intermune annual report 2006

INTERMUNE®

about intermune

InterMune, Inc. is a biotechnology company focused on developing and commercializing innovative therapies in pulmonology and hepatology. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. Hepatology is the field of medicine concerned with the diagnosis and treatment of disorders of the liver.

InterMune has a late-stage development pipeline in the pulmonology area and an early-stage development pipeline in the hepatology area. The pulmonolog1Y program, which is evaluating pirfenidone as a possible therapeutic candidate for the treatment of patients with idiopathic pulmonary fibrosis (IPF), and a research program focused on small molecules for pulmonary disease.

In hepatology, the portfolio includes the hepatitis C virus (HCV) protease inhibitor compound ITMN-191 in a Phase 1a clinical trial, a second-generation HCV protease inhibitor program and a research program evaluating a new target in hepatology.

development pipeline

pulmonology

Pirfenidone
Idiopathic pulmonary fibrosis

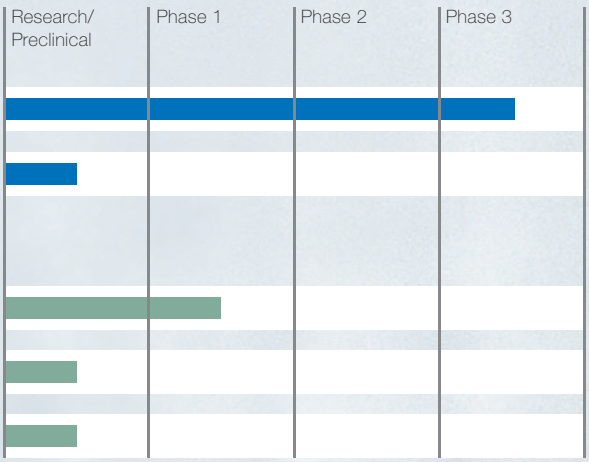
New Pulmonology Targets

hepatology

Protease Inhibitor (ITMN-191)
Hepatitis C Virus

Second-generation Protease Inhibitor
Hepatitis C Virus

New Hepatology Target



2006 highlights

- Initiated enrollment in CAPACITY, our pivotal Phase 3 clinical program to evaluate pirfenidone, a small molecule p38-gamma inhibitor, as a treatment for patients with idiopathic pulmonary fibrosis (IPF). CAPACITY's clinical endpoint is change in forced vital capacity (FVC), a measurement of lung function. Approximately 720 patients in more than 120 centers in North America and Europe will be evaluated as part of the program.
- Established with Roche a global research, development and commercialization collaboration for our hepatitis C virus (HCV) protease inhibitor program, including ITMN-191 and second-generation HCV protease inhibitor drug candidates. We received $60 million up front and could receive another $470 million in milestones for ITMN-191. The upfront and milestone payments we expect to receive during the development period will help provide the resources for our 33% share of our development costs.
- Advanced ITMN-191 into a Phase 1a clinical trial in Europe. The process began with the filing of a Clinical Trial Authorization (CTA) with regulatory authorities in Europe. This was our first CTA for a compound that we advanced from discovery to the clinic, signaling our maturation as a research and development company.
- Finalized a comprehensive settlement with the government concerning promotional activities on Actimmune® by former employees during a period that ended in June 2003. We were very pleased to resolve, without criminal sanctions, all outstanding government investigations of InterMune. We agreed to make a financial settlement and entered into corporate integrity and deferred prosecution agreements.

to our stockholders

Daniel G. Welch
President and
Chief Executive Officer

In 2006, we completed our transformation to become a focused research and development organization.

After making dramatic changes to our business model in late 2005 to maximize our research and development opportunities, we achieved aggressive goals for our clinical development programs and reported solid financial performance in 2006. We achieved these things while we advanced our research and clinical programs that focus on developing novel therapeutics to treat serious pulmonary and hepatic diseases.

Pulmonology:

A Leader in the Development of New Therapies for Idiopathic Pulmonary Fibrosis

Individuals with Idiopathic Pulmonary Fibrosis (IPF) motivate us to develop and commercialize treatments for this rapidly fatal disease. Approximately 83,000 patients in the United States live with the disease, and we believe there is a similar number of patients in Europe. This is a relatively large patient population when compared with other diseases that support very attractive pharmaceutical markets, such as pulmonary arterial hypertension, multiple sclerosis or ovarian cancer. With no current FDA- or EMEA-approved therapies, patients with IPF are underserved, creating an appealing opportunity for a company such as ours that hopes to bring meaningful treatment benefits to patients.

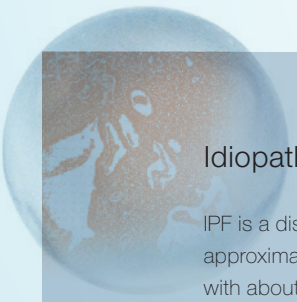
In 2006, we launched CAPACITY, our Phase 3 program for pirfenidone in IPF. This program consists of two multinational trials that are running concurrently and will enroll approximately 720 patients. The primary efficacy endpoint, change in forced vital capacity (FVC), has been supported in several Phase 2 studies. We are optimistic that InterMune is well positioned to become the leader in this potentially attractive market.

