FORM 8-K

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 14, 2013

INTERMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	0-29801	94-3296648
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On January 14, 2013, InterMune, Inc. issued a press release announcing that its intention to offer shares of its common stock and convertible senior notes due 2017 in concurrent underwritten public offerings pursuant to the Company' s effective shelf registration statement. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In addition, in connection with the planned concurrent public offerings, InterMune has updated the risk factors contained in its periodic reports filed under the Securities Exchange Act of 1934, as amended. A copy of the updated risk factors is attached as Exhibit 99.2 to this Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated January 14, 2013.
99.2	Risk Factors.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 14, 2013

INTERMUNE, INC.

By: /s/ John C. Hodgman

John C. Hodgman

Senior Vice President of Finance Administration and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated January 14, 2013.
99.2	Risk Factors.

Exhibit 99.1

Contact:
Jim Goff, InterMune, Inc., 415-466-2228, jgoff@intermune.com

INTERMUNE ANNOUNCES PROPOSED CONCURRENT PUBLIC OFFERINGS OF COMMON STOCK AND CONVERTIBