 2001, we entered into an agreement with Abbott to provide the bulk manufacturing of oritavancin. The agreement will provide us with additional clinical supply, commercial scale-up and production to meet significant commercial quantities after the launch of oritavancin, which we expect to be in 2005. Under the agreement, Abbott will be responsible for the technology transfer of the manufacturing process of oritavancin from Eli Lilly. Abbott will also be responsible for providing the necessary chemical manufacturing control information for our oritavancin regulatory filings with the FDA.

*Amgen Inc. Supply Agreement (Infergen)*

Under our June 2001 agreement with Amgen through which we license Infergen, Amgen is obligated to manufacture and supply Infergen to us for our sales in the United States and Canada.

*Ben Venue Laboratories Supply Agreement (Amphotec)*

We presently have an agreement with Ben Venue for the manufacture of Amphotec for all purposes. We are negotiating a new agreement.

**Patents and Proprietary Rights**

We have acquired a license under certain Genentech patents to develop, make, use and sell interferon gamma-1b, the active ingredient in Actimmune, in particular fields in the United States, Canada and Japan under our license agreement with Genentech. This license agreement covers more than 12 U.S. patents and related foreign patents and/or patent applications filed in Japan and Canada. Certain of the U.S. patents covering DNA vectors and host cells relating to interferon gamma-1b expire in 2005 and 2006. In addition, a U.S. patent relating to the composition of interferon gamma-1b expires in 2014. Other material U.S. patents expire between 2009 and 2013.

We have acquired a license under certain Amgen patents to develop, use and sell Infergen in the United States and Canada and to develop new forms of Infergen's active ingredient, interferon alfacon-1, including pegylated forms of interferon alfacon-1, under our license and commercialization agreement with Amgen. The license and commercialization agreement covers nine U.S. patents, one Canadian patent and several pending patent applications. Two of Amgen's U.S. patents relating to interferon alfacon-1 expire in 2004. However, the U.S. Patent and Trademark Office recently issued a Certificate of Extension of Patent Term, officially extending the term of this patent by five years to 2009. This extension will enable us to exclude others from using interferon alfacon-1 until 2009 for the treatment of chronic hepatitis C infections. After expiration of the extended patent term in 2009, we will rely on a U.S. patent, which expires in 2011, related to the use of interferon alfacon-1 at a dose within the range of 2 million to 30 million units of interferon alfacon-1 per administration for the treatment of chronic hepatitis C infections to block others from marketing the interferon alfacon-1 for the treatment of chronic hepatitis C infections at these doses.

We have acquired a license under certain Eli Lilly patents to develop, make, use and sell oritavancin worldwide for any human disease under an asset purchase and license agreement with Eli Lilly. This agreement covers 38 U.S. patents, one U.S. patent application and corresponding foreign patents and patent applications. Certain U.S. and foreign patents related to the oritavancin molecule expire in 2015. Other material patents included in the licensed portfolio expire between 2014 and 2018.

We have acquired certain ALZA patents and patent applications relating to the manufacture, use and sale of Amphotec in particular fields worldwide under our product acquisition agreement with ALZA. In January 2001, ALZA assigned to us three U.S. patents and 14 related foreign patents. Two of the patents relating to the composition of Amphotec expire in 2007. The third patent relating to a method of using Amphotec to treat fungal infections expires in 2008.

We have acquired a license under certain Marnac/KDL patents and patent applications relating to the manufacture, use and sale of pirfenidone for antifibrotic use worldwide, excluding Japan, Korea and Taiwan. The Marnac/KDL patent in the United States will expire in 2011. When this patent expires in 2011, we will not be able to use this patent to block others from marketing pirfenidone for the treatment of fibrotic disorders in the United States.

### Competition

Actimmune is the only FDA approved therapy for chronic granulomatous disease and severe, malignant osteopetrosis.

There is no FDA approved therapy available for the treatment of idiopathic pulmonary fibrosis. We believe that the primary competition for Actimmune, if approved by the FDA for the treatment of idiopathic pulmonary fibrosis, will initially consist of products that are approved for other indications and for which clinical development for idiopathic pulmonary fibrosis is contemplated or underway, such as Enbrel® (etanercept), Gleevec® (imatinib mesylate) and Tracleer® (bosentan).

In the area of cancer and liver fibrosis, there are numerous programs and products that may have a significant competitive impact on our ability to effectively market Actimmune for the treatment of these diseases.

Infergen competes with other forms of interferon alpha, such as PEG-Intron® and Intron A®, which are marketed by Schering-Plough Corp., and Pegasys® and Roferon-A®, which are marketed by Roche Laboratories Inc. These competitive products, which are marketed in combination with ribavirin, dominate the chronic hepatitis C infection market. Pegylated interferon alpha products, such as PEG-Intron and Pegasys, may have an advantage over non-pegylated products because they circulate longer in the body, permitting a less frequent dosing schedule and enhancing efficacy in some patients infected with the hepatitis C virus.

If approved for marketing by the FDA, oritavancin will compete against Eli Lilly's Vancocin® and generics such as vancomycin. In addition, Pharmacia's Zyvox® and Aventis' Synercid® are approved for vancomycin-resistant *Enterococcus faecium* infections, as well as other indications. Two potentially competitive products in late-stage development are daptomycin, by Cubist Pharmaceuticals, Inc., and dalbavancin, by Versicor Inc.

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

### Sales, Marketing and Distribution

We are developing a sales and marketing organization to support the approximately 8,000 pulmonologists who treat lung disease and 10,000 gastroenterologists and hepatologists who treat liver disease. We believe a focused marketing organization and a specialized sales force can effectively address these physician audiences, who are primarily concentrated in major metropolitan areas. Accordingly, as of January 2003, we had placed 80 specialists into the field to educate physicians regarding the safe and appropriate use of our products. We heighten awareness of our products through physician education, including medical symposia and continuing medical education programs.

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, 2002, the primary specialty pharmacies and distributors for our products were Priority Health Care, Merck Medco and Caremark, who accounted for 57%, 11% and 10%, respectively, of our total net product sales. In Europe and other parts of the world, Amphotec is sold through a number of distributors and agents.

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
United States . . . . .	\$109,537	\$37,838	\$11,201
Rest of world . . . . .	2,428	2,113	—
Totals . . . . .	<u>\$111,965</u>	<u>\$39,951</u>	<u>\$11,201</u>

**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 as drugs by the FDA.

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

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

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

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

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

- Phase I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase II: Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical study sites. It is not uncommon for a drug that appears promising in a Phase II clinical trial to fail in a more rigorous and reliable Phase III clinical trial.

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

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

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

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

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

The FDA's fast track program is intended to facilitate the development and expedite the review of drugs intended for the treatment of serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs for such conditions. Under this program, the FDA can, for

example, review portions of a BLA or NDA for a fast track product 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 idiopathic pulmonary fibrosis and intend to ask for fast track designation for qualified submissions of our other products. We cannot guarantee that the FDA will grant any of our additional requests for fast track designation, that any fast track designation will affect the time of review, or that the FDA will approve the BLA or NDA submitted for any of our product candidates, whether or not fast track designation is granted. Additionally, the FDA's approval of a fast track product can include restrictions on the product's use or distribution, such as permitting use only for specified medical procedures or limiting distribution to physicians or facilities with special training or experience. Approval of fast track products can be conditional with a requirement for additional Phase IV clinical trials after approval.

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

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with these products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with 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 do not market Actimmune for the treatment of idiopathic pulmonary fibrosis, and the FDA has not approved the use of Actimmune for the treatment of this disease. However, we are aware that physicians are prescribing Actimmune for the treatment of idiopathic pulmonary fibrosis. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use. Companies cannot promote FDA approved drugs for off-label uses. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. Failure to comply with these requirements can result in regulatory enforcement action by the FDA, which would have an adverse effect on our revenues, business and financial prospects.

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

existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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

#### Research and Development

We direct financial resources efficiently to goal-oriented projects by reducing the time and infrastructure spent on research and development. We established an in-house applied research group in 2002 to conduct applied research. We also currently contract preclinical research to qualified third-party research institutions such as academia or private contract labs. Our research and development expenses were \$129.6 million, \$52.0 million and \$20.8 million for the years ended December 31, 2002, 2001 and 2000, respectively.

#### Employees

As of March 21, 2003, we had 250 full-time employees. Of the full-time employees, 106 were engaged in research and development, and 144 were engaged in sales, general and administrative positions. We believe our relations with our employees are good.

#### Facilities

All of our facilities and long-lived assets are located in the United States. Our facilities currently consist of 55,898 square feet of office space located at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this building. We believe that this facility has sufficient space to accommodate expansion of our operations until at least the end of the second quarter of 2003. We are currently seeking additional space in vacant facilities near our building.

#### Available Information

We file electronically with the United States Securities and Exchange Commission (SEC) our annual reports on Form 10-K, quarterly interim reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at <http://www.intermune.com>, free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing the information 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 email to [ir@intermune.com](mailto:ir@intermune.com).

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

In December 2002, our board of directors approved and we adopted a formal code of business conduct and ethics applicable to all of our employees, including our chief executive officer, chief financial officer and controller. The purpose of this code is to deter wrongdoing and to promote:

- (1) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- (2) full, fair, accurate, timely and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications that we make;
- (3) compliance with applicable governmental laws, rules and regulations;
- (4) the prompt internal reporting of violations of the code to an appropriate person or persons identified in the code;
- (5) the prompt public disclosure of any waivers under the code granted to any of our executive officers, including our chief executive officer, chief financial officer and controller; and
- (6) accountability for adherence to the code.

The code is available on our Internet website at: [http://media.corporate-ir.net/media\\_files/NSD/itm/itmnetethics.pdf](http://media.corporate-ir.net/media_files/NSD/itm/itmnetethics.pdf). We intend to promptly disclose (1) the nature of any amendment to the code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and (2) the nature of any waiver, including an implicit waiver, from a provision of the code that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our Internet website in the future.

#### **RISK FACTORS**

An investment in our common stock is risky. Stockholders and potential investors in shares of our stock should carefully consider the following risk factors, which hereby update those risks contained in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 that was filed with the SEC on November 14, 2002, 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.

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

We commenced operations in 1998 and have incurred significant losses to date. Our revenues have been limited primarily to sales of Actimmune. Although we are developing Actimmune for the treatment of idiopathic pulmonary fibrosis, ovarian cancer, cryptococcal meningitis, invasive aspergillosis, non-Hodgkin's lymphoma and liver fibrosis, Actimmune will not be marketed for any of these diseases before 2006, if at all. We market Infergen for the treatment of chronic hepatitis C infections, but we do not believe that Infergen will provide significant revenue to us before 2004, if ever. Although Amphotec has received regulatory approvals for commercial sales for invasive aspergillosis, we do not believe that it will provide significant revenue to us in the near future, if ever.

We are developing oritavancin for the treatment of complicated skin and skin-structure infections and bacteremia, are planning a Phase III clinical trial of oritavancin for the treatment of nosocomial pneumonia, and are considering developing oritavancin for the treatment of other gram-positive bacterial infections, but oritavancin will not be marketed for any diseases before 2005, if at all. We are developing PEG-Infergen, a pegylated form of Infergen, for the treatment of chronic hepatitis C infections, but PEG-Infergen will not be marketed for the treatment of chronic hepatitis C infections before 2007, if at all. We are developing pirfenidone for the treatment of anti-fibrotic diseases, but pirfenidone will not be marketed for any diseases before 2008, if at all.

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful.

For example, we recently reported data from our Phase III clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis. The data show that Actimmune did not demonstrate statistically significant efficacy with respect to the primary or secondary endpoints of the Phase III clinical trial, although we believe that the data suggest possible survival benefits for certain patients with a mild-to-moderate form of the disease. We expect to analyze and disclose an additional four months of patient data and to disclose our additional analyses of the data from this Phase III clinical trial. If the additional data or our additional analyses show safety concerns, or do not confirm our survival observations of the initial data, we may decide to delay or stop further development of Actimmune for the treatment of idiopathic pulmonary fibrosis. The cessation of, or a significant delay in, Actimmune development activities for the treatment of idiopathic pulmonary fibrosis would have a material adverse effect on our business prospects and may cause our stock price to drop dramatically. Even if we do not delay or stop Actimmune development activities, any report of clinical trial results that are below the expectations of financial analysts or investors may result in a precipitous decline in our stock price.

We plan to meet with the FDA to discuss the results of this Phase III clinical trial, potential next steps to substantiate our survival observations and the possibility of conducting an additional Phase III trial of Actimmune for the treatment of patients with mild-to-moderate idiopathic pulmonary fibrosis. Generally, before granting a marketing approval of a drug for the treatment of a disease, the FDA requires that the drug demonstrate safety and statistically significant efficacy with respect to the primary and/or secondary endpoints of the clinical trial. We therefore believe that the FDA will require us to conduct an additional Phase III clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis prior to approving Actimmune for the treatment of idiopathic pulmonary fibrosis.

If the FDA requires us to conduct another Phase III clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis, we may not be able to reach agreement with the FDA as to the appropriate protocol for the additional Phase III clinical trial. In addition, even if we were to conduct another Phase III clinical trial, Actimmune may not demonstrate safety or statistically significant efficacy with respect to the primary or secondary endpoints of the protocol of that or any additional clinical trial. If such an additional Phase III clinical trial were to fail to demonstrate statistically significant efficacy, we may abandon the development of Actimmune for the treatment of idiopathic pulmonary fibrosis.



We have conducted other clinical trials that have not had positive results. For example, we terminated our Phase III clinical trial of Actimmune for the treatment of multidrug-resistant tuberculosis after early microbiological results indicated that a standard nebulizer may not be an effective route of administration of Actimmune in patients with multidrug-resistant tuberculosis. We also terminated our Phase II clinical trial of Actimmune administered subcutaneously for the treatment of cystic fibrosis after interim results showed no treatment benefit. Our Phase II clinical trial of Actimmune administered by nebulizer for the treatment of cystic fibrosis was completed, but showed no treatment benefit.

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 our clinical trials may be delayed or halted for numerous reasons, including the following:

- a country's regulatory authority does not approve a clinical trial protocol;
- patients do not enroll in clinical trials at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial for a variety of reasons, including the advanced status of their disease and medical problems that are not related to our products or product candidates;
- third-party clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, and other third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- the results of the clinical trial are inconclusive or negative; or
- sufficient quantities of the trial drug may not be 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 the use of Actimmune for the treatment of idiopathic pulmonary fibrosis will increase as a result of the statistically insignificant results in our recently completed Phase III clinical trial. If the delays are significant, our financial results and the commercial prospects for our products and product candidates will be harmed, and our prospects for profitability will be impaired.

**Our failure to comply with FDA regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained could result in regulatory enforcement action by the FDA, which would harm our business.**

Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those uses tested by us and approved by the FDA. Such off-label uses are common across medical specialties. For example, even though the FDA has not approved the use of Actimmune for the treatment of idiopathic pulmonary fibrosis, we are aware that physicians are prescribing Actimmune for the treatment of idiopathic pulmonary fibrosis and Infeogen in combination with ribavirin for the treatment of chronic hepatitis C infections. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use. Companies may not promote FDA approved drugs for off-label uses. Accordingly, we may not market Actimmune for the treatment of idiopathic pulmonary fibrosis, or Infeogen in combination with ribavirin for the treatment of chronic hepatitis C infections. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. Failure to comply with these requirements can result in regulatory enforcement action by the FDA, which would have an adverse effect on our revenues, business and financial prospects, which would harm our business.

Budget 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 such 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 budget. Accordingly, we may choose to delay our research and development efforts for a promising product candidate to allocate those resources to another valuable 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, as they will be delayed in reaching the market.

**The actual maximum market or peak revenue opportunity associated with our products or product candidates for the treatment of particular diseases may be much lower than our current or future estimates, causing a delay in our ability to become profitable.**

In the course of conducting clinical trials, we may obtain results that require us to significantly revise our initial estimate for the maximum market or peak revenue opportunity for a product or product candidate for the treatment of particular diseases. For example, in light of the data from our recent Phase III clinical trial for Actimmune for the treatment of idiopathic pulmonary fibrosis, we are no longer projecting a peak revenue opportunity of \$400-500 million for Actimmune or achieving profitability in 2004.

In addition, even if our products or product candidates are approved for use in connection with one or more particular diseases, the actual maximum market or peak revenue opportunity for our products or product candidates for each disease may be much less than our estimates. There are a number of reasons why there can be no assurance as to the portion of these maximum market or peak revenue opportunities we will realize, if at all, including 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 is different than currently anticipated;
- the treatment regimen is different in duration than currently anticipated;
- treatment is sporadic;
- we cannot sell a product at the price we expect;
- there are current and future competitive products that have greater acceptance in the markets than our products do; or
- we decide to launch a product, such as oritavancin, in fewer indications than we originally anticipated.

In the future, we may continue to make projections as to the potential market size or peak revenues for our products and product candidates and our anticipated date of profitability, but such projections remain subject to these factors and other risks described in this report.

If the FDA limits our communications with physicians related to the use of our products for any disease or withdraws its approval of any of our products for any disease for which they have been approved, our revenues would decline.

The FDA and foreign regulatory authorities may impose significant restrictions on the use or marketing of our products or impose ongoing requirements for post-marketing studies. Later discovery of previously unknown problems with any of our products or their manufacture may result in further restrictions, including withdrawal of the product from the market. Our existing approvals for disease, 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-marketing commitments. If approval for a disease is withdrawn, we could no longer market the affected product for that disease. In addition, governmental authorities could seize our inventory of such product, or force us to recall any product already in the market, if we fail to comply with FDA or other governmental regulations.

If our clinical trials fail to demonstrate to the FDA and foreign regulatory authorities that any of our products or product candidates are safe and effective for the treatment of particular diseases, the FDA and foreign regulatory authorities will not permit us to market 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 prevent our receipt of the FDA's and other 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 its 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 other regulatory authorities. Preclinical and clinical data can be interpreted by the FDA and other regulators in different ways, which could delay, limit or prevent regulatory approval.

If regulatory delays are significant, 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.

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

We may determine that certain preclinical product candidates or programs do not have sufficient potential to warrant the allocation of resources. Accordingly we may elect to terminate our programs for and, in certain cases, our licenses to such product candidates or programs. For example, we have terminated our current research programs and licenses relating to *Pseudomonas aeruginosa*, *Staphylococcus aureus* and Moli1901 (duramycin) for cystic fibrosis.

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 the scope and breadth of patent claims that may be afforded to other companies' patents. In addition, we could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate these suits.

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

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

Others have filed and in the future may file patent applications covering uses and formulations of interferon gamma-1b, interferon alpha, pegylated versions of these products and other products in our development program. If a third party were issued a patent that blocked our ability to commercialize any of our products for any or all of the diseases that we are targeting, we would be prevented from commercializing that product for that disease or diseases unless we obtained a license from the patent holder. We may not be able to obtain such a license to a blocking patent on commercially reasonable terms, if at all.

Any legal action against our collaborators or us claiming damages and seeking to stop our commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require our collaborators or us to obtain a license to continue to manufacture or market the affected products and processes. We cannot predict whether our collaborators or we 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. We believe that there is and will continue to be significant litigation in our industry regarding patent and other intellectual property rights.

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

We have licensed certain patents relating to Actimmune from Genentech. Certain of the U.S. patents covering DNA vectors and host cells relating to interferon gamma-1b expire in 2005 and 2006. In addition, a U.S. patent relating to the composition of interferon gamma-1b expires in 2014. Other material U.S. patents expire between 2009 and 2013. Six of Genentech's U.S. patents and certain Amgen patent applications were involved in an interference as originally declared by the U.S. Patent and Trademark Office. In May 2002, we purchased the Amgen patent applications involved in the interference. In a decision granting a motion we filed in the interference, the U.S. Patent and Trademark Office redeclared the interference between our (formerly Amgen's) patent applications and only one of the six Genentech patents that were involved in the original interference. As a result, the

claims of the five Genentech patents no longer involved in the interference are not subject to revocation in that interference. Nevertheless, one or more claims of the sole Genentech patent and/or one or more claims of our (formerly Amgen's) patent applications remaining in the interference may be revoked as a result of that interference. However, even if all of the claims in the interference were revoked, we would still retain patent protection for interferon gamma-1b through 2014.

We have licensed certain patents throughout the world relating to oritavancin from Eli Lilly. After patents related to the oritavancin compound expire in 2015, we will not be able to use such patents to block others from marketing oritavancin. In addition, we are aware of two U.S. patents, and corresponding European, Australian, Korean, Canadian and Japanese patents, that relate to a molecule that is produced during the manufacture of oritavancin. A derivative of this molecule is retained in the final oritavancin product. If any of these patents is interpreted to cover the oritavancin manufacturing process, any molecules formed during the manufacturing process or the final oritavancin product itself, we believe that such patent or patents could enable the patent holder to block our ability to commercialize oritavancin unless we obtained a license under such patent or patents. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. If we were not able to obtain such a license under the patents on commercially reasonable terms, or at all, it would have a material adverse effect on our ability to commercialize the oritavancin product.

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

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

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

settlement agreement may have a material adverse effect on our ability to commercialize Infergen in the United States.

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

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

We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements generally provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees and consultants, our agreements generally provide that all inventions made by the individual while engaged by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Under some of our research and development agreements, inventions discovered in certain cases become jointly owned by our corporate partner and us and in other cases become the exclusive property of one of us. It can be difficult to determine who owns a particular invention, and disputes could arise regarding those inventions.

Our research collaborators and scientific advisors have some rights to publish our data and proprietary information in which we have rights. Such publications may impair our ability to obtain patent protection or protect our proprietary information.

We rely on distributors and specialty pharmacies to sell approximately 86% of our product revenue, and currently one specialty pharmacy sells approximately 57% of our product revenue. If those parties do not perform satisfactorily, our business will be harmed.

Approximately 86% of sales of our products are sold through distributors and specialty pharmacies. As a result, our success depends on the continued customer support efforts of our network of distributors and specialty pharmacies. In addition, one specialty pharmacy accounts for approximately 59% of our outstanding receivables and 57% of our total product sales. If this or any other specialty pharmacy or distributor that sells our products were to experience financial difficulties, or otherwise become unable or unwilling to sell our products, our business would be harmed. Additionally any reduction, delay or loss of orders from our significant distributors and specialty pharmacies could harm our revenues.

The use of distributors and specialty pharmacies involves certain risks, including risks that distributors and specialty pharmacies will:

- not effectively sell or support our products;
- reduce its efforts or discontinue to sell or support our products;

- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

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

Our products and product candidates are expensive, and we anticipate that the annual cost for treatment under 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:

- 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;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

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

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

- governmental payors, such as Medicare and Medicaid;
- private health insurers, including managed care organizations; and
- other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of pharmaceutical products. 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 for only FDA approved indications.

**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 products. For example, in some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to governmental control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost-control initiatives could decrease the price that we would receive for

Actimmune, Infergen, Amphotec or any other products we may develop in the future, such as oritavancin or piperfenidone, which would reduce our revenues and potential profitability.

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

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to 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. We seek to comply with the safe harbors. 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 and willingly 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 sale and marketing of its products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on us, including our stock price. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

**Discoveries or developments of new technologies by established drug companies or others may make our products obsolete.**

Our commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the diseases that we target that:

- 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 than our products or product candidates.

Even if we are successful in developing effective drugs, our products may not compete effectively with our competitors' products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. Our competitors may succeed in developing and marketing products either that are more effective than those that we may develop, alone or with our collaborators, or that are marketed before any products we develop are marketed.



Our competitors include fully integrated pharmaceutical companies and biotechnology companies that currently have drug and target discovery efforts, as well as universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do.

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

If third parties do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to obtain regulatory approvals for our products and product candidates and will not be able to successfully commercialize our products and product candidates for targeted diseases. We do not have the ability to independently conduct clinical trials for our products and product candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to perform this function. If these third parties do not perform satisfactorily, our clinical trials may be extended or delayed. We may not be able to locate any necessary acceptable replacements or enter into favorable agreements with them, if at all.

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

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

*Regulatory.* We believe that market acceptance of and demand for Infergen for the treatment of chronic hepatitis C infections may depend upon our ability to use Infergen in combination therapy with ribavirin or other anti-viral drugs. Before we may market Infergen in combination therapy with ribavirin or any other anti-viral drug, we will need to obtain FDA approval for such combination. To seek and obtain such approval, we will need to supplement Infergen's current FDA approval with data that support combination use of Infergen and ribavirin or another anti-viral drug for increased effectiveness in treating chronic hepatitis C infections. We cannot be certain how long it would take us to submit such data and obtain such an approval from the FDA, if at all. Seeking FDA approval for Infergen combination therapy may, in certain circumstances, involve our complying with FDA patent certification and notice provisions relating to ribavirin that could result in deferral of up to 30 months or, in the case of judicial intervention, longer, of FDA approval pending the outcome of ongoing patent infringement litigation.

*Supply.* Even if we are able to obtain regulatory approval for Infergen in combination therapy with ribavirin or another anti-viral drug, there may not be a source of commercial supply for ribavirin or another anti-viral drug. We are not aware of any U.S. or Canadian manufacturer of ribavirin that has regulatory approval, other than the company that sells ribavirin capsules exclusively to Schering-Plough Corp., which is, along with Roche Laboratories Inc., one of our primary competitors in the chronic hepatitis C infections market. There can be no assurance that an independent source of commercial supply will become available.

*Intellectual Property.* Our competitors and their strategic partners have substantial and extensive patent rights in connection with combination therapy of interferon alpha and ribavirin for the treatment of chronic hepatitis C infections. For example, we are aware of three U.S. patents that relate to the use of interferon alpha and ribavirin to treat chronic hepatitis C infections. These patents expire in 2015, 2016 and 2017. We believe that these patents may prevent us from marketing Infergen in combination

therapy with ribavirin for certain patients. If, because of these patents we are unable to market Infergen with ribavirin or with another anti-viral drug, the commercial prospects for Infergen are likely to be reduced, and our prospects for profitability may be impaired. Further, we believe that our competitors and their strategic partners may obtain additional patent rights in connection with filed patent applications for combination therapy of interferon alpha and other anti-viral drugs for the treatment of chronic hepatitis C infections. If those patent applications were to issue, we may be unable to market Infergen with ribavirin or with another anti-viral drug, reducing the commercial prospects for Infergen and our prospects for profitability.

In addition, we are aware of a U.S. patent that relates to the use of pegylated interferon alpha to treat chronic hepatitis C infections. The term of this patent expires in 2015. We believe that this patent may prevent us from marketing PEG-Infergen (a pegylated form of Infergen) for the treatment of chronic hepatitis C infections. If because of this patent we are unable to market PEG-Infergen for the treatment of chronic hepatitis C infections, the commercial prospects for PEG-Infergen are likely to be reduced. Also, we believe that our competitors and their strategic partners have substantial and extensive patent rights relating to pegylation technology in general and the use of pegylated interferon alpha for the treatment of chronic hepatitis C infections in particular. Further, several third parties have substantial and extensive patent rights in connection with the use of pegylation to modify biologically active compounds generally. Although we have licensed from Amgen rights to PEG-Infergen, we may not have, and may not be able to license on commercially reasonable terms, if at all, sufficient rights to all the intellectual property necessary for us to commercialize PEG-Infergen for the treatment of chronic hepatitis C infections.

*Competition.* Pegylated interferon alpha products may have an advantage over non-pegylated products because they circulate longer in the body, permitting a less frequent dosing schedule and enhancing efficacy in some patients infected with the hepatitis C virus. Because our competitors Schering and Roche have commenced marketing their respective pegylated interferon alpha products, Infergen has a significant disadvantage in the market with respect to the frequency of administration. In addition, both of these companies have obtained and will likely continue to obtain significant patent protection relating to their respective products.

Further, specific targeted agents directed against the hepatitis C virus (HCV) may be effective in reducing the amount of virus in infected chronic hepatitis C patients. If the use of these specific targeted anti-HCV agents proves to be effective in the treatment of chronic hepatitis C, then the use of interferon-based therapies may diminish, which would harm our business.

Although we have relaunched Amphotec, this product may not be commercially successful.

In January 2002, we relaunched Amphotec. However, market acceptance of and demand for Amphotec will depend largely on the following factors:

- *Acceptance by physicians of Amphotec as a safe and effective therapy for invasive aspergillosis:* Competitors have spent considerable time positioning Amphotec in an unfavorable light within the medical community as inferior due to more infusion-related side effects, including high levels of chills and fever, relative to some other liposomal formulations of amphotericin.
- *Pricing of alternative products:* Competitive products may be discounted by competitors to limit Amphotec's market penetration.
- *Prevalence and severity of adverse side effects associated with Amphotec:* The most frequent infusion-related events after initial dosages are chills and fever.

**If we are unable to contract with third parties to manufacture our products in sufficient quantities, on a timely basis or at an acceptable cost, we may be unable to meet demand for our products and may lose potential revenues.**

We do not have the resources, facilities or experience to manufacture any of our products or product candidates, such as PEG-Infergen or oritavancin, 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. We depend on third parties for the manufacture of our product candidates for preclinical and clinical purposes, and we rely on third parties with FDA approved manufacturing facilities for the manufacture of our products for commercial purposes.

Our manufacturing strategy for our products and product candidates also presents many risks, including the following:

- before we can obtain approval of any of our products or product candidates for the treatment of a particular disease, we must demonstrate to the FDA's satisfaction that the drug used in the clinical trials is comparable to the commercial drug;
- delays in increasing manufacturing capacity to meet our needs for multiple clinical trials could delay clinical trials, regulatory submissions and commercialization of our product candidates;
- delays in transferring manufacturing technology between third parties could delay clinical trials, regulatory submissions and commercialization of our product candidates;
- manufacturers of our products are subject to ongoing periodic inspection 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;
- if we need to contract with other manufacturers, the FDA and foreign regulatory authorities must approve these manufacturers prior to our use or sale of their products. This would require new testing and compliance inspections. The new manufacturers would need to adopt existing manufacturing processes or develop comparable processes necessary for the production of our products;
- our manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand;
- if market demand for our products is less than our purchase obligations to our manufacturers, we may incur substantial penalties; and
- 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.

Any of these factors could delay clinical trials 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.

If we are unable to contract with third parties to manufacture Actimmune, Infergen or Amphotec in sufficient quantities, on a timely basis or at an acceptable cost, we may be unable to meet demand for Actimmune, Infergen or Amphotec and may lose potential revenues.

During 2002, we transitioned from Genentech to Boehringer Ingelheim Austria GmbH (BI Austria) for the manufacture of Actimmune. Under our supply agreement, BI Austria is required to supply commercially marketed Actimmune to us, subject to certain limits. If we do not receive sufficient quantities of commercial Actimmune from BI Austria, we may experience a shortage of commercial supply, which would have a material and adverse effect on our revenues, business and financial prospects. Even if we believe that BI Austria will be unable to meet our requirements for the manufacture of Actimmune, our agreement with BI Austria precludes us from seeking a secondary source until BI Austria has indicated to us its inability or unwillingness to meet our requirements.

Under our June 2001 agreement with Amgen by which we license Infergen, Amgen is obligated to manufacture and supply Infergen to us for our sales in the United States and Canada.

We presently have an agreement with Ben Venue Laboratories, Inc. for the manufacture of Amphotec for all purposes, which we are currently renegotiating. Our inability to receive terms in the new manufacturing agreement as favorable to us as those in our original agreement may have an adverse effect on our revenues, business and financial prospects.

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

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

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 250 employees as of March 21, 2003, 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 W. Scott Harkonen, our Chief Executive Officer, President and Chairman of our Board of Directors, as well as the other principal members of our management. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. In addition, we may need to hire additional personnel and develop additional academic collaborations as we continue to expand our research and development activities. We do not know if we will be able to attract, retain or motivate personnel or cultivate academic collaborations. Our inability to hire, retain or motivate qualified personnel or cultivate academic collaborations would harm our business and hinder the planned expansion of our business.

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

Our research and development involves the controlled use and disposal of hazardous materials, chemicals, infectious disease agents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by

state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for significant damages or fines.

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

While we currently have insurance for our business, directors and officers, property and products, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policy may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

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

We believe that our existing cash, cash equivalents, short-term investments and cash flow from revenues will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the end of 2004. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and development activities. We may need to spend more money than currently expected because we may need to change our product development plans or product offerings to address difficulties encountered in clinical studies or preparing for commercial sales for new diseases. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable to our stockholders or us. If additional funds are not available, we may be forced to delay or terminate clinical trials, curtail operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights or potential markets, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we will not be able to successfully execute our business plan.

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

We have lost money since inception, and our accumulated deficit was approximately \$299.2 million at December 31, 2002. We expect to incur substantial additional net losses for at least the next two years. The extent of our future net losses and the timing of our profitability are highly uncertain, and we may never achieve profitable operations. We are planning to expand the number of diseases for which our products may be marketed, and this expansion will require significant expenditures. To date, we have generated revenues primarily through the sale of Actimmune. However, since we do not expect to seek FDA approval for the use of Actimmune for the treatment of idiopathic pulmonary fibrosis for at least three more years, Actimmune revenues may not continue to increase. After inclusion of the direct costs of marketing Actimmune and royalties we must pay to Genentech on sales of Actimmune, we do not currently generate significant operating profits on those sales. If the time required for us to achieve profitability is longer than we anticipate, we may not be able to continue our business.

#### **Other Risks**

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

Our annual debt service obligations on our 5.75% convertible subordinated notes due 2006 are approximately \$8.6 million per year in interest payments. We intend to fulfill our 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 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:

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

If a change in control occurs, we may be required to redeem our 5.75% convertible subordinated notes due 2006.

If there is a change in control of our company, the holders of our 5.75% convertible subordinated notes due 2006 may require us to redeem some or all of the notes. Although the indenture governing the notes allows us in certain circumstances to pay the redemption price in shares of our common stock, if a change in control were to occur, we may not have sufficient funds to pay the redemption price for all the notes tendered. We have not established a sinking fund for payment of the notes, nor do we anticipate doing so.

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 best interests and not necessarily those of other stockholders.

At December 31, 2002, our directors, executive officers and greater than 5% stockholders and their affiliates beneficially owned approximately 54% of our issued and outstanding common stock. Accordingly, they collectively may have the ability to significantly influence the election of all of our directors and to significantly influence the outcome of corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

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

The existence of our stockholder rights plan and provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;

- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

The trading price of our common stock has been and is likely to continue to be extremely volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

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

In addition, the stock market in general, and the Nasdaq National Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business.

**Substantial sales of shares may 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 5.75% convertible subordinated notes due 2006, the market price of our common stock may decline. These sales also might make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the then-prevailing market price of our common stock.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. 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.

#### Executive Officers of the Registrant

The following table provides information regarding our executive officers and key employees:

<u>Name</u>	<u>Age</u>	<u>Title</u>
W. Scott Harkonen, M.D.	51	Chief Executive Officer, President and Chairman of the Board of Directors
James E. Pennington, M.D.	60	Executive Vice President of Medical and Scientific Affairs
Stephen N. Rosenfield	53	Executive Vice President of Legal Affairs, General Counsel and Secretary
Marianne Armstrong, Ph.D.	48	Senior Vice President of Global Regulatory Operations and Corporate Compliance
Sharon Surrey-Barbari	48	Chief Financial Officer, Senior Vice President of Finance and Administration
Peter Van Vlasselaer, Ph.D.	44	Senior Vice President of Technical Operations
John J. Wulf	50	Senior Vice President of Corporate Development

*W. Scott Harkonen, M.D.* Dr. Harkonen founded InterMune in February 1998 and has served as a member of the Board since inception and as Chairman of the Board since January 2000. Dr. Harkonen has been InterMune's Chief Executive Officer and President since inception. From September 1995 to April 1999, Dr. Harkonen served as senior vice president of product development and operations at Connetics Corporation, a biopharmaceutical company. From March 1991 to September 1995, Dr. Harkonen served as vice president of medical and regulatory affairs at Univax Biologics, a biopharmaceutical company. Dr. Harkonen is a member of the board for the emerging companies section governing board and the board of directors of the Biotechnology Industry Organization. Dr. Harkonen is a director of several private companies, including Mondobiotec S.A. Dr. Harkonen holds an M.D. from the University of Minnesota and an M.B.A. from the Haas School of Business at the University of California at Berkeley.

*James E. Pennington, M.D.* Dr. Pennington has served as our Executive Vice President of Medical and Scientific Affairs since January 2001. From June 1999 to January 2001, Dr. Pennington served as senior vice president of research, development and clinical affairs at Alpha Therapeutics Corporation, a biological and biopharmaceutical company. From October 1997 to February 1999, Dr. Pennington served as senior vice president of clinical research at Shaman Pharmaceuticals, a biopharmaceutical company. From September 1986 to June 1994, Dr. Pennington served as director and from July 1994 to October 1997, served as vice president of biological clinical research at Bayer Corporation, a publicly held biopharmaceutical company. Prior to joining the pharmaceutical industry, Dr. Pennington spent 12 years as a member of the Harvard Medical School faculty. Dr. Pennington holds an M.D. from the University of Oregon and is Board Certified in Internal Medicine and Infectious Diseases.

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



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

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

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

*John J. Wulf.* Mr. Wulf has served as our Senior Vice President of Corporate Development since June 2000. From April 1998 until June 2000, Mr. Wulf served as vice president of business development at Axys Pharmaceuticals, Inc., a biopharmaceutical company. Prior to joining Axys, Mr. Wulf was employed by Genentech, Inc., a biopharmaceutical company, in various positions in business, product and process development. From April 1996 until April 1998, Mr. Wulf served as director of business development and Far East representative. From 1994 until 1996, he served as licensing manager. Mr. Wulf holds an M.B.A. from San Francisco State University and an M.S. from Oregon State University.

## ITEM 2. PROPERTIES

Our facilities currently consist of 55,898 square feet of office space located at 3280 Bayshore Boulevard, Brisbane, California. In December 2000, we entered into a ten-year lease for this building. We believe that this facility has sufficient space to accommodate expansion of our operations until at least the end of the second quarter of 2003. We are currently seeking additional space.

## ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Since InterMune's initial public offering of its Common Stock, \$0.001 par value ("Common Stock"), on March 24, 2000, InterMune's Common Stock has been traded on the NASDAQ National Market under the symbol "ITMN."

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

<u>Fiscal Year:</u>	<u>High</u>	<u>Low</u>
2002		
First Quarter .....	\$51.19	\$27.86
Second Quarter .....	32.48	20.37
Third Quarter .....	33.44	15.76
Fourth Quarter .....	38.25	24.90
2001		
First Quarter .....	\$44.88	\$12.50
Second Quarter .....	42.07	15.63
Third Quarter .....	46.53	26.76
Fourth Quarter .....	52.96	35.75

As of March 11, 2003, there were 180 stockholders of record.

#### Dividend Policy

No cash dividends have been paid to date by us and we do not anticipate the payment of dividends in the foreseeable future.

#### Use of Proceeds from Registered Securities

On March 13, 2002 the Company completed a follow-on public offering of 3.0 million shares of common stock at a price of \$37.00 per share, raising \$111.0 million in gross proceeds. The Company received net proceeds of \$104.5 million after deducting underwriting fees of \$5.8 million and related expenses of \$0.7 million.

As of December 31, 2002, the Company had not allocated any funds received from this offering. The Company may use the net proceeds from this offering for clinical development, commercialization of existing products, working capital, in-licensing or acquisition of preclinical and development stage programs and FDA approved products, investment in applied research and general corporate purposes.

The Company retains broad discretion over the use of the net proceeds from this offering. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of the Company's research and development efforts, technological advances and the competitive environment for the Company's products. The Company may use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies.

## 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 in the period ended December 31, 2002, and the selected consolidated balance sheet data as of December 31, 2002 and 2001, 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, 1999 and 1998, and the selected consolidated balance sheet data as of December 31, 2000, 1999 and 1998, are derived from audited financial statements not included in this Report.

	Years ended December 31,				For the period from February 25, 1998 (inception to December 31,
	2002	2001	2000	1999	1998
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Product sales:					
Actimmune . . . . .	\$ 105,802	\$ 36,320	\$ 11,201	\$ 556	\$ —
All others . . . . .	6,163	3,631	—	—	—
Total product sales, net . . . . .	111,965	39,951	11,201	556	—
Costs and expenses:					
Cost of goods sold . . . . .	24,161	15,474	4,990	240	—
Amortization of acquired product rights . . . . .	3,593	4,805	1,777	—	—
Research and development . . . . .	129,590	52,049	20,821	2,969	1,235
Selling, general and administrative . . . . .	62,752	35,895	16,152	2,656	892
Acquired in-process research and development . . . . .	33,750	56,400	—	1,094	4,000
Total costs and expenses . . . . .	253,846	164,623	43,740	6,959	6,127
Loss from operations . . . . .	(141,881)	(124,672)	(32,539)	(6,403)	(6,127)
Interest income . . . . .	7,375	11,253	8,484	240	55
Interest expense . . . . .	(9,803)	(4,772)	(191)	(186)	—
Net loss . . . . .	(144,309)	(118,191)	(24,246)	(6,349)	\$(6,072)
Preferred stock accretion . . . . .	—	—	(269)	(657)	—
Redeemable preferred stock dividend . . . . .	—	—	(27,762)	—	—
Net loss applicable to common stockholders . . . . .	\$(144,309)	\$(118,191)	\$(52,277)	\$(7,006)	—
Historical basic and diluted net loss per share . . . . .	\$ (4.72)	\$ (4.67)	\$ (3.05)	\$ (9.12)	—
Shares used in computing historical basic and diluted net loss per share . . . . .	30,589	25,322	17,114	768	—
	December 31,				
	2002	2001	2000	1999	1998
	(In thousands)				
<b>Balance sheet data:</b>					
Cash, cash equivalents and available-for-sale securities . . . . .	\$ 316,411	\$ 332,067	\$ 194,520	\$ 4,214	\$ 4,720
Working capital . . . . .	285,633	320,345	194,706	1,222	4,181
Total assets . . . . .	384,881	387,246	201,649	5,855	4,720
Long-term obligations . . . . .	149,500	149,500	—	1,624	—
Redeemable convertible preferred stock . . . . .	—	—	—	7,417	—
Accumulated deficit . . . . .	(299,167)	(154,858)	(36,667)	(12,421)	(6,072)
Total stockholders' equity (deficit) . . . . .	182,718	215,059	195,801	(7,541)	4,181

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

### Overview

InterMune was incorporated in Delaware on March 23, 2000. We are an independent biopharmaceutical company focused on developing and commercializing innovative products for the treatment of serious pulmonary, infectious and hepatic diseases. We have three marketed products, growing product revenues and advanced-stage clinical programs, addressing a range of diseases with attractive markets. Our three marketed products are Actimmune, Infergen and Amphotec. Actimmune is approved in the United States for two rare congenital disorders: chronic granulomatous disease and severe malignant osteopetrosis. We market Infergen in the United States and Canada for the treatment of chronic hepatitis C infections. We market Amphotec worldwide for the treatment of invasive aspergillosis. Our total product revenues increased to \$112.0 million for the year ended December 31, 2002 from \$40.0 million for the year ended December 31, 2001, an increase of 180%.

Since our inception, we have incurred significant losses and, as of December 31, 2002, we had an accumulated deficit of \$299.2 million.

Our expenses have consisted primarily of those incurred for research and development, including the acquisition of product candidates under development, sales and marketing and general and administrative costs associated with our operations. We expect that our expenditures for research and development expenses will increase as we continue clinical development of our products, and other expenses will increase as we expand our operations domestically and internationally. As a result, we expect to incur losses through at least the end of 2004.

We have a limited history of operations and our quarterly and annual results of operations may fluctuate due to several factors, including market acceptance of current or new products, the introduction of new products by our competitors, the timing and extent of our research and development efforts, and the timing of significant orders. Our limited operating history makes accurate prediction of future operating results difficult or impossible.

Drug development in the United States is a process that includes several steps defined by the FDA. The process begins with the filing of an investigational new drug application (or IND) which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically accounts for an average of seven years of a drug's total development time to complete the three phases of clinical studies: Phase I, II and III. The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so called Phase IV studies may be made a condition to be satisfied after a drug receives approval. The results of Phase IV studies can confirm the effectiveness of a drug and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system. The most significant costs associated with clinical development are Phase III trials as they tend to be the longest and largest studies conducted during the drug development process. The successful development of our products is highly uncertain. An estimation of product completion dates and completion costs can vary significantly for each product and are difficult to 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 have a material adverse affect on our business. In responding to a new drug application (or NDA), a biologic license application (or BLA) or an NDA or BLA supplement the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

In 2002, we reported data from our Phase III clinical trial of Actimmune® (interferon gamma-1b) injection for the treatment of idiopathic pulmonary fibrosis (IPF), a debilitating and usually fatal lung

disease for which there are no therapies currently approved by the FDA. These data did not show Actimmune to demonstrate statistically significant efficacy with respect to the primary or secondary endpoints of the Phase III clinical trial. The analysis of survival, a secondary endpoint in this trial, suggested that although Actimmune did not demonstrate a statistically significant increase in survival in the overall patient group, it may provide a survival benefit for patients with mild-to-moderate IPF. Generally, before granting a marketing approval of a drug for the treatment of a disease, the FDA requires that the drug demonstrate safety and statistically significant efficacy with respect to the primary and/or secondary endpoints of the clinical trial. We therefore believe that the FDA will require us to conduct an additional Phase III clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis prior to approving Actimmune for the treatment of idiopathic pulmonary fibrosis.

In May 2002, we acquired certain interferon gamma patents of Amgen Inc. in exchange for \$3.5 million, of which \$1.5 million was paid in the second quarter of 2002 and the remaining \$2.0 million was an accrued liability at December 31, 2002 and was paid in January 2003. We expect to amortize these product rights to operations over the expected useful lives of the particular patent rights acquired for Actimmune through the end of 2008.

In March 2002, we licensed from Marnac, Inc., a privately held biopharmaceutical company, and its co-licensor, KDL GmbH, their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including pulmonary, liver and renal fibrosis. Pirfenidone is not approved by the FDA. At the time of the product acquisition from Marnac and KDL, pirfenidone was in Phase II clinical trials. We will be required to file our own IND before commencing additional studies with pirfenidone. Under the terms of the agreement, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of \$18.8 million and future milestone and royalty payments. We expensed the \$18.8 million as acquired in-process research and development in the first quarter of 2002 since pirfenidone is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses.

In October 2001, we entered into an asset purchase and license agreement with Eli Lilly and Company pursuant to which we acquired worldwide rights to oritavancin. The agreement provides us with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. If we wish to enter into a relationship with a third party to commercialize oritavancin in any country, we must first offer Eli Lilly the opportunity to enter into such a commercialization relationship with us. After we negotiate with Eli Lilly, the agreement prohibits us from entering into an agreement with a third party on more favorable terms than those we offered to Eli Lilly. Pursuant to the agreement, we paid Eli Lilly \$50.0 million in 2001 and will be obligated to pay Eli Lilly significant milestone and royalty payments upon any successful development and commercialization of oritavancin by us. All of the \$50.0 million was expensed in 2001 as acquired in-process research and development since oritavancin was in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses. In September 2002, Eli Lilly exercised its option under the asset purchase and license agreement to reduce the agreed percentage of royalty payable by us to Eli Lilly upon successful commercialization of oritavancin. The exercise of this option required us to pay \$15.0 million to Eli Lilly. The total fee of \$15.0 million was recorded as a liability as of December 31, 2002, and was paid in January 2003. All of the \$15.0 million was expensed in the third quarter of 2002 as acquired in-process research and development since oritavancin is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses. Our rights to oritavancin could revert to Eli Lilly if we do not meet our diligence obligations under the agreement or otherwise commit a material breach of the agreement. Additionally, if we are acquired by a company with a certain type of competing program and Eli Lilly has notified us prior to the acquisition that it believes in good faith that its economic interests in oritavancin under the agreement will be harmed in light of the acquisition, Eli Lilly may terminate the agreement and our rights to oritavancin would revert to Eli

Lilly. In any event, we may not assign the agreement to a potential acquirer without the advance, written consent of Eli Lilly.

In September 2001, we entered into a license and collaboration agreement with Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, Inc., to develop and commercialize novel, next-generation interferon gamma products that have enhanced pharmacokinetics and a potential for less frequent dosing regimens. We plan to take forward into clinical development selected protein-modified interferon gamma product candidates created by Maxygen that meet these criteria. We are funding optimization and development of these next-generation interferon gamma products and retain exclusive worldwide commercialization rights for all human therapeutic indications. The terms of the agreement include up-front license fees, which were included in research and development expenses, full research funding and development and commercialization milestone payments. In addition, Maxygen will receive royalties on product sales. Our rights to the licensed products under the agreement could revert to Maxygen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

In June 2001, we entered into a licensing and commercialization agreement with Amgen, Inc. to obtain an exclusive license in the United States and Canada to Infergen (interferon alfacon-1), an interferon alpha product, and the rights to an early stage program to develop a pegylated form of Infergen, PEG-Infergen. Infergen is currently approved in both the United States and Canada to treat chronic hepatitis C infections. Under the agreement, we have the exclusive right to market Infergen and PEG-Infergen and clinically develop them for other indications in the United States and Canada. We have paid Amgen a total of \$29.0 million for up-front license and other fees and performance milestones, and are obligated to pay royalties on sales of Infergen. Based upon an independent appraisal, the fair value of the in-process research and development program for PEG-Infergen was \$5.4 million. At the time of acquisition the PEG-Infergen program had not reached technical feasibility. The remainder of the purchase price of approximately \$23.6 million was allocated to developed technology is being amortized over ten years. We evaluate this intangible asset, like our other intangible assets, for impairment on a regular basis. We are also required to pay Amgen other milestone payments on the PEG-Infergen program and royalties on sales of the product, if any. Our rights to Infergen could revert to Amgen if we do not meet our diligence obligations or otherwise commit a material breach of the agreement.

The value assigned to acquired in-process research and technology was determined by estimating the costs to develop the purchased in-process research and development into a commercially viable product, including development milestones, estimating the resulting net cash flows from the project and discounting the net cash flows to their present value. A discount rate of 33% was used for valuing the in-process research and development and is intended to be commensurate with the our corporate maturity, the state of the potential product's development and the uncertainties in the economic estimates described above. The technology under development has no foreseeable alternative future uses.

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

In May 2001, we entered into a joint development and commercialization agreement for Moli1901, a drug compound under development with MoliChem Medicines, Inc. We paid an up-front license fee of \$1.5 million in 2001 to MoliChem, which was charged to research and development expense in 2001. The parties jointly funded the development and commercialization of Moli1901 for all diseases worldwide, starting with cystic fibrosis. MoliChem led the development efforts. In December 2002,

upon appropriate notice, we terminated this agreement and we are not obligated to make further payments.

In March 2001, we formed an international strategic collaboration with Boehringer Ingelheim International GmbH, to develop and commercialize interferon gamma-1b under Boehringer Ingelheim's trade name, Imukin®, in all countries outside of the United States, Canada and Japan. Indications to be developed include idiopathic pulmonary fibrosis, tuberculosis, non-Hodgkin's lymphoma, liver fibrosis, systemic fungal infections, chronic granulomatous disease, osteopetrosis and ovarian cancer. Under the agreement, we will fund and manage clinical and regulatory development of interferon gamma-1b for all indications. Boehringer Ingelheim has an option to exclusively promote Imukin, and we may opt to promote the product where Boehringer Ingelheim does not do so. Furthermore, both companies will share in the profits from commercializing interferon gamma-1b through a specified royalty schedule.

In January 2001, we acquired worldwide rights from ALZA Corporation to Amphotec (sold under the tradename Amphocil in certain countries outside the United States). The transaction terms included an up-front product acquisition fee of \$9.0 million, which was recorded as an intangible asset, milestone payments based upon sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune, and royalties payable upon net sales of Amphotec. We evaluate this intangible asset, like our other intangible assets, for impairment on a regular basis. Under the agreement, we obtained access to certain existing distributorships for Amphotec, and assumed ALZA's obligations under agreements with its existing Amphotec distributors and service providers. We have diligence obligations under the agreement to establish additional distributorships for Amphotec or establish a sales force and begin to promote Amphotec in specified countries at specified times. Our rights to Amphotec could revert to ALZA if we do not meet our diligence obligations or otherwise commit a material breach of the agreement. We are also subject to certain royalty obligations to the University of California under this agreement.

#### **Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenue recognition and related revenue reserves. Estimates are based on historical experience, information received from third parties and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

- **Revenue recognition and revenue reserves**

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We sell to a limited number of customers, mainly specialty pharmacies and distributors. We obtain written purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred at the time of shipment. Revenue is recognized at shipment and reserves are recorded for estimated returns, rebates and chargebacks. 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

significant historical experience. We review all sales transactions for potential rebates and chargebacks each month and monitor product ordering cycles and actual returns, product expiration dates and wholesale inventory levels to estimate potential product return rates. We believe that our reserves are adequate.

- Accounting for intangible assets

Our intangible assets are comprised principally of acquired technology rights. We apply judgments in determining the useful lives of our intangible assets and whether such assets are impaired. Factors we consider include the life of the underlying patent, the expected period of benefit from the use of the technology, existence of competing technology and potential obsolescence. To date, we have not experienced any impairment of our intangible assets.

In accordance with U.S. GAAP, we perform tests for impairment of our intangible assets whenever events or circumstances suggest that these assets may be impaired. To date, we have not experienced any impairment to our intangible assets. To evaluate potential impairment, U.S. GAAP requires us to assess whether the future cash flows related to the asset will be greater than its carrying value at the time of the test. Accordingly, while our cash flow assumptions are consistent with the plans and estimates we are using to manage our underlying businesses, there is significant judgment in determining the cash flows attributable to our intangible assets over their respective estimated useful lives. If, however, we reduced the estimated useful life of all intangible assets by two years or assumed zero growth in revenues for the next three years, our intangible assets would still not be considered to be impaired and no write down would be required.

- Clinical trial accruals

Our accrued costs for clinical trial activities performed by contract research organizations are based upon estimates of the percentage of work completed over the life of the individual study. These estimates may or may not match the actual services performed by the organization as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible, however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods. All such costs are charged to R&D expense as incurred.

#### Deferred Stock Compensation

In connection with the grant of stock options to employees, we recorded deferred stock compensation totaling \$8.6 million and \$5.6 million in the fiscal years ended December 31, 2000 and 1999, respectively. No such deferred stock compensation was recorded in the years 2002 and 2001. Deferred stock compensation for options granted to employees has been determined as the difference between the fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise prices. Such amount is included as a reduction of stockholders' equity and is being amortized using the graded vesting method over the vesting period of the individual options, which is generally five years. This graded vesting method provides for accelerated vesting of portions of the overall award at interim dates and results in higher vesting in earlier years than straight-line vesting. During the year ended December 31, 2002, we reversed approximately \$0.8 million of amortization of deferred stock-based compensation recorded in prior years due to the termination of certain employees. We recorded amortization of deferred stock compensation of \$1.8 million, \$3.8 million and \$6.7 million for the years ended December 31, 2002, 2001 and 2000, respectively. Included in the \$1.8 million amortization for the year 2002 was approximately \$0.2 million recognized on the vesting acceleration of options for a terminated employee. At December 31, 2002, we had a total of \$0.9 million to be amortized over the remaining vesting periods of the stock options. The amount of deferred stock compensation expense to be recorded in future periods could decrease if options, for which accrued but unvested compensation has been recognized, are forfeited prior to vesting.



## Results of Operations

### Comparison of years ended December 31, 2002 and 2001

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

Product revenues in 2001 included all sales of Actimmune in the United States, worldwide sales of Amphotec for the period from January 5, 2001 (the date we acquired the marketing rights to Amphotec) and sales of Infergen in the United States for the period from June 15, 2001 (the date we acquired the marketing rights to Infergen). The Company projects total net product sales for 2003 to be in the range of \$170 million to \$195 million, with Actimmune net product sales projected to be in the range of \$160 million to \$180 million for the year.

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

The gross margin percentage for our products were 78% and 61% for the periods in 2002 and 2001, respectively. The improved gross margin percentage in 2002, when compared to the same period in 2001, primarily reflects lower product costs of Actimmune associated with the transfer of manufacturing to Boehringer Ingelheim at the end of 2001.

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

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

*Research and development expenses.* Research and development expenses were \$129.6 million and \$52.0 million for the years ended December 31, 2002 and 2001, respectively, representing an increase of 149% or \$77.6 million. The increased spending in 2002 was due primarily to increased costs for Phase II and Phase III clinical trial expenses for Actimmune in new disease indications, clinical trial expenses and pre-FDA approval manufacturing qualification expenses for oritavancin, increased staffing and related expenses necessary to manage the expansion of our operations. We expect that for the 2003 fiscal year, research and development expenses will be approximately \$140 million to \$150 million.

*Selling, general and administrative expenses.* Selling, general and administrative expenses were \$62.8 million and \$35.9 million for the years ended December 31, 2002 and 2001, respectively, representing an increase of 75% or \$26.9 million. The increased spending in 2002 was attributable primarily to increased staffing and related expenses necessary to manage the growth of our operations, expansion of our field sales force, re-launch efforts for Infergen and the expansion into our new company headquarters in Brisbane, California. We believe that selling, general and administrative expenses will increase as a result of the anticipated expansion of our administrative staff and increased marketing and selling expenses for our approved products, and the expenses associated with the expansion of our operations. We expect for the 2003 fiscal year, selling, general and administrative expenses will be approximately \$80 million to \$85 million.

*Acquired in-process research and development.* We recorded charges for acquired in-process research and development of \$33.8 million and \$56.4 million for the years ended December 31, 2002 and 2001, respectively.

During 2002, we recorded a charge for acquired in-process research and development of \$15.0 million related to the exercise of an option by Eli Lilly under the asset purchase and license agreement entered into October 2001, to reduce the agreed percentage of royalty payable by us to Eli Lilly upon successful commercialization of oritavancin. Oritavancin is not currently approved by the FDA. We expensed the \$15.0 million in 2002 as acquired in-process research and development cost as oritavancin is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses. At December 31, 2002, the \$15.0 million was recorded as an accrued liability and was paid in January 2003.

Also in 2002, we recorded a one-time charge of \$18.8 million related to the payment to Marnac, Inc. for our March 2002 license of its worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Pirfenidone is not currently approved by the FDA. We expensed the \$18.8 million as acquired in-process research and development cost as pirfenidone is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses.

For the year ended December 31, 2001, we licensed worldwide rights to oritavancin from Eli Lilly and Company. We paid an up-front fee of \$50.0 million to Eli Lilly and an additional \$1.0 million in related expenses. We recorded the total of \$51.0 million as acquired in-process research and development. We expensed the \$51.0 million as acquired in-process research and development cost as oritavancin is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses. We will also pay Eli Lilly significant milestone and royalty payments upon successful development and commercialization. Oritavancin is not currently approved by the FDA and is in Phase II and Phase III clinical trials for various indications. We expect to commercialize oritavancin no earlier than 2005.

Also in 2001, we entered into a licensing and commercialization agreement with Amgen Inc. and obtained an exclusive license in the United States and Canada to Infergen (a therapeutic approved by the FDA for the treatment of hepatitis C infections) and the rights to an early stage program to develop a pegylated form of Infergen (PEG-Infergen) for a total consideration of \$29.0 million, plus development milestones and royalties. Under the agreement, we also have the exclusive right to clinically develop Infergen and PEG-Infergen for other indications in the United States and Canada. We do not expect the PEG-Infergen program, which is currently in its early stages (approximately 20% completed), to reach the FDA approval stage prior to 2007 at the earliest, if at all. Based upon an independent appraisal, the fair value of the in-process research and development program for PEG-Infergen was determined to be \$5.4 million. We expensed this amount as acquired in-process research and development as PEG-Infergen is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses. The remainder of the purchase price of approximately \$23.6 million was for Infergen and was allocated to developed technology and is being amortized over ten years. We evaluate this asset, like our other intangible assets, for impairment on a regular basis.

The value we assigned to acquired in-process research and development for the PEG-Infergen program was determined by estimating the costs to develop Amgen's purchased in-process research and development into a commercially viable product including development milestones; estimating the resulting net cash flows from the project; and discounting the net cash flows to their present value. We assigned a discount rate of 33% for valuing the in-process research and development, which is intended to be commensurate with our corporate maturity and the uncertainties in the economic estimates described above. The technology under development has no foreseeable alternative future uses.

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

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

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

*Provision for income taxes.* Due to operating losses and the uncertainty of recognizing the benefits therefrom, there was no provision for income taxes for the years ended December 31, 2002 and 2001.

As of December 31, 2002, we had federal net operating loss carryforwards of approximately \$196.0 million. The net operating loss carryforwards will expire at various dates beginning in 2018 through 2022 if not utilized. We also have federal research and development tax credits of approximately \$2.3 million that will expire in the years 2018 through 2022. In addition, we had net operating loss carryforwards for state income tax purposes of approximately \$29.0 million, that expire in the years 2008 through 2013, and state research and development tax credits of approximately \$1.0 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, 2001 and 2000

*Revenue.* Total product revenues were \$40.0 million and \$11.2 million for the years ended December 31, 2001 and 2000, respectively. The growth in product sales for the year 2001 was primarily attributable to a \$25.2 million increase in sales of Actimmune. The product revenues in 2001 included all sales of Actimmune in the United States, worldwide sales of Amphotec for the period from January 5, 2001 (the date we acquired the marketing rights to Amphotec) and sales of Infergen in the United States for the period from June 15, 2001 (the date we acquired the marketing rights to Infergen). The product revenues in 2000 included sales of Actimmune outside the United States related to a supply arrangement and for the period from April 1, 2000 to December 31, 2000 in the United States. On June 27, 2000, we terminated an agreement with Connetics for Actimmune sales below a contractual baseline. For the three-month period ended March 31, 2000, sales transacted for Connetics below the annual contractual baseline were recorded on a net basis, which was zero, and any amounts in excess of net revenues less costs to produce and market were paid to Connetics.

*Cost of goods sold.* Cost of goods sold were \$15.5 million and \$5.0 million for the years ended December 31, 2001 and 2000, respectively. Cost of goods sold included manufacturing costs, royalties and distribution costs associated with our revenues. The increase in 2001 was due entirely to costs associated with increased product sales volumes.

The gross margin percentage for our products were 61% and 55% for the periods in 2001 and 2000, respectively. The improved gross margin percentage in 2001, when compared to the same period in 2000, reflects a lower effective royalty percentage payable for Actimmune and partially offset by product mix associated with the addition of Amphotec in 2001.

*Amortization of acquired product rights.* We recorded amortization of acquired product rights of \$4.8 million and \$1.8 million for the years ended December 31, 2001 and 2000, respectively. On June 28, 2000, we purchased rights to all of the Actimmune revenues and related expenses that we had previously transacted for Connetics. The amortization of those rights was completed in 2001 and expensed based upon product units shipped under the previous contractual unit baseline for the year 2001. In addition, we recognized a total of \$2.2 million in 2001 for the amortization of product rights acquired in 2001.

*Research and development expenses.* Research and development expenses were \$52.0 million and \$20.8 million for the years ended December 31, 2001 and 2000, respectively, representing an increase of 150% or \$31.2 million. Of the increased costs in the year 2001, a total of \$2.5 million was related to non-cash stock-based compensation and the amortization of deferred stock compensation and a total of \$7.2 million was incurred for external collaboration support for next-generation interferon gamma products, technology licenses and an investment in a privately held development stage company. The remaining increase in 2001 was due primarily to increased costs for clinical trial expenses for Actimmune in new and existing disease indications and internal support personnel.

*Selling, general and administrative expenses.* Selling, general and administrative expenses were \$35.9 million and \$16.2 million for the years ended December 31, 2001 and 2000, respectively, representing an increase of 122% or \$19.7 million. Of the increased costs in 2001, a total of \$2.6 million was related to non-cash stock-based compensation and the amortization of deferred stock compensation. The remaining increase in 2001 was attributable primarily to increased staffing and related expenses necessary to manage the growth of our operations, expansion of our field sales force and the expansion into our new company headquarters. In December 2001, we added 48 additional field personnel to support our products.

*Acquired in-process research and development.* As described above, we recorded charges for acquired in-process research and development totaling \$56.4 million for the year ended December 31, 2001 related to the acquisition of Infergen and oritavancin (no charges in 2000).

*Interest income.* Interest income totaled \$11.3 million and \$8.5 million for the years ended December 31, 2001 and 2000, respectively. The increase in interest income in 2001 was due to increased cash available for investments as a result of the completion of \$149.5 million in debt financing and \$128.8 million in an equity financing during the year, offset by lower interest rates.

*Interest expense.* Interest expense totaled \$4.8 million and \$191,000 for the years ended December 31, 2001 and 2000, respectively. The increase in 2001 was attributable to interest expense on \$149.5 million aggregate principal amount of our 5.75% convertible subordinated notes issued during the year. The amount in 2000 related to imputed interest on the obligations to Connetics that were paid in full on March 2001.

*Deemed Dividend Upon Issuance of Redeemable Convertible Preferred Stock.* We recorded a deemed dividend of \$27.8 million in January 2000, upon the issuance of 4,966,361 shares of Series B redeemable convertible preferred stock. At the dates of issuance, we believed the per share price of \$5.59 represented the fair value of the preferred stock and was in excess of the deemed fair value of our common stock. Subsequent to the commencement of our initial public offering process, we re-evaluated the deemed fair value of our common stock and determined it to be \$12.60 to \$14.40 per share. Accordingly, the aggregate proceeds of \$27.8 million were deemed to be the equivalent of a preferred stock dividend. We recorded the deemed dividend at the date of issuance by offsetting charges and credits to additional paid-in capital of \$27.8 million, without any effect on total stockholders' equity. The amount increased the loss applicable to common stockholders in the calculation of basic net loss per share the year ended December 31, 2000.

*Provision for income taxes.* Due to operating losses and the uncertainty of recognizing the benefits therefrom, there was no provision for income taxes for the years ended December 31, 2001 and 2000.

#### Liquidity and Capital Resources

Since inception, we have funded our operations through issuances of equity and debt securities and sales of our products. At December 31, 2002, we had cash, cash equivalents and available-for-sale investments of \$316.4 million. 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. Government and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than eighteen months.

Net cash used in operations for the year ended December 31, 2002 totaled \$97.4 million, compared to \$42.5 million in 2001 and \$19.5 million in 2000. A net loss of \$144.3 million for the year ended December 31, 2002 included non-cash charges of \$1.0 million for the amortization of deferred stock compensation, \$1.8 million related to non-cash stock compensation, and \$6.6 million for depreciation and amortization. In addition, net cash used in operations for the year ended December 31, 2002 was further impacted by acquired in-process research and development expenditures of \$33.8 million, an increase in accounts receivable of \$6.8 million resulting from increased product sales and an increase in product inventories of \$2.7 million. These uses of operating cash were offset by an increase of \$11.0 million in accounts payable and accrued compensation resulting from increases in operating expense levels and commission and vacation liabilities from additional personnel added during the year and an increase of \$3.4 million in other accrued liabilities.

Net cash used for investing activities in the year ended December 31, 2002, was \$32.1 million, compared to \$157.4 million in 2001 and \$146.8 million used in 2000. In 2002, the net cash used for investing activities was primarily due to the purchases of short-term available-for-sale investments, offset by sales and maturities of short-term available-for-sale investments and payments for acquisition of product rights. In 2001, the net cash used for investing activities was primarily due to the net purchases of short-term available-for-sale investments and cash used for the acquisition of product rights. In 2000, the net cash used for investing activities was primarily due to the net purchases of short-term available-for-sale investments. Capital expenditures for equipment and leasehold improvements to support our operations were \$5.2 million, \$7.5 million and \$1.0 million in 2002, 2001 and 2000, respectively.

Net cash provided by financing activities for the year ended December 31, 2002 totaled \$108.3 million, compared to \$274.6 million in 2001 and \$210.7 million in 2000. In 2002, net cash provided by financing activities included \$104.5 million received in net proceeds from the sale of 3.0 million shares of common stock at \$37.00 per share prior to deducting underwriters' fees and expenses in a follow-on public offering, \$2.3 million from stock option exercises and \$1.5 million received under our employee stock purchase plan. In 2001, net cash provided by financing activities included \$128.8 million in net proceeds from the sale of common stock in a follow-on public offering, \$144.4 million received from the sale of 5.75% convertible subordinated notes, \$0.8 million from stock option exercises and \$0.5 million received under our employee stock purchase plan. In 2000, net cash provided by financing activities included \$25.2 million in net proceeds from the sale of Series B convertible preferred stock to investors in January 2000, \$115.0 million in net proceeds from the sale of common stock in our initial public offering, \$71.1 million in net proceeds from a private placement of common stock which closed on August 18, 2000, \$0.4 million from stock option exercises and \$0.1 million received under our employee stock purchase plan offset by \$1.0 million paid to Connetics upon the close of our initial public offering. We recorded this payment as a "return of capital to parent." The timing of and amounts realized from stock option exercises and employee stock purchase

plan purchases are determined by the decisions of the respective option or right holders, and are not controlled by us. Therefore, funds raised from exercises of stock options or employee stock purchase plan purchases in the past periods should not be considered an indication of additional funds to be raised in future periods.

Working capital of \$285.6 million at December 31, 2002 decreased from \$320.4 million at December 31, 2001. The decrease in working capital for the period in 2002 was primarily due to funding our operating loss.

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

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We have no commercial commitments or loans with related parties, except for ongoing payments to Mr. Simon, a former director of our Board of Directors who resigned in February 2003, in connection with the oritavancin acquisition from Eli Lilly, and an executive employee loan to Dr. Armstrong that was in place prior to the enactment of the Sarbanes-Oxley Act of 2002.

We believe that we will continue to require substantial additional funding in order to complete the research and development activities currently contemplated and to commercialize our proposed products. 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 through at least the end of 2004. However, this forward-looking statement is based upon our current plans and assumptions, which may change, and our capital requirements may increase in future periods. Our future capital requirements will depend on many factors, including, but not limited to:

- the commercial performance of any of our products or product candidates in development that receive commercial approval;
- our ability to partner our development and commercialization programs;
- the progress of our research and development efforts;
- the scope and results of pre-clinical studies and trials;
- the costs, timing and outcome of regulatory reviews;
- determinations as to the commercial potential of our products in development;
- the pace of expansion of administrative expenses;
- the status of competitive products,
- the establishment of manufacturing capacity through third-party manufacturing agreements;
- the pace of expansion of our sales and marketing capabilities, in preparation for product launches;
- our possible geographic expansion;
- the establishment of collaborative relationships with other companies;
- the payments of the annual interest on our convertible subordinated debt; and
- whether in 2006 we must repay the principal in connection with our convertible subordinated debt.

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

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

<u>Contractual obligations</u>	<u>Total</u>	<u>2003</u>	<u>2004- 2005</u>	<u>2006- 2007</u>	<u>After 2007</u>
Convertible subordinated debt . . . . .	\$149.5	\$ —	\$ —	\$149.5	\$ —
Operating leases . . . . .	30.7	3.8	6.9	7.1	12.9
Unconditional purchase obligations . . . . .	63.2	32.2	31.0	—	—
Research and development funding commitments . . . . .	4.2	2.6	1.6	—	—
Total contractual cash obligations . . . . .	<u>\$247.6</u>	<u>\$38.6</u>	<u>\$39.5</u>	<u>\$156.6</u>	<u>\$12.9</u>

#### Recent accounting pronouncements

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." Among other provisions, SFAS No. 145 rescinds SFAS No. 4, "Reporting Gains and Losses from Extinguishment of Debt." Accordingly, gains or losses from extinguishment of debt shall not be reported as extraordinary items unless the extinguishment qualifies as an extraordinary item under the criteria of Accounting Principles Board ("APB") Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." Gains or losses from extinguishment of debt that do not meet the criteria of APB No. 30 should be reclassified to income from continuing operations in all prior periods presented. The provisions of SFAS No. 145 are effective for certain transactions occurring after May 15, 2002 and financial statements issued on or after May 15, 2002. Adoption of SFAS No. 145 did not have a material impact on our consolidated financial statements. We will assess the impact of SFAS No. 145 on all future transactions.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs To Exit an Activity (Including Certain Costs Associated with a Restructuring)* and requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, as opposed to when management is committed to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. This Statement is effective for exit or disposal activities initiated after December 31, 2002. The provisions of SFAS No. 146 are required to be applied prospectively after the adoption date to newly initiated exit activities, and may affect the timing of recognizing future restructuring costs, as well as the amounts recognized.

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a rollforward of the entity's product warranty liabilities. FIN 45 is effective on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements for interim and annual periods ending after December 31, 2002.

We do not expect the adoption of FIN 45 will have a material impact on our consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for our 2002 fiscal year. See "Stock-based compensation" in Note 2 of our Notes to Consolidated Financial Statements for disclosures required by SFAS 148.