We are developing pirfenidone for IPF in the United States and Europe. The Japanese pharmaceutical company Shionogi & Co., Ltd. has rights to the compound in Japan, Taiwan and South Korea. In late 2006, Shionogi reported positive efficacy results for its Phase 3 trial evaluating pirfenidone in IPF. Using vital capacity as the trial's primary endpoint – a slightly different measurement of lung function than the endpoint used in CAPACITY – Shionogi reported that pirfenidone significantly inhibited worsening of the disease. No safety data were reported. Shionogi filed for registration of pirfenidone with the Japanese authorities in March 2007. We are encouraged by the Shionogi announcement and view it as a positive signal for our CAPACITY program that, if positive, will help support our planned request for marketing authorization in the territories to which we have marketing rights for pirfenidone.

In March 2007, we were pleased to announce that the enrollment of CAPACITY will be completed several months sooner than previous guidance due to stronger than expected patient enrollment. We also announced that we will refine the CAPACITY program to increase its statistical power. We plan to add a total of 135 patients to the previously planned enrollment of 585 patients and we plan to increase the treatment duration by 12 weeks, from 60 to 72 weeks. The primary efficacy endpoint remains change in forced vital capacity (FVC). We now expect enrollment to be completed in July 2007 and the final results to be available in Q1 2009.

We were disappointed to announce in March of 2007 that we had discontinued the Phase 3 INSPIRE trial evaluating Actimmune® (interferon gamma-1b) in patients with IPF. A planned interim analysis conducted by an independent Data Monitoring Committee found that the overall survival result crossed a pre-defined stopping boundary for lack of benefit of treatment with Actimmune® relative to placebo. There were no new safety concerns identified in the Phase 3 INSPIRE trial.

Following termination of the INSPIRE trial, we reaffirmed our commitment to developing our two clinical candidates, pirfenidone and ITMN-191. We also announced planned cost-saving initiatives that we believe will produce an estimated $40 to $50 million in annual savings when fully implemented by 2008. We quickly and aggressively responded to reduce our annual operating expenses in light of the INSPIRE news and remain very excited about the progress and potential of pirfenidone and ITMN-191.



Idiopathic Pulmonary Fibrosis (IPF)

IPF is a disabling and fatal disease that affects approximately 83,000 people in the United States, with about 30,000 new cases diagnosed each year. InterMune estimates a significant IPF population in Europe, as well. Those diagnosed with IPF are usually between the ages of 40 and 70 and predominantly male. IPF causes inflammation and scarring (fibrosis) in the lungs, hindering a person's ability to process oxygen and causing shortness of breath (dyspnea) and cough. IPF is a progressive disease, meaning that over time, lung scarring and symptoms increase in severity. The current median survival time from diagnosis is two to five years in patients with IPF, a survival rate that is lower than most cancers. There are no medicines approved for the treatment of IPF.

Hepatology:

Hepatitis C Virus Protease Inhibitor Program

Our most advanced hepatology program addresses the hepatitis C virus (HCV). In 2006, we made substantial progress in our HCV protease inhibitor discovery and development program.

In October 2006, we signed a major collaboration agreement with Roche for the worldwide research, development and commercialization of compounds from our HCV protease inhibitor program, including drug candidate ITMN-191. Roche is the world leader in HCV therapeutics and shares our vision regarding the development of novel, oral HCV medicines, such as protease inhibitors, that could play an important role in the eradication of this terrible disease.

We believe this collaboration could enable us to access essential strategic capabilities that we expect will accelerate development of ITMN-191 in a broader set of indications and geographical reach, and with far greater resources, than we could on our own. The collaboration is structured so that during the development phase of ITMN-191, the upfront and milestone payments we receive will cover our portion of development expenses. Thereafter, the collaboration agreement could allow us to receive additional registration, approval and commercial milestone payments from Roche, as well as attractive profit-sharing and royalty payments. Our collaboration also involves the research and development of novel, second-generation HCV protease inhibitors.

We could not have chosen a more capable and compatible partner than Roche, and we have already made significant progress since we announced our collaboration in October 2006. This progress includes the initiation of our Phase 1a clinical trial for ITMN-191 and successful completion of large-scale manufacturing and delivery to Roche of high-quality ITMN-191 material for future studies. For the successful completion of certain manufacturing commitments, InterMune received a $10 million collaboration payment from Roche in early 2007.

In 2007, we plan to complete the Phase 1a safety study in healthy subjects and conduct a Phase 1b clinical study with patients infected with HCV. The Phase 1b study in patients with chronic hepatitis C is designed to evaluate safety and provide our first viral kinetic results, an indication of the compound's ability to reduce the amount of hepatitis C virus in patients. We expect to announce these results in the second half of 2007.