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

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

We maintain an investment portfolio of depository accounts, master notes and liquidity optimized investment contracts. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market rates would have a significant negative impact on the value of our investment portfolio. At December 31, 2002, the average maturity of our available-for-sale securities was 96 days.

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



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

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

We have some obligations in foreign currencies, principally the purchase of Actimmune inventory, which is denominated in Euros. We do not currently use derivative financial instruments to mitigate this exposure.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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## REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders  
InterMune, Inc.

We have audited the accompanying consolidated balance sheets of InterMune, Inc. as of December 31, 2002 and 2001, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of InterMune, Inc. at December 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

ERNST & YOUNG LLP

Palo Alto, California  
February 10, 2003

INTERMUNE, INC.  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands except share and per share data)

	December 31, 2002	December 31, 2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$101,683	\$122,915
Available-for-sale securities . . . . .	214,728	209,152
Accounts receivable, net of allowances of \$3,415 in 2002 and \$949 in 2001 . . . . .	12,135	5,355
Inventories . . . . .	6,604	3,922
Prepaid expenses . . . . .	2,269	1,307
Total current assets . . . . .	337,419	342,651
Property and equipment, net . . . . .	10,833	7,593
Acquired product rights, net . . . . .	30,336	30,429
Restricted cash . . . . .	1,675	1,675
Notes receivable from employees . . . . .	906	146
Other assets . . . . .	3,712	4,752
	\$384,881	\$387,246
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 16,843	\$ 8,277
Accrued compensation . . . . .	5,353	2,878
Other accrued liabilities . . . . .	29,590	11,151
Total current liabilities . . . . .	51,786	22,306
Deferred rent . . . . .	877	381
Convertible subordinated notes . . . . .	149,500	149,500
Commitments		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2002 and 2001 . . . . .	—	—
Common stock, \$0.001 par value, 45,000,000 authorized shares; 31,695,672 shares and 28,450,912 shares issued and outstanding at December 31, 2002 and 2001, respectively . . . . .	32	28
Additional paid-in capital . . . . .	481,881	373,310
Notes receivable from stockholder . . . . .	(38)	(56)
Deferred stock compensation . . . . .	(947)	(3,414)
Accumulated other comprehensive income . . . . .	957	49
Accumulated deficit . . . . .	(299,167)	(154,858)
Total stockholders' equity . . . . .	182,718	215,059
	\$384,881	\$387,246

See Accompanying Notes.

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

	For the year ended December 31,		
	2002	2001	2000
Product sales			
Actimmune .....	\$ 105,802	\$ 36,320	\$ 11,201
All others .....	6,163	3,631	—
Total product sales, net .....	111,965	39,951	11,201
Costs and expenses:			
Cost of goods sold .....	24,161	15,474	4,990
Amortization of acquired product rights .....	3,593	4,805	1,777
Research and development .....	129,590	52,049	20,821
Selling, general and administrative .....	62,752	35,895	16,152
Acquired in-process research and development .....	33,750	56,400	—
Total costs and expenses .....	253,846	164,623	43,740
Loss from operations .....	(141,881)	(124,672)	(32,539)
Other income (expense):			
Interest income .....	7,375	11,253	8,484
Interest expense .....	(9,803)	(4,772)	(191)
Net loss .....	(144,309)	(118,191)	(24,246)
Preferred stock accretion .....	—	—	(269)
Deemed dividend on redeemable preferred stock .....	—	—	(27,762)
Net loss applicable to common stockholders .....	<u>\$(144,309)</u>	<u>\$(118,191)</u>	<u>\$(52,277)</u>
Historical basic and diluted net loss per common share .....	<u>\$ (4.72)</u>	<u>\$ (4.67)</u>	<u>\$ (3.05)</u>
Shares used in computing historical basic and diluted net loss per common share .....	<u>30,589</u>	<u>25,322</u>	<u>17,114</u>

See Accompanying Notes.

INTERMUNE, INC.

CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)  
(In thousands except share and per share data)

	Redeemable convertible preferred stock		Convertible preferred stock		Common stock		Stockholders' Equity					
	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	Notes receivable from stockholder	Deferred compensation related to stock options	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity/(deficit)
<b>Balance at December 31, 1999</b>	6,000	7,417	1,835	4,507	1,891	5,659	—	—	(5,286)	—	(12,421)	(7,541)
Return of capital to Connecticut	—	—	—	—	—	—	(1,000)	—	—	—	—	(1,000)
Net unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	107	—	107
Net loss	—	—	—	—	—	—	—	—	—	—	(24,246)	(24,246)
Comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	—
Reincorporation in Delaware	—	—	—	—	—	(5,657)	5,657	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock for cash, net of issuance costs of \$1,424 at \$5.59 per share	4,757	25,166	—	—	—	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock to agent upon completion of private placement financing	120	671	—	—	—	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock as milestone payment to Connecticut	89	500	—	—	—	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	1,075	1	462	(90)	—	—	—	373
Interest on note receivable from stockholder	—	—	—	—	—	—	—	(5)	—	—	—	(5)
Preferred stock accretion	—	—	—	—	—	—	—	—	—	—	—	(269)
Repurchase of common stock	—	—	—	—	(124)	—	(269)	—	—	—	—	(15)
Conversion of preferred stock upon close of initial public offering	(10,966)	(34,023)	(1,835)	(4,507)	12,801	13	38,517	—	—	—	—	34,023
Issuance of common stock in initial public offering at \$20.00 per share, net of issuance costs of \$10,015	—	—	—	—	6,250	6	114,979	—	—	—	—	114,985
Issuance of common stock in a private placement at \$38.00 per share, net of issuance costs of \$4,932	—	—	—	—	2,000	2	71,066	—	—	—	—	71,068
Stock compensation related to options granted to consultants for services	—	—	—	—	—	—	1,555	—	—	—	—	1,555
Stock issued under employee stock purchase plan	—	—	—	—	5	—	85	—	—	—	—	85
Deferred stock compensation	—	—	—	—	—	—	8,583	(8,583)	—	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	—	6,681	—	—	—	6,681
<b>Balance at December 31, 2000</b>	—	—	—	—	23,898	24	239,620	(95)	(7,188)	107	(36,667)	195,801
Net unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—	—	(58)	—	(58)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(118,191)
Comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(118,249)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	835
Stock issued under employee stock purchase plan	—	—	—	—	189	—	835	—	—	—	—	835
Issuance of common stock in a public offering at \$32.00 per share, net of issuance costs of \$8,628	—	—	—	—	25	—	534	—	—	—	—	534
Issuance of common stock for technology license and common stock investment in a private company	—	—	—	—	4,296	4	128,837	—	—	—	—	128,841
Payment of note receivable net of accrued interest	—	—	—	—	43	—	2,160	—	—	—	—	2,160
Stock compensation related to options granted to consultants for services	—	—	—	—	—	—	—	39	—	—	—	39
Amortization of deferred stock compensation	—	—	—	—	—	—	1,324	—	—	—	—	1,324
<b>Balance at December 31, 2001</b>	—	—	—	—	28,451	28	373,310	(56)	(3,414)	49	(154,858)	215,059
Net unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	908	—	908
Net loss	—	—	—	—	—	—	—	—	—	—	(144,309)	(144,309)
Comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(143,401)
Exercise of stock options	—	—	—	—	227	1	2,333	—	—	—	—	2,334
Stock issued under employee stock purchase plan	—	—	—	—	67	—	1,464	—	—	—	—	1,464
Issuance of common stock in a public offering at \$37.00 per share, net of issuance costs of \$6,540	—	—	—	—	3,000	3	104,457	—	—	—	—	104,460
Repurchase of common stock at \$0.125 per share	—	—	—	—	(49)	—	(6)	—	—	—	—	(6)
Reversal of deferred stock compensation due to employees termination	—	—	—	—	—	—	(1,447)	—	—	—	—	(790)
Payment of note receivable net of accrued interest	—	—	—	—	—	—	—	18	—	—	—	18
Acceleration of unvested stock options	—	—	—	—	—	—	965	—	—	—	—	965
Stock compensation related to options granted to consultants for services	—	—	—	—	—	—	805	—	—	—	—	805
Amortization of deferred stock compensation	—	—	—	—	—	—	—	—	—	—	—	1,568
<b>Balance at December 31, 2002</b>	—	—	—	—	31,696	32	\$481,881	\$(28)	\$(947)	957	\$(299,167)	\$ 182,718

INTERMUNE, INC.  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	For the year ended December 31		
	2002	2001	2000
<b>Cash flows used for operating activities:</b>			
Net loss	\$(144,309)	\$(118,191)	\$ (24,246)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization of deferred compensation, net of reversals	1,020	3,774	6,681
Non-cash stock compensation	1,770	1,324	2,226
Non-cash charge related to acquisition of technology license and common stock investment	—	2,160	—
Accretion of obligations payable to Connetics	—	30	144
Acquired in-process research and development	33,750	56,400	—
Amortization	4,619	2,685	—
Depreciation	1,964	766	160
Deferred rent	496	381	—
Interest receivable on stockholder note	—	—	(5)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable	(6,780)	(3,555)	(1,391)
Inventories	(2,682)	(2,873)	(218)
Notes receivable from officer	—	—	104
Prepaid expenses	(962)	(755)	(533)
Restricted cash	—	(1,425)	—
Notes receivable from employees and other assets	(746)	(284)	—
Accounts payable and accrued compensation	11,041	8,313	2,609
Payable to Connetics	—	1,691	(3,527)
Other accrued liabilities	3,439	7,057	(1,490)
Net cash used for operating activities	(97,380)	(42,502)	(19,486)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(5,204)	(7,516)	(977)
Acquisition of product rights	(22,250)	(87,000)	—
Purchases of available-for-sale securities	(223,869)	(407,146)	(235,870)
Maturities of available-for-sale securities	163,873	170,370	27,417
Sales of available-for-sale securities	55,328	173,895	62,673
Net cash used for investing activities	(32,122)	(157,397)	(146,757)
<b>Cash flows from financing activities:</b>			
Return of capital to Parent (Connetics)	—	—	(1,000)
Proceeds from issuance of common stock, net	108,252	130,210	186,496
Proceeds from redeemable preferred stock, net	—	—	25,166
Proceeds from convertible subordinated notes, net	—	144,374	—
Repayment of notes receivable from stockholder	18	39	—
Net cash provided by financing activities	108,270	274,623	210,662
Net increase (decrease) in cash and cash equivalents	(21,232)	74,724	44,419
Cash and cash equivalents at beginning of period	122,915	48,191	3,772
Cash and cash equivalents at end of period	\$ 101,683	\$ 122,915	\$ 48,191
<b>Supplemental disclosure of cash flow information:</b>			
Return of capital on obligation to Parent (Connetics)	\$ —	\$ —	\$ (1,000)
Interest paid	8,836	30	122
<b>Schedule of non-cash transactions:</b>			
Deferred stock compensation	\$ —	\$ —	\$ 8,583
Issuance of shares for note receivable	—	—	90
Issuance of common stock as settlement of obligation	—	—	500
Issuance of common stock for technology license and common stock investment	—	2,160	—
Payable for acquired product rights	2,000	2,000	—
Payable for royalty rate buy down	15,000	—	—

See Accompanying Notes.

**InterMune, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. ORGANIZATION**

**Overview**

InterMune, Inc. ("InterMune" or the "Company") develops and commercializes innovative products for the treatment of serious pulmonary, infectious and hepatic diseases. The Company has the exclusive license rights in the United States to Actimmune (interferon gamma-1b) injection for a range of indications, including chronic granulomatous disease, osteopetrosis, idiopathic pulmonary fibrosis, cancer, mycobacterial infections, systemic fungal infections and cystic fibrosis. The Company has active development programs underway for many of these indications, several of which are in mid- or advanced-stage human testing, known as clinical trials. The FDA has approved Actimmune for the treatment of chronic granulomatous disease and for the treatment of severe, malignant osteopetrosis. The Company markets and sells Actimmune in the United States for these diseases. In January 2001, the Company acquired from ALZA Corporation the worldwide rights to Amphotec, an FDA approved lipid-complexed form of amphotericin B indicated for the treatment of invasive aspergillosis, a life-threatening fungal infection. In June 2001, the Company acquired Infergen, a therapeutic approved by the FDA for the treatment of chronic hepatitis C infections, which was developed and commercialized by Amgen Inc. The Company is incorporated in the state of Delaware.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Principles of consolidation**

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

**Reclassifications**

Certain prior year balance sheet amounts have been reclassified to conform with current year presentation.

**Use of estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ significantly from these estimates under different assumptions or conditions.

On an on-going basis we evaluate our estimates, including those related to revenue recognition, bad debts, inventories, accrued clinical and pre-clinical expenses and contingencies. We base our estimation on historical experience and on various other specific assumptions that are believed 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. The Company classifies all debt securities as available-for-sale. Cash equivalents and available-for-sale securities are carried at fair value, with unrealized gains and



InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

losses, reported as a separate component of stockholders' equity. The estimated fair value amounts have been determined by the Company using available market information. The cost of securities sold is based on the specific identification method.

**Fair value of financial instruments**

Financial instruments, including cash, accounts receivable, accounts payable and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments. The fair value of convertible subordinated debt was \$148.6 million at December 31, 2002, determined by the Company using available market information.

**Concentration of risks**

Cash equivalents, investments and trade receivables are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the balance sheet. Management of the Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. The Company invests its excess cash in debt instruments of the U.S. Government and its agencies and high-quality corporate issuers, and, by policy, restricts its exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, the Company currently maintains investments with an average maturity of 96 days to maturity. The Company's revenues and trade receivables are concentrated with a few customers. The Company performs credit evaluations of its customers' financial condition and limits the amount of credit extended when necessary, but generally does not require collateral on accounts receivable. See Note 13 for additional customer concentrations details.

**Risks from third-party manufacturing concentration**

The Company relies on single source manufacturers for each of its products. Actimmune is produced solely by Boehringer Ingleheim Austria GmbH, for all clinical and commercial supplies. Amphotec is produced solely by Ben Venue Laboratories Inc, and Infergen is produced solely by Amgen Inc. Any extended interruption in the supply of any products could result in the failure to meet clinical or customer demand.

**Inventories**

Inventories consist principally of raw materials and finished good products and are stated at the lower of cost or market. 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.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Acquired product rights

Initial payments for the acquisition of products that, at the time of acquisition by the Company, are already marketed or are approved by the FDA for marketing are typically 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 management's assessment of future sales and profitability of the product. This estimate is assessed regularly during the amortization period, and the asset value or useful life adjusted when appropriate. Initial payments for the acquisition of products that, at the time of acquisition by the Company, are under development or are not approved by the FDA for marketing, have not reached technical feasibility and have no foreseeable alternative future uses are expensed as research and development.

Acquired product rights in 2002 related to the acquisition of interferon gamma patents. Acquired product rights in 2001 related to the acquisition of Amphotec and Infergen. At December 31, 2002, accumulated amortization amounted to \$5.8 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, the Company assesses 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, the Company 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. To date, no such indicators of impairment have been identified.

Revenue recognition

Revenues from product sales are recognized upon shipment when title passes to a credit-worthy customer, net of allowances for estimated returns, rebates, chargebacks and cash discounts. The Company is obligated to accept from customers the return of pharmaceuticals that have reached their expiration date. The Company monitors product ordering cycles and actual returns, product date codes and wholesale inventory levels to estimate potential product return rates. The Company has not experienced any significant returns of expired product. The Company monitors all sales of products and estimates a reserve for those sales subject to rebates, chargebacks and discounts. Shipping and handling costs are included in cost of good sold.

Prior to March 31, 2000, sales and related costs of sales and accounts receivable for sales below a baseline amount were transacted on behalf of Connetics Corporation under an agreement. For sales below the baseline amount, any amounts in excess of net revenues less costs to produce and market were paid to Connetics. These sales, costs of sales and the amounts receivable were recorded by the Company on a net basis, which is equivalent to zero in the accompanying consolidated financial statements. Sales, costs of sales and accounts receivable were not subject to the risks and rewards of ownership by the Company. Revenues excluded from the consolidated financial statements under this agreement amounted to \$1.8 million for the year ended December 31, 2000.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

**Research and development expenses**

Research and development (or R&D) expenses include salaries, contractor and consultant fees, external clinical trial expenses performed by contract research organizations, in-licensing fees and facility and administrative expense allocations. In addition, the Company funds R&D at research institutions under agreements, which are generally cancelable at the Company's option. Research costs typically consist of preclinical and toxicology work. Pharmaceutical 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.

Management accrues costs for clinical trial activities performed by contract research organizations based upon estimates of the percentage of work completed over the life of the individual study. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. The Company monitors patient enrollment levels and related activities to the extent possible; however, if the Company underestimated activity levels associated with various studies at a given point in time, the Company could record significant research and development expenses in future periods. All such costs are charged to R&D expense as incurred.

**Advertising costs**

The Company expenses advertising costs as incurred. Advertising costs were \$93,000, \$130,000 and \$581,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

**Income taxes**

In accordance with SFAS No. 109, Accounting for Income Taxes, a deferred tax asset or liability is determined 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. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

**Patent costs**

Costs related to patents are expensed as incurred.

**Stock-based compensation**

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

When the exercise price of the employee or director stock options is less than the deemed fair value of the underlying stock on the grant date, the Company records deferred compensation for the difference. Deferred compensation is being amortized using the graded vesting method over the vesting

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

period of the original award, generally five years. Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123, and are recognized over the related service period and are periodically remeasured as the underlying options vest.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation to stock-based employee compensation (in thousands, except per share data):

	Year Ended December 31		
	2002	2001	2000
Net loss, as reported . . . . .	\$(144,309)	\$(118,191)	\$(52,277)
Add: Stock-based employee compensation expense, included in reported net loss, net of related tax effects . . . . .	2,790	5,098	8,236
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects . . . . .	(30,611)	(20,158)	(8,500)
Pro forma net loss . . . . .	<u>\$(172,130)</u>	<u>\$(133,251)</u>	<u>\$(52,541)</u>
Net loss per share:			
Basic and diluted—as reported . . . . .	\$ (4.72)	\$ (4.67)	\$ (3.05)
Basic and diluted—pro forma . . . . .	\$ (5.63)	\$ (5.26)	\$ (3.07)

Comprehensive income (loss)

SFAS No. 130, Reporting Comprehensive Income, requires components of other comprehensive income, including unrealized gains or losses on the Company's available-for-sale securities to be included in total comprehensive income (loss). Total comprehensive loss for each of the periods presented has been disclosed in the statements of stockholders' equity.