Sustained Financial Strength and Flexibility

Our decision in late 2005 to transform our company to an R&D organization strengthened our balance sheet, improved our P&L and focused our efforts and funds on our exciting development programs. We ended the year with a strong financial profile that included, as of December 31, 2006, $214.5 million in cash, cash equivalents and available-for-sale securities. This profile reflects the upfront infusion of funds from our collaborator Roche.

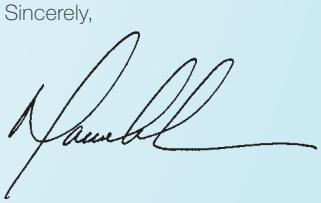
Looking to 2007

In summary, 2006 was a very good year for our company, the patients who are waiting for our medicines and our investors who fund our efforts.

In 2007, we look forward to two major milestones for our two development programs. First, we expect to receive important data on ITMN-191 in patients chronically infected with HCV. Second, we expect to complete the enrollment in the Phase 3 CAPACITY program evaluating pirfenidone in IPF. We are working diligently to achieve these goals, with our driving force being the patients with IPF or HCV who are waiting for new medicines to help them.

We appreciate your continued support of InterMune and look forward to updating you on our progress.

Sincerely,



Daniel G. Welch
President and Chief Executive Officer

March 30, 2007

Hepatitis C Virus (HCV)

According to the Centers for Disease Control and Prevention (CDC), an estimated 3.9 million Americans (1.8%) have been infected with HCV, of whom 2.7 million are chronically infected. It is estimated that 170 million people worldwide are afflicted with this disease. Currently available therapies are insufficient, creating a need for the development of novel therapeutic approaches. The HCV NS3/4 protease is an attractive drug target because of its potential involvement in viral replication and suppressive effects on host response to viral infection. Inhibitors of the HCV protease, such as ITMN-191, represent a promising new class of drugs for HCV and are likely candidates for use in combination with existing or future compounds.

corporate directory

executive management

Daniel G. Welch
President and Chief Executive Officer

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

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

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

John C. Hodgman
Senior Vice President and
Chief Financial Officer

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

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

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

board of directors

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

Lars G. Ekman, M.D., Ph.D
Executive Vice President and
President of Global Research and
Development and Director
Elan Corporation

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

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

Jonathan S. Leff
Partner
Warburg Pincus LLC

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

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

annual meeting

The annual stockholders meeting will be held on May 15, 2007 at 9:00 a.m. at InterMune, Inc., 3280 Bayshore Boulevard, Brisbane, CA 94005

corporate secretary

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

independent registered public accounting firm

Ernst & Young LLP
Palo Alto, California

transfer agent

Mellon Investor Services LLC
525 Market Street, Suite 35
San Francisco, CA 94105
(415) 951-4180

stock listing

Symbol: ITMN
Stock Exchange: NASDAQ

corporate headquarters

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

website

www.intermune.com

investor services

A copy of the Company's 2006 Form 10-K, which is filed with the Securities and Exchange Commission, is available for download at www.intermune.com or 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 System under the symbol ITMN. As of January 31, 2007, there were 88 stockholders of record. No cash dividends have been paid to date by us, and we do not anticipate the payment of any dividends in the foreseeable future.

Forward-Looking Statements/Risk Factors

This annual report contains forward-looking statements within the meaning of section 21E of the Securities Exchange Act of 1934, as amended, that reflect the company's judgment and involve risks and uncertainties as of the date of this report, including without limitation the statements related to anticipated future financial results and product development. All forward-looking statements and other information included in this annual report are based on information available to InterMune as of the date hereof, and InterMune assumes no obligation to update any such forward-looking statements or information. The company's actual results could differ materially from those described in the 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' in the most recent annual report issued by InterMune on Form 10-K filed with the SEC on March 30, 2007 (the "Form 10-K") and included herewith, and updates included in the most recent Form 10-Q filed with the SEC on November 9, 2006 (the "Form 10-Q"), and other periodic reports filed with the SEC, and include the following: (i) the information herein is of a preliminary nature and therefore subject to further adjustment; (ii) risks related to the development of our product and product candidates; (iii) risks related to timely patient enrollment and retention in clinical trials, including the use of third parties to conduct such clinical trials; (iv) risks related to achieving positive clinical trial results; (v) risks related to the uncertain, lengthy and expensive clinical development and regulatory process, including having no unexpected safety, toxicology, clinical or other issues; (vi) reimbursement risks associated with third-party payors; (vii) risks related to whether InterMune is able to obtain, maintain and enforce patents and other intellectual property; (viii) risks related to significant regulatory, supply and competitive barriers to entry; (ix) risks related to our collaboration agreement with Roche; (x) the results of the InterMune CAPACITY trials of pirfenidone may differ materially from those of the Shionogi & Co., Ltd. Phase 3 trial of pirfenidone; and (xi) the results as reported by Shionogi concerning their Phase 3 trial may differ materially from those published or presented in a peer-reviewed forum. The risks and other factors discussed above should be considered only in connection with the fully discussed risks and other factors discussed in detail in the Form 10-K and InterMune's other periodic reports filed with the SEC.

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