Net loss per share

Basic net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Shares subject to repurchase are deducted from the outstanding shares in arriving at the weighted average shares outstanding. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding for the period. The Company excluded potentially dilutive common equivalent shares from stock options (on the treasury stock method), and preferred stock and convertible notes (on an if-converted basis). These potentially dilutive securities were excluded from

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

historical diluted loss per share because of their anti-dilutive effect. The securities excluded were as follows (in thousands):

	Year ended December 31,		
	2002	2001	2000
Options . . . . .	4,491	2,988	1,223
Shares issuable upon conversion of convertible subordinated notes . . . . .	3,893	3,893	—

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

	Year ended December 31,		
	2002	2001	2000
Net loss . . . . .	\$(144,309)	\$(118,191)	\$(24,246)
Preferred stock accretion . . . . .	—	—	(269)
Deemed dividend to preferred stockholders . . . . .	—	—	(27,762)
Net loss allocable to common stockholders . . . . .	<u>\$(144,309)</u>	<u>\$(118,191)</u>	<u>\$(52,277)</u>
Basic and diluted net loss per common share:			
Weighted-average shares of common stock outstanding . . . . .	30,976	26,080	18,236
Less: weighted-average shares subject to repurchase . . . . .	<u>(387)</u>	<u>(758)</u>	<u>(1,122)</u>
Weighted-average shares used in computing basic and diluted net loss per common share . . . . .	<u>30,589</u>	<u>25,322</u>	<u>17,114</u>
Basic and diluted net loss per common share . . . . .	<u>\$ (4.72)</u>	<u>\$ (4.67)</u>	<u>\$ (3.05)</u>

Recent accounting pronouncements

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." Among other provisions, SFAS No. 145 rescinds SFAS No. 4, "Reporting Gains and Losses from Extinguishment of Debt." Accordingly, gains or losses from extinguishment of debt should not be reported as extraordinary items unless the extinguishment qualifies as an extraordinary item under the criteria of Accounting Principles Board ("APB") Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." Gains or losses from extinguishment of debt that do not meet the criteria of APB No. 30 should be reclassified to income from continuing operations in all prior periods presented. The provisions of SFAS No. 145 are effective for certain transactions occurring after May 15, 2002 and financial statements issued on or after May 15, 2002. The adoption of SFAS No. 145 did not have a material impact on the Company's consolidated financial statements.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 supersedes Emerging Issues Task Force

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs To Exit an Activity (Including Certain Costs Associated with a Restructuring)* and requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, as opposed to when management is committed to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. This Statement is effective for exit or disposal activities initiated after December 31, 2002. The provisions of SFAS No. 146 are required to be applied prospectively after the adoption date to newly initiated exit activities, and may affect the timing of recognizing future restructuring costs, as well as the amounts recognized.

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a rollforward of the entity's product warranty liabilities. FIN 45 is effective on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements for interim and annual periods ending after December 31, 2002. The Company does not expect the adoption of FIN 45 will have a material impact on its consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for the Company's fiscal year 2002. See "Stock-based compensation" above for disclosures required by SFAS 148.

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

## 3. ACQUIRED PRODUCT RIGHTS

### Marnac, Inc. ("Marnac")

In March 2002, the Company licensed from Marnac, Inc., a privately held biopharmaceutical company, and its co-licensor, KDL GmbH, their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Pirfenidone is not approved by the FDA and is currently in Phase II clinical development for

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**3. ACQUIRED PRODUCT RIGHTS (Continued)**

fibrotic diseases of the lung, kidney, liver and heart. Under the terms of the license agreement, the Company 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. The Company expensed the \$18.8 million as acquired in-process research and development in the first quarter of 2002 since pirfenidone is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses.

**Amgen Inc. ("Amgen")**

In May 2002, the Company acquired certain interferon gamma patents of Amgen Inc. in exchange for \$3.5 million, of which \$1.5 million was paid in the second quarter of 2002, and \$2.0 million was an accrued liability as of December 31, 2002, and was paid in January 2003. The Company is amortizing these product rights to operations over the expected useful product life of Actimmune.

In June 2001, the Company entered into a licensing and commercialization agreement with Amgen to obtain an exclusive license in the United States and Canada to Infergen (interferon alfacon-1), an interferon alpha product, and the rights to an early stage program to develop a pegylated form of Infergen (PEG-Infergen). Infergen is currently approved in both the United States and Canada to treat chronic hepatitis C infections. Under the agreement, the Company will have the exclusive right to market Infergen and clinically develop it for other indications in the United States and Canada. The Company paid Amgen total consideration of \$29.0 million (including up-front license and other fees and milestones) and is obligated to pay royalties on sales of Infergen (included in cost of goods sold). The Company is also required to pay Amgen additional milestone payments on the PEG-Infergen program and royalties on sales of the resulting product, if any. The Company's rights to Infergen could revert to Amgen if the Company does not meet its diligence obligations or otherwise commits a material breach of the agreement.

The Company does not expect the PEG-Infergen program, which is currently in its early stages (approximately 20% completed), to reach the FDA approval stage until 2007 at the earliest, if at all. Based upon independent appraisal, the fair value of the in-process research and development program for PEG-Infergen was \$5.4 million. The remainder of the purchase price of approximately \$23.6 million was allocated to developed technology and will be amortized over ten years.

The value assigned to acquired in-process research and technology was determined by estimating the costs to develop the purchased in-process research and development into a commercially viable product, including development milestones, estimating the resulting net cash flows from the project and discounting the net cash flows to their present value. A discount rate of 33% was used for valuing the in-process research and development and is intended to be commensurate with the Company's corporate maturity, the potential product's stage of development and the uncertainties in the economic estimates described above. The technology under development has no foreseeable alternative future uses.

The estimates used by the Company in valuing in-process research and development were based upon assumptions the Company believes to be reasonable but which are inherently uncertain and unpredictable. The Company's assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur. Accordingly, actual results may vary from the projected results.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. ACQUIRED PRODUCT RIGHTS (Continued)

Eli Lilly and Company ("Eli Lilly")

In October 2001, the Company entered into an asset purchase and license agreement with Eli Lilly and Company pursuant to which the Company acquired worldwide rights to oritavancin from Eli Lilly. Oritavancin is presently under development for the treatment of complicated skin and skin-structure infections. The agreement provides the Company with exclusive worldwide rights to develop, manufacture and commercialize oritavancin. If the Company wishes to enter into a relationship with a third party to commercialize oritavancin in any country, however, the Company must first offer Eli Lilly the opportunity to enter into such a commercialization relationship with the Company. After the Company negotiates with Eli Lilly, the agreement prohibits the Company from entering into an agreement with a third party on more favorable terms than those the Company offered to Eli Lilly. Pursuant to the agreement, the Company paid Eli Lilly \$50.0 million and will be obligated to pay Eli Lilly significant milestone and royalty payments upon any successful development and commercialization of oritavancin by the Company. The license fee of \$50.0 million was expensed as acquired in-process research and development in the fourth quarter of 2001 since the oritavancin program is currently in clinical development, has not reached technical feasibility and has no foreseeable alternative future uses.

From March 2002 through March 2003, Eli Lilly had an option to reduce the agreed royalty percentages by requiring the Company to pay \$15.0 million to Eli Lilly. In September 2002, Eli Lilly exercised this option. As a result, the Company expensed a total of \$15.0 million in the third quarter of 2002. This amount was recorded as an accrued liability at December 31, 2002, and was paid in January 2003.

The Company's rights to oritavancin could revert to Eli Lilly if the Company does not meet its diligence obligations under the agreement or otherwise commits a material breach of the agreement. Additionally, if the Company is acquired by a company with a certain type of competing program and Eli Lilly has notified the Company prior to the acquisition that it believes in good faith that its economic interests in oritavancin under the agreement will be harmed in light of the acquisition, Eli Lilly may terminate the agreement and the Company's rights to oritavancin would revert to Eli Lilly. In any event, the Company may not assign the agreement to a potential acquirer without the advance, written consent of Eli Lilly.

ALZA Corporation ("ALZA")

In January 2001, the Company acquired from ALZA the worldwide rights to Amphotec (amphotericin B cholesteryl sulfate complex for injection), which is sold under the tradename Amphocil in certain countries outside the United States. Amphotec is currently approved in North America and many other countries for the treatment of invasive aspergillosis. The transaction terms included an up-front product acquisition fee of \$9.0 million, milestone payments based upon sales levels and specific achievements in the clinical development and regulatory approval of Amphotec in combination with Actimmune, and royalties payable upon net sales of Amphotec (included in cost of goods sold). Under the agreement, the Company obtained access to certain existing distributorships for Amphotec, and assumed ALZA's obligations under agreements with its existing Amphotec distributors and service providers. The Company has diligence obligations under the agreement to establish additional distributorships for Amphotec or establish a sales force and begin to promote Amphotec in specified countries at specified times. The Company's rights to Amphotec could revert to ALZA if the Company



NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. ACQUIRED PRODUCT RIGHTS (Continued)

does not meet its diligence obligations or otherwise commits a material breach of the agreement. The Company is also subject to certain royalty obligations to the University of California under this agreement. The product acquisition fee has been capitalized as acquired product rights and will be amortized over its estimated useful life of ten years.

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

At its formation, the Company entered into an agreement with Connetics under which the Company obtained an exclusive sublicense under the rights granted to Connetics by Genentech through a license agreement relating to interferon gamma-1b, the active ingredient in Actimmune, in exchange for shares of the Company's common stock. The Company also agreed to assume many of Connetics' obligations to Genentech under that license agreement. The Company entered into an agreement with Connetics in April 1999 in order to broaden the scope of rights granted to the Company. In June 2000, the Company entered into an assignment and option agreement with Connetics, by which Connetics assigned the Genentech license to the Company. In August 2002, the Company mutually terminated Connetics' option in the assignment agreement for any rights in the field of dermatology. 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.

The Company's licensed Actimmune rights include exclusive and non-exclusive rights under Genentech's patents. 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 rights include a license to make or have made Actimmune for clinical and commercial purposes within the field of use in the United States and Canada. In Japan, the Company has 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 chronic granulomatous disease or osteopetrosis. The Company also has the opportunity, under specified conditions, to obtain further rights to Actimmune in Japan and other countries. In addition, the Company received an exclusive sublicense under certain of Genentech's patents outside the United States, Canada and Japan under the Boehringer Ingelheim agreement discussed in Note 4. Under the Genentech license, the Company pays Genentech royalties on the sales of Actimmune (included in cost of goods sold), and makes one-time payments to Genentech upon the occurrence of specified milestone events. The Company must satisfy specified obligations under the agreement with Genentech to maintain its license from Genentech. The Company is obligated under the agreement to develop and potentially commercialize Actimmune for a number of diseases. Royalties are payable upon net sales of Actimmune to Connetics. Through an assignment and option agreement with Connetics, the Company became obligated to pay to Connetics, beginning on January 1, 2002, a royalty of 0.25% of net U.S. sales for Actimmune until net U.S. sales cumulatively surpass \$1.0 billion. Above \$1.0 billion, the Company is obligated to pay a royalty of 0.5% of net U.S. sales for Actimmune.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS

Array BioPharma Inc. ("Array")

In September 2002, the Company entered into a drug discovery collaboration agreement to create small molecule therapeutics targeting hepatitis with Array. The Company will fund drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and will be responsible for all development and commercialization. Array will be entitled to receive milestone payments based on the selection and progress of clinical drug candidates, as well as royalties on net sales of products derived from the collaborative efforts.

Medical College of Wisconsin ("MCW") Research Foundation

Under an agreement with MCW Research Foundation, Inc. dated March 25, 1999, the Company acquired an exclusive worldwide license to develop, manufacture and sell the *Pseudomonas V* antigen in the field of human disease therapy. The Company paid a license fee of \$50,000 in 1999, agreed to fund certain research activities, make future milestone payments upon the completion of specified developmental milestones and pay a royalty on net sales of licensed product. The Company can terminate the agreement at any time upon giving at least 90 days written notice. Total expenses related to this agreement were \$167,000 in 2002, \$229,000 in 2001, and \$212,000 in 2000. The Company sent a notice of termination for this agreement in February 2003.

Panorama Research Inc. ("Panorama")

Under a three year agreement with Panorama dated January 1, 2000, the Company acquired an exclusive worldwide license to develop and commercialize peptides that block *Staphylococcus aureus* infections. The Company agreed to fund research as incurred, make future milestone payments upon completion of specified developmental milestones and pay a royalty on net sales of licensed product. The Company paid a total of \$150,000 in each of the years ended December 31, 2002, 2001 and 2000 under this agreement. The research program under the agreement expired on December 31, 2002, and the Company did not renew it.

Molichem Medicines, Inc. ("Molichem")

In May 2001, the Company and MoliChem initiated a collaboration to jointly develop and commercialize MoliChem's pulmonary molecule Moli1901 (duramycin) for the treatment of a range of pulmonary indications, including cystic fibrosis. The terms of the collaboration included an up-front payment of \$1.5 million to MoliChem which was charged to research and development expense in 2001 as well as the payment of development milestones to MoliChem. In December 2002, upon appropriate notice, the Company terminated this agreement and is not obligated to make any further payments.

Maxygen, Inc. ("Maxygen")

In September 2001, the Company and Maxygen Holdings Ltd., a wholly owned subsidiary of Maxygen, signed a license and collaboration agreement to develop and commercialize novel, next-generation interferon gamma products. Under the terms of the agreement, InterMune will take forward into clinical development certain product candidates created by Maxygen. InterMune will fund optimization and development of these next-generation interferon gamma products, and will retain

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS (Continued)

exclusive worldwide commercialization rights for all human therapeutic indications. The terms of the agreement include up-front license fees, full research funding and development and commercialization milestone payments. The Company paid Maxygen a total of \$5.1 million and \$3.5 million for the years ended December 31, 2002 and 2001, respectively. The payments were charged to research and development expense. In addition, Maxygen will receive royalties on product sales.

**Protein Design Labs, Inc. ("PDL")**

On November 28, 2000, the Company signed an agreement with PDL under which PDL will humanize an InterMune monoclonal antibody targeted to the bacteria *Pseudomonas aeruginosa*. InterMune paid an up-front fee and will be required to pay milestone payments upon the achievement of specified objectives, annual maintenance payments and royalties on any product sales. The Company paid PDL a total of \$150,000, \$500,000 and \$1.0 million for the years ended December 31, 2002, 2001 and 2000, respectively, under the terms of this agreement. The payments were charged to research and development expense.

**Boehringer Ingelheim International GmbH ("BI")**

In March 2001, the Company and BI formed an international strategic collaboration to develop and commercialize interferon gamma-1b under BI's trade name, Imukin®, in all countries outside of the United States, Canada and Japan. Indications to be developed include idiopathic pulmonary fibrosis (IPF), tuberculosis, systemic fungal infections, chronic granulomatous disease (CGD), osteopetrosis, as well as additional indications to be agreed upon later. During 2002, the strategic collaboration agreement was amended to include the additional indications of ovarian cancer, liver fibrosis and non-Hodgkins lymphoma. This strategic alliance adds worldwide scope to the Company's existing rights to develop and commercialize interferon gamma-1b under the trade name Actimmune in the United States, Canada and Japan.

Under the agreement, the Company will fund and manage clinical and regulatory development of interferon gamma-1b for all indications. BI has an option to exclusively promote Imukin and the Company may opt to promote the product where BI does not do so. Furthermore, the two companies will share in the profits from commercializing interferon gamma-1b through a specified royalty schedule. Prior to receiving the first regulatory approval for any of IPF, tuberculosis or systemic fungal infections, the agreement provides the Company with royalties on Imukin net sales above 2000 levels. No royalties have been earned or paid under the terms of this agreement. Imukin is currently approved and marketed for CGD in 36 countries. Boehringer Ingelheim and the Company plan to immediately seek expedited EU approvals for Imukin for the treatment of severe, malignant osteopetrosis, an indication for which Actimmune is already approved in the United States. The Company also plans to expand its Phase III clinical development programs to target approvals in the expanded international markets. No royalties have been earned to date.

In addition to the above agreement, BI's affiliate Boehringer Ingelheim Austria GmbH manufactures all commercial and clinical supply of Actimmune for the Company at contractually determined unit prices.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. SPONSORED RESEARCH, LICENSE AND COLLABORATION AGREEMENTS (Continued)

Mondobiotech SA. ("Mondobiotech")

In December 2001, the Company paid cash and issued 42,822 shares of its common stock with an aggregate value of \$3.7 million to Mondobiotech, a European privately held development stage company, in exchange for technology licenses and equity in the privately held company. This amount was charged to research and development expense. Under the terms of the research and development agreement, the Company will pay for certain expenses associated with clinical trials and development milestones. In addition, the Company will pay royalties on product sales in certain European countries upon regulatory approval. The Company expensed the equity component of this transaction because of the early stage of development of the investee and the uncertainty of future realization.

Funding Commitments

The Company's non-cancelable funding commitments under the above arrangements total \$4.2 million at December 31, 2002. Such amounts are payable over the next two years.

5. AVAILABLE-FOR-SALE INVESTMENTS

The following is a summary of the Company's available-for-sale investments as of December 31, 2002 and 2001 (in thousands):

December 31, 2002

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Obligations of U.S. government agencies . . . . .	\$ 64,733	\$583	\$—	\$ 65,316
Corporate debt securities . . . . .	106,606	376	(2)	106,980
Other debt securities . . . . .	108,242	—	—	108,242
	<u>\$279,581</u>	<u>\$959</u>	<u>\$(2)</u>	<u>\$280,538</u>

Reported as:

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

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. AVAILABLE-FOR-SALE INVESTMENTS (Continued)

December 31, 2001

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Obligations of U.S. government Agencies . . . . .	\$168,374	\$282	\$(328)	\$168,328
Corporate debt securities . . . . .	128,016	148	(53)	128,111
Other debt securities . . . . .	27,318	—	—	27,318
	<u>\$323,708</u>	<u>\$430</u>	<u>\$(381)</u>	<u>\$323,757</u>

Reported as:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash equivalents . . . . .	\$114,626	\$ 6	\$ (27)	\$114,605
Available-for sale securities . . . . .	209,082	424	(354)	209,152
	<u>\$323,708</u>	<u>\$430</u>	<u>\$(381)</u>	<u>\$323,757</u>

The realized gains and losses for the years 2002 and 2001 were not material. Realized gains and losses were calculated based on the specific identification method. At December 31, 2002, the average maturity of our available-for-sale securities was 96 days.

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>2002</u>		<u>2001</u>	
	<u>Amortized Cost</u>	<u>Fair Value</u>	<u>Amortized Cost</u>	<u>Fair Value</u>
Mature in less than one year . . . . .	\$261,149	\$261,523	\$305,758	\$305,747
Mature in one to three years . . . . .	18,432	19,015	17,950	18,010
Total . . . . .	<u>\$279,581</u>	<u>\$280,538</u>	<u>\$323,708</u>	<u>\$323,757</u>

6. INVENTORIES

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

	<u>2002</u>	<u>2001</u>
Raw materials . . . . .	\$ 182	\$1,838
Finished goods . . . . .	6,422	2,084
Total . . . . .	<u>\$6,604</u>	<u>\$3,922</u>

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. PROPERTY AND EQUIPMENT

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

	<u>2002</u>	<u>2001</u>
Computer and laboratory equipment . . . . .	\$ 2,322	\$1,138
Office furniture and fixtures . . . . .	3,233	2,079
Leasehold improvements . . . . .	8,172	5,306
	<u>13,727</u>	<u>8,523</u>
Less accumulated depreciation and amortization . . . . .	<u>(2,894)</u>	<u>(930)</u>
	<u>\$10,833</u>	<u>\$7,593</u>

8. OTHER ACCRUED LIABILITIES

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

	<u>2002</u>	<u>2001</u>
Accrued clinical trial costs . . . . .	\$ 4,342	\$ 2,725
Accrued interest . . . . .	3,940	4,216
Payable to Amgen . . . . .	2,000	2,000
Payable to Eli Lilly . . . . .	15,000	—
Royalties payable . . . . .	4,101	1,523
Other accrued liabilities . . . . .	207	687
Total other accrued liabilities . . . . .	<u>\$29,590</u>	<u>\$11,151</u>

9. CONVERTIBLE SUBORDINATED NOTES

On July 5, 2001, the Company completed a public offering of \$149.5 million aggregate principal amount of 5.75% convertible subordinated notes due July 15, 2006. The notes are unsecured and rank junior to all the Company's future unsecured and unsubordinated debts. The notes are convertible at any time at the option of the note holders into the Company's common stock at a conversion price of \$38.40 per share subject to adjustment in certain circumstances. Interest on the notes is payable semi-annually in arrears in January and July and the Company can redeem all or a portion of the notes at any time on or after July 15, 2004. Offering expenses of \$5.1 million related to the sale of these notes have been included in other assets and are amortized to interest expense over the life of the notes. As of December 31, 2002, the fair value of these notes approximated \$148.6 million.

10. STOCKHOLDERS' EQUITY

Common stock subject to repurchase

In connection with the issuance of common stock to founders and the exercise of options pursuant to the Company's 1999 and 2000 Equity Incentive Plans, certain employees and non-employee directors entered into restricted stock purchase agreements with the Company. Under the terms of these agreements, upon termination of employment or service as a director, the Company has a right to repurchase any unvested shares at the original issuance price of the shares. With continuous

**InterMune, Inc.**

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

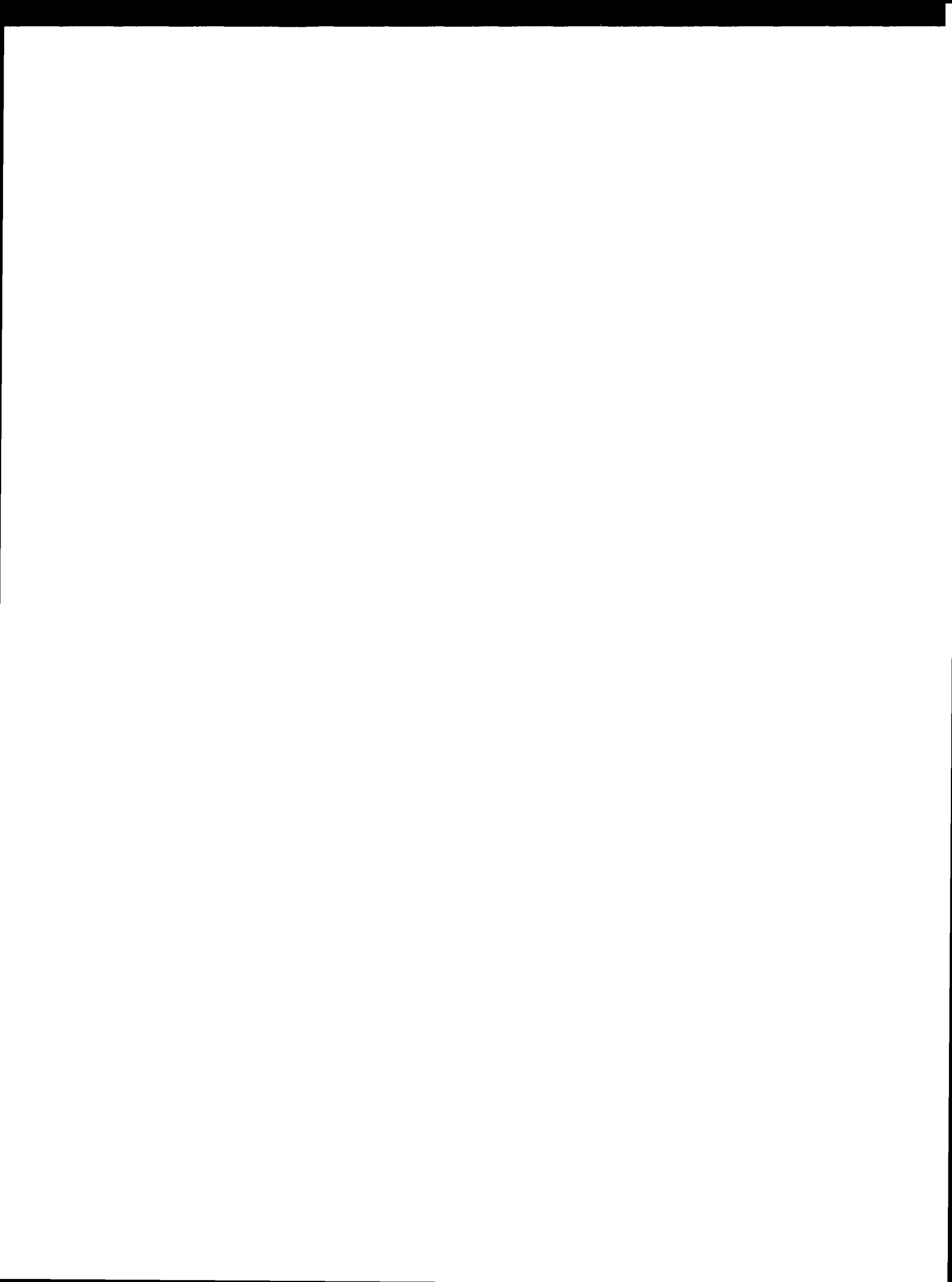
**10. STOCKHOLDERS' EQUITY (Continued)**

employment or services provided to the company, generally the repurchase rights lapse at a rate of 25% at the end of the first year and at a rate of 1/36th of the remaining purchased shares for each continuous month of service thereafter. The total number of shares subject to repurchase by the Company were 192,000 shares, 596,000 shares and 935,000 shares as of December 31, 2002, 2001 and 2000, respectively.

**Stock compensation plans**

In 1999, the Company 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 Company repurchase rights, to directors, employees and consultants. Certain options were immediately exercisable, at the discretion of the board of directors. Shares issued pursuant to the exercise of an unvested option are subject to the Company's right of repurchase which lapses over periods specified by the board of directors, generally five years from the date of grant. In March 2000, the Company terminated all remaining unissued shares under the 1999 Plan amounting to 121,584 shares. In 2002, the Company repurchased from certain terminated employees a total of 49,501 early exercised and unvested shares at a purchase price of \$0.125. The shares repurchased in 2002 were granted to employees under the 1999 Plan and are not available for future grant.

In January 2000, the Board of Directors adopted the 2000 Equity Incentive Plan and the 2000 Non-Employee Directors' Stock Option Plan. A total of 2,000,000 shares of common stock were reserved for issuance under the 2000 Equity Incentive Plan and 180,000 shares under the 2000 Non-Employee Directors' Stock Option Plan. The 2000 Equity Incentive Plan and 2000 Non-Employee Directors' Stock Option Plans provide for the granting of options to purchase common stock and the issuance of shares of common stock, subject to Company repurchase rights, to directors, employees and consultants. Certain options are immediately exercisable, at the discretion of the board of directors. Shares issued pursuant to the exercise of an unvested option are subject to the Company's right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. Options not immediately exercisable generally vest over 4 years. Options granted under the plans have a maximum term of 10 years.





InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

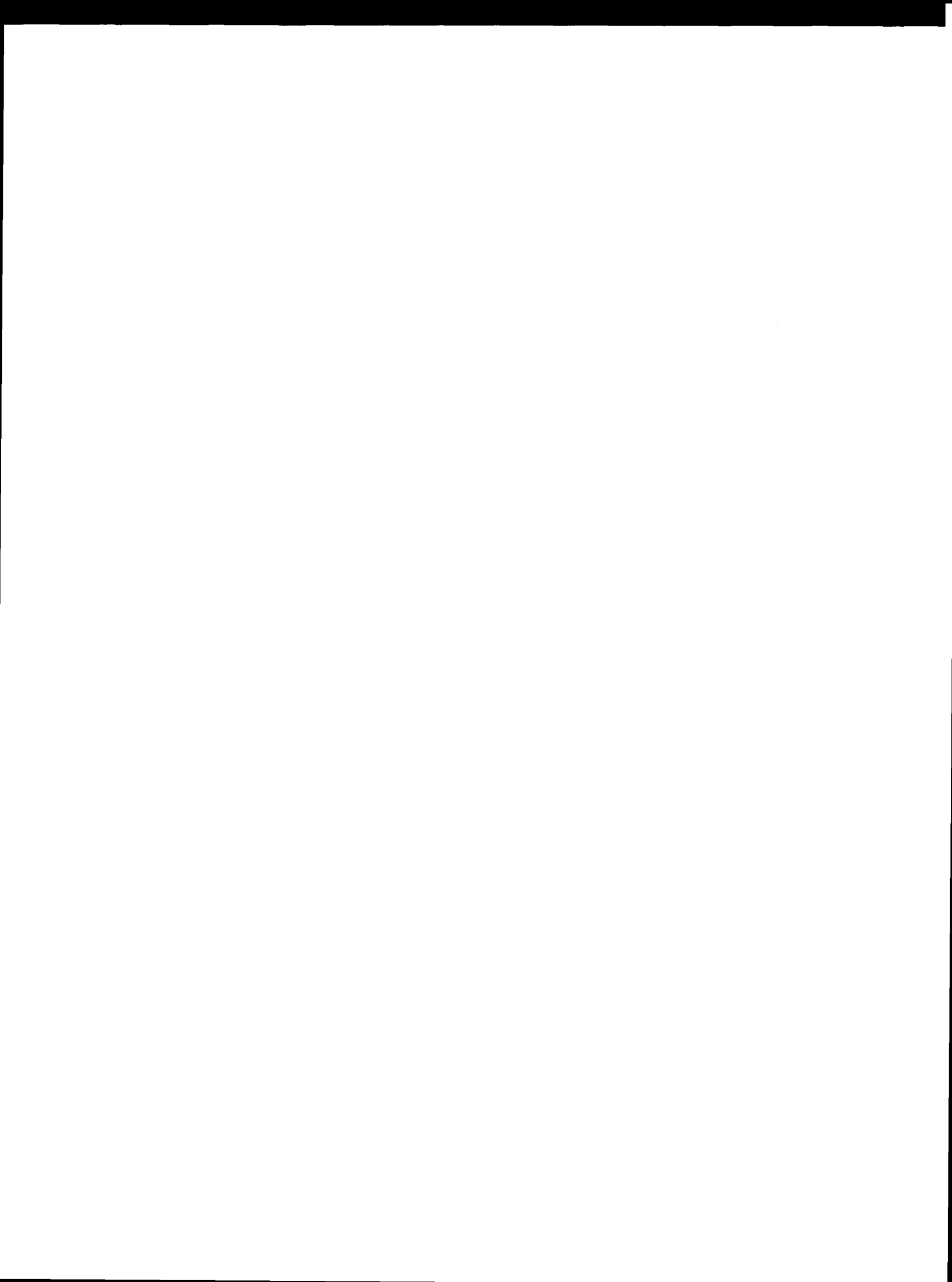
10. STOCKHOLDERS' EQUITY (Continued)

The stock option activity under all InterMune's 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, 1999	830,000	990,000	\$0.125
Authorized	2,180,000	—	—
Shares terminated under 1999 plan	(121,584)	—	—
Granted	(1,370,500)	1,370,500	\$14.34
Cancelled	63,334	(63,334)	\$10.09
Exercised	—	(1,074,513)	\$ 0.43
Repurchased	123,750	—	\$0.125
Balance at December 31, 2000	1,705,000	1,222,653	\$15.27
Authorized	896,939	—	—
Shares terminated under 1999 plan and not available for future grants	(41,000)	—	—
Granted	(2,094,501)	2,094,501	\$35.59
Cancelled	139,668	(139,668)	\$24.14
Exercised	—	(189,398)	\$ 4.41
Balance at December 31, 2001	606,106	2,988,088	\$29.79
Authorized	3,741,287	—	—
Shares terminated under 1999 plan and not available for future grants	(138,219)	—	—
Granted	(2,561,300)	2,561,300	\$33.81
Cancelled	831,358	(831,358)	\$32.73
Exercised	—	(227,326)	\$10.27
Repurchased	49,501	—	\$0.125
Balance at December 31, 2002	2,528,733	4,490,704	\$32.46

The following table summarizes information about options outstanding at December 31, 2002:

Options outstanding			Options exercisable		
Range of exercise prices	Number of shares	Weighted average remaining contractual life	Weighted average exercise price	Number of shares	Weighted average exercise price
\$0.125 - \$ 4.50	277,662	7.1	\$ 4.12	277,662	\$ 4.12
\$17.32 - \$28.00	1,455,000	8.9	\$23.93	302,509	\$25.16
\$28.33 - \$39.37	961,172	8.8	\$33.74	249,260	\$34.50
\$39.45 - \$53.00	1,796,870	8.8	\$43.07	508,936	\$42.94
	4,490,704		\$32.46	1,338,367	\$29.30



InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. STOCKHOLDERS' EQUITY (Continued)

Employee stock purchase plan

To provide employees with an opportunity to purchase common stock of InterMune through payroll deductions, InterMune established the 2000 Employee Stock Purchase Plan. Under this plan, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the date of eligibility for enrollment or the date of purchase, whichever is less. Purchases are limited to 15% of each employee's eligible compensation. Through the end of December 2002, the Company had issued a total of 96,774 shares under this plan, and 695,968 shares remain available for future issuance.

Pro forma information

The Company accounts for its stock based compensation plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Accordingly, the Company does not recognize compensation cost for options granted to employees with exercise prices not less than fair value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and losses per share if the company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	Years ended December 31,		
	2002	2001	2000
	(in thousands except per share data)		
Net loss applicable to common stockholders:			
As reported . . . . .	\$(144,309)	\$(118,191)	\$(52,277)
Pro forma . . . . .	\$(172,130)	\$(133,251)	\$(52,541)
Net loss per share:			
As reported . . . . .	\$ (4.72)	\$ (4.67)	\$ (3.05)
Pro forma . . . . .	\$ (5.63)	\$ (5.26)	\$ (3.07)

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

	Years ended December 31,		
	2002	2001	2000
Expected stock price volatility . . . . .	85%	90%	90%
Risk-free interest rate . . . . .	2.3%	3.7%	6.0%
Expected life (in years) . . . . .	3.4	3.3	6.8
Expected dividend yield . . . . .	—	—	—

The weighted average fair value of options granted was \$18.99 in 2002, \$20.99 in 2001 and \$19.27 in 2000.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. STOCKHOLDERS' EQUITY (Continued)

The Company estimates the fair value of the employees' purchase rights was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Years ended December 31,		
	2002	2001	2000
Expected stock price volatility . . . . .	78%	90%	90%
Risk-free interest rate . . . . .	1.7%	5.0%	6.0%
Expected life (in years) . . . . .	2.0	2.0	2.0
Expected dividend yield . . . . .	—	—	—

The weighted-average fair value for shares issued under the employee stock purchase plan for 2002 was \$18.44, for 2001 was \$24.82 and for 2000 was \$20.74.

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

Stock compensation

In January 2000, the Company issued 133,000 options to purchase shares of common stock at a weighted average exercise price of \$0.37 per share to consultants in exchange for research and development consulting services. Compensation expense is recorded as the options vest based upon the fair value of the options, determined using the Black-Scholes pricing model. The Company granted a fully vested option to purchase 10,000 shares of common stock to a consultant in 2001 and recorded a stock compensation charge of \$298,000 to selling, general and administrative expense.

In connection with the grant of certain stock options to employees for the years ended December 31, 2000 and 1999, the Company recorded deferred stock compensation of approximately \$8.6 million and \$5.6 million, respectively. These amounts represent the difference between the deemed fair value of the common stock and the option exercise price at the date of grant. No stock-based employee compensation cost is reflected in the results of operations for the year ended December 31, 2002 and 2001, as all options granted under those plans had an exercise price equal to the market price of the underlying common stock on the date of grant. The Company recorded amortization of deferred stock compensation of approximately \$1.8 million, \$3.8 million and \$6.7 million for the years ended December 31, 2002, 2001 and 2000, respectively. Included in the \$1.8 million amortization for the year 2002 was approximately \$0.2 million recognized on the vesting acceleration of options for a terminated employee. Deferred stock compensation expense is being amortized using the graded vesting method over the vesting period of the individual award, generally five years. This method is in accordance with Financial Accounting Standards Board Interpretation No. 28. During the year ended December 31, 2002, the Company reversed approximately \$0.8 million of 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. The amount

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**10. STOCKHOLDERS' EQUITY (Continued)**

of deferred compensation expense to be recorded in future periods could decrease if options for which accrued but unvested compensation has been recorded are forfeited.

**Common stock**

On March 13, 2002, we completed a follow-on public offering of three million shares of registered common stock, at a price of \$37.00 per share, raising \$111.0 million in gross proceeds. We received net proceeds of \$104.5 million after deducting underwriting fees of \$5.8 million and related expenses of \$0.7 million.

**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 common stock of the Company. The dividend was paid on August 3, 2001 to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the "Preferred Shares"), at a price of \$390.00 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. The Rights will be exercisable the earlier of (i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of the outstanding common shares (an "Acquiring Person"), or (ii) ten business days (or such later date as may be determined by action of the Board of Directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person.

In the event that any person, entity or group of affiliated or associated persons become an Acquiring Person, each holder of a Right will have the right to receive, upon exercise, the number of common shares having a market value of two times the exercise price of the Right. In the event that the Company is acquired in a merger or other business combination transaction or 50% or more of its 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, the Board of Directors of the Company 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 the election of the Company, the Company 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 redeemed or exchanged by the Company.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. STOCKHOLDERS' EQUITY (Continued)

Reserved Shares

At December 31, 2002, common stock subject to future issuance is as follows:

Common stock issuable upon conversion of convertible subordinated debt . . . . .	3,893,229
Outstanding common stock options . . . . .	4,490,704
Common stock available for grant under stock option plan . . . . .	2,528,733
Common stock available for grant under the 2000 Employee Stock Purchase Plan . . . . .	695,968
	<u>11,608,634</u>

11. INCOME TAXES

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

	2002	2001
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 68,000	\$29,300
Research and development credits . . . . .	3,000	600
Capitalized research and development costs . . . . .	42,000	24,900
Other, net . . . . .	2,000	300
Total deferred tax assets . . . . .	<u>115,000</u>	<u>55,100</u>
Valuation allowance . . . . .	<u>(115,000)</u>	<u>(55,100)</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 allowance increased by \$59.9 million, \$45.2 million and \$5.0 million during 2002, 2001 and 2000, respectively.

Deferred tax assets related to carryforwards at December 31, 2002 include approximately \$3.5 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders equity.

As of December 31, 2002, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$196.0 million which expire in the years 2018 through 2022 and federal research and development credits of approximately \$2.3 million which expire in the years 2018 through 2022. In addition, the Company had net operating loss carryforwards for state income tax purposes of approximately \$29.0 million which expire in the years 2008 through 2013 and state research and development tax credits of approximately \$1.0 million which do not expire. As a result of California legislation, the utilization of a substantial portion of the Company's California state net operating loss carryforward is suspended for 2003.

**InterMune, Inc.**

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

**11. INCOME TAXES (Continued)**

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

**12. COMMITMENTS**

**Leases**

The Company has two non-cancellable leases for facilities which expire at various dates through 2011. Total rent expense was approximately \$3.7 million in 2002, \$2.6 million in 2001 and \$247,000 in 2000. In addition, the Company has entered into 3-year auto leases for the field sales force.

In 2001, the Company subleased a former facility and recognized rental income of \$175,000 in 2002 and \$30,000 in 2001. Aggregate future rental income to be received amounts to \$366,000 through 2004.

The following is a schedule by year of future minimum lease payments of all leases at December 31, 2002 (in thousands):

<u>Year</u>	<u>Operating Leases</u>
2003 .....	\$ 3,841
2004 .....	3,536
2005 .....	3,366
2006 .....	3,489
2007 .....	3,573
Thereafter .....	12,913
	<u>\$30,718</u>

The operating leases for the Company's facilities require letters of credit secured by a restricted cash balance with the Company's bank. The amount of each letter of credit approximates 6-12 months of operating rent payable to the landlord of each facility and are effective until the Company reaches profitability. At December 31, 2002 and 2001, restricted cash under these letters of credit amounted to \$1.7 million for each year-end.

The Company has purchase commitments with Boehringer Ingelheim Austria GmbH, Amgen and Ben Venue Laboratories for the manufacture and supply of Actimmune, Infergen and Amphotec, respectively. These commitments are comprised of a twelve and twenty-four month fixed purchase orders that totaled \$63.2 million at December 31, 2002.

**13. GEOGRAPHIC SALES AND SIGNIFICANT CUSTOMERS**

The Company has determined that, in accordance with statement of Financial Accounting Standards No. 131, it operates in one segment as it only reports operating results on an aggregate basis to chief operating decision makers of the Company. The Company currently markets Actimmune in the United States for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis, Amphotec worldwide for invasive aspergillosis and Infergen in the United States and Canada for hepatitis C.

InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. GEOGRAPHIC SALES AND SIGNIFICANT CUSTOMERS (Continued)

The Company's product sales by region for the years ended December 31, are as follows (in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
United States .....	\$109,537	\$37,838	\$11,201
Rest of world .....	2,428	2,113	—
Totals .....	<u>\$111,965</u>	<u>\$39,951</u>	<u>\$11,201</u>

Product sales to customers, comprised of specialty pharmacies, reporting 10% or more of total sales during 2002, 2001 and 2000 are as follows:

<u>Customer</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Bergen Brunswig .....	2%	22%	21%
Cardinal Healthcare .....	3%	18%	33%
Caremark .....	10%	—	—
Merck Medco .....	11%	—	—
McKesson HBOC .....	2%	23%	25%
Priority Healthcare .....	57%	21%	—

14. RELATED PARTY TRANSACTIONS

In connection with the acquisition of the rights to oritavancin from Eli Lilly and Company in the fourth quarter of 2001 (see Note 3), the Company paid an execution fee of \$1.0 million to the SGO Group LLC. Mr. Simon, a member of the Company's Board of Directors at the time of the acquisition of the oritavancin rights from Eli Lilly, is a principal with the SGO Group, and as such, received compensation in connection with this transaction. In addition to the fee, the Company is obligated to pay The SGO Group certain pro-rated fees on the achievement of development milestones for oritavancin. The \$1.0 million fee was charged to in-process research and development expense as part of the acquisition costs of oritavancin.

15. EMPLOYEE SAVINGS PLAN

On May 1, 1999, the Company adopted a 401(k) defined contribution plan that covers all full time employees, as defined, who meet certain length-of-service requirements. Employees may contribute up to a maximum of 15% of their annual compensation (subject to a maximum limit imposed by federal tax law). The Company makes no matching contributions.



InterMune, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. QUARTERLY FINANCIAL DATA (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands except per share amounts)				
<b>2002</b>					
Product sales					
Actimmune . . . . .	\$ 17,714	\$ 22,596	\$ 28,531	\$ 36,961	\$ 105,802
All others . . . . .	1,038	1,062	1,706	2,357	6,163
Total Product sales, net . . . . .	18,752	23,658	30,237	39,318	111,965
Cost of goods sold . . . . .	5,403	4,742	6,095	7,921	24,161
Amortization of acquired product rights . . . . .	815	815	1,024	939	3,593
Loss from operations . . . . .	(44,372)	(29,667)	(42,996)	(24,846)	(141,881)
Net loss . . . . .	(45,128)	(30,097)	(43,480)	(25,604)	(144,309)
Historical basic and diluted net loss per common share . . . . .	\$ (1.58)	\$ (0.97)	\$ (1.39)	\$ (0.81)	\$ (4.72)
<b>2001</b>					
Product sales					
Actimmune . . . . .	\$ 4,929	\$ 7,278	\$ 10,306	\$ 13,807	\$ 36,320
All others . . . . .	613	750	1,010	1,258	3,631
Total Product sales, net . . . . .	5,542	8,028	11,316	15,065	39,951
Cost of goods sold . . . . .	3,515	3,084	3,915	4,960	15,474
Amortization of acquired product rights . . . . .	2,118	1,057	815	815	4,805
Loss from operations . . . . .	(13,319)	(20,272)	(16,991)	(74,090)	(124,672)
Net loss . . . . .	(10,569)	(18,214)	(15,454)	(73,954)	(118,191)
Historical basic and diluted net loss per common share . . . . .	\$ (0.46)	\$ (0.79)	\$ (0.56)	\$ (2.67)	\$ (4.67)

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The response to this item is submitted as a separate section of this Form 10-K. see Item 14.

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

Not applicable.

### PART III

Certain information required by Part III is omitted from this report on Form 10-K because the registrant will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for the Company's Annual Meeting of Stockholders to be held on May 29, 2003 (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 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.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the information under the section 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 "Certain Relationships and Related-Party Transactions" contained in the Proxy Statement.

#### ITEM 14. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to the Securities Exchange Act Rule 13a-14 within 90 days of the filing date of this annual report. Based on their evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective. There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of evaluation, and there were no corrective actions undertaken with regard to significant deficiencies and material weaknesses.

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

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for listing the non-audit services approved by our Audit Committee to be performed by Ernst & Young LLP, our external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. Our Audit Committee currently has approved the engagement of Ernst & Young to perform up to \$25,000 in non-audit services in 2003, and authorized the Chairman of the Audit Committee to pre-approve the engagement of Ernst & Young to perform additional non-audit and non-tax services of less than \$10,000.

PART IV

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

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

(1) *Financial Statements*

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

(2) *Financial Statement Schedules*

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

Schedule II

InterMune, Inc.  
Valuation and Qualifying Accounts and Reserves  
Years ended December 31, 2002, 2001 and 2000

(in thousands)

<u>Description</u>	<u>Balance at beginning of year</u>	<u>Charged to revenue/ expense, net of reversals</u>	<u>Utilizations</u>	<u>Balance at end of year</u>
2002:				
Accounts receivable, product returns and chargebacks, rebates and doubtful accounts allowances . . . . .	\$ 949	\$10,811	\$(8,345)	\$3,415
2001:				
Accounts receivable, product returns and chargebacks, rebates and doubtful accounts allowances . . . . .	418	3,986	(3,455)	949
2000:				
Accounts receivable, product returns and chargebacks, rebates and doubtful accounts allowances . . . . .	39	1,342	(963)	418

(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)
4.1	Specimen Common Stock Certificate.(1)
4.2	Amended and Restated Investor Rights Agreement, dated January 7, 2000, between Registrant and certain holders of the common stock.(1)
4.3	Indenture, dated as of July 5, 2001, between Registrant and The Bank of New York(8)
4.4	Stockholder Rights Agreement, dated July 17, 2001, between Registrant and Mellon Investor Services LLC.(9)
4.5	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock(9)
10.1 +	Form of Indemnity Agreement.(1)
10.2 +	1999 Equity Incentive Plan and related documents.(1)
10.3 +	2000 Equity Incentive Plan and related documents.(1)
10.4 +	2000 Employee Stock Purchase Plan and related documents.(1)
10.5 +	2000 Non-Employee Directors' Stock Option Plan and related documents.(1)
10.6	Lease Agreement, dated November 9, 1999, between Registrant and American Heart Association, Western States Affiliate.(1)
10.7 +	Employment Agreement, dated April 27, 1999, between Registrant and W. Scott Harkonen.(1)
10.9 +	Employment Offer Letter, dated October 22, 1999, between Registrant and Peter Van Vlasselaer.(1)
10.11+	Secured Loan Agreement, Secured Promissory Note, and Security Agreement, dated July 1, 1999, between Registrant and W. Scott Harkonen.(1)
10.12*	Amended and Restated Exclusive Sublicense Agreement, dated April 27, 1999, between Registrant and Connetics Corporation.(1)
10.17*	Sponsored Research and License Agreement, dated January 1, 2000, between Registrant and Panorama Research, Inc.(1)
10.18*	License Agreement, dated March 25, 1999, between Registrant and MCW Research Foundation, Inc.(1)
10.19*	Data Transfer, Clinical Trial, and Market Supply Agreement, dated January 27, 1999, between the Registrant and Boehringer Ingleheim.(1)
10.20+	Form of Change of Control Provisions for Officers.(3)
10.22+	Employment Offer Letter, dated March 3, 2000, between Registrant and Stephen N. Rosenfield.(3)
10.24	Assignment and Option Agreement, dated June 23, 2000, between Registrant and Connetics Corporation.(4)
10.25	Consent to Assignment Agreement, dated June 23, 2000, between Registrant, Connetics Corporation and Genentech, Inc.(4)
10.27	Notice re: Return of Rights to Gamma Interferon for Treatment of Infectious Diseases in Japan, dated July 25, 2000, between Registrant and Genentech, Inc.(4)
10.28	Lease Agreement, dated May 15, 2000, between Registrant and American Heart Association, Western States Affiliate.(4)
10.29	Form of Common Stock Purchase Agreement, dated August 11, 2000, between the Company and Investors.(5)
10.30+	Employment Offer Letter, dated May 15, 2000, between Registrant and John Wulf.(2)
10.31	Lease Agreement, dated December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)

NUMBER	DESCRIPTION OF DOCUMENT
10.32	First Amendment to Brisbane Technology Park Lease, effective as of December 18, 2000, between Registrant and GAL-BRISBANE, L.P.(6)
10.33+	Employment offer letter, dated November 27, 2000, between Registrant and Dr. James E. Pennington, M.D.(7)
10.34	Product Acquisition Agreement, dated January 2, 2001, between Registrant and ALZA Corporation.(7)
10.35	Development and Marketing Agreement, dated March 23, 2001, between Registrant and Boehringer Ingelheim International GmbH.(7)
10.36	Lease Agreement, dated February 14, 2001, between Registrant and Harvard Investment Company.(7)
10.37+	Amendment to Employment Agreement, dated January 1, 2001, between Registrant and Dr. W. Scott Harkonen.(7)
10.38	Amendment No. 5, dated January 25, 2001, to License Agreement, dated May 5, 1998, between Registrant and Genentech, Inc.(7)
10.39*	License and Commercialization Agreement, dated June 15, 2001, between Registrant and Amgen, Inc.(10)
10.40	Letter Amendment, dated August 1, 2001, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(11)
10.41*	Agreement for Consulting Services, dated August 1, 2001, between Registrant and The SGO Group LLC.(11)
10.42*	Asset Purchase and License Agreement, dated September 19, 2001, between Registrant and Eli Lilly and Company.(11)
10.43*	Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbot Laboratories.(12)
10.44+	Timothy P. Lynch Separation Agreement dated May 8, 2002, between Registrant and Timothy P. Lynch.(13)
10.45+	2000 Equity Incentive Plan, as amended as of June 19, 2002.(14)
10.46+	Non-Employee Directors' Stock Option Plan, amended as of June 19, 2002.(15)
10.47+	Employment Offer Letter, dated April 5, 2002, between Registrant and Marianne Armstrong, Ph.D.(15)
10.48+	Bonus Plan Memorandum, dated April 18, 2002, from Registrant to Marianne Armstrong, Ph.D.(15)
10.49+	Secured Promissory Note, dated May 1, 2002, between Registrant and Marianne Armstrong, Ph.D.(15)
10.50*	Amendment No. 1, dated April 26, 2002, to the Development and Supply Agreement, dated December 28, 2001, between Registrant and Abbott Laboratories.(15)
10.51*	Amendment No. 1, dated April 25, 2002, to the License and Commercialization Agreement (dated June 15, 2001), between Registrant and Amgen Inc.(15)
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.(15)
10.53	Letter Amendment, dated May 28, 2002, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(15)
10.54	Letter Amendment, dated July 1, 2002, to Development and Marketing Agreement (dated March 23, 2001), between Registrant and Boehringer Ingelheim International GmbH.(15)
10.55+	Employee Offer Letter, dated August 29, 2002, between Registrant and Sharon Surrey-Barbari.(16)
10.56+	Amendment to Proprietary Information and Inventions Agreement, dated September 3, 2002, between Registrant and Sharon Surrey-Barbari.(16)

NUMBER	DESCRIPTION OF DOCUMENT
21.1	List of Subsidiaries.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (included on the signature pages hereto).
99.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* 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.

+ Management contract or compensation plan or arrangement.

- (1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 2, 2000 (No. 333-96029), as amended by Amendment No. 1 filed with the Commission on February 18, 2000, as amended by Amendment No. 2 filed with the Commission on March 6, 2000, as amended by Amendment No. 3 filed with the Commission on March 22, 2000, as amended by Amendment No. 4 filed with the Commission on March 23, 2000 and as amended by Amendment No. 5 filed with the Commission on March 23, 2000.
- (2) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 8, 2000 (No. 333-45460).
- (3) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (4) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
- (5) Filed as an exhibit to the Registrant's Current Report on Form 8-K on August 23, 2000.
- (6) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
- (7) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- (8) Filed as an exhibit to the Registrant's Current Report on Form 8-K on July 10, 2001.
- (9) Filed as an exhibit to the Registrant's Current Report on Form 8-K on July 18, 2001.
- (10) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (11) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (12) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (13) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
- (14) Filed as an exhibit to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on July 12, 2002 (No. 333-92276).
- (15) Filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed for the quarter ended June 30, 2002.

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

(b) Reports on Form 8-K

The Registrant did not file any Current Reports on Form 8-K during the fourth quarter of 2002.

(c) Exhibits

See Item 15(a) above.

(d) Financial Statement Schedules

See Item 15(a) above.





## POWER OF ATTORNEY

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

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

<u>SIGNATURES</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ W. SCOTT HARKONEN</u> W. Scott Harkonen	President and Chief Executive Officer and Director (principal executive officer)	3/27/03
<u>/s/ SHARON SURREY-BARBARI</u> Sharon Surrey-Barbari	Senior Vice President of Finance Administration and Chief Financial Officer (principal financial and accounting officer)	3/28/03
<u>/s/ WILLIAM HALTER</u> William A. Halter	Director	3/26/03
<u>/s/ JAMES HEALY</u> James I. Healy	Director	3/28/03
<u>/s/ WAYNE T. HOCKMEYER</u> Wayne T. Hockmeyer	Director	3/28/03
<u>Thomas R. Hodgson</u>	Director	
<u>/s/ JONATHAN LEFF</u> Jonathan S. Leff	Director	3/27/03
<u>/s/ WILLIAM R. RINGO</u> William R. Ringo, Jr.	Director	3/28/03

## CERTIFICATION

I, W. Scott Harkonen, certify that:

1. I have reviewed this annual report on Form 10-K of InterMune, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27<sup>th</sup>, 2003

/s/ W. SCOTT HARKONEN

W. Scott Harkonen  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Sharon Surrey-Barbari, certify that:

1. I have reviewed this annual report on Form 10-K of InterMune, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28<sup>th</sup>, 2003

/s/ SHARON SURREY-BARBARI

Sharon Surrey-Barbari  
Senior Vice President of Finance  
Administration  
and Chief Financial Officer  
(Principal Financial Officer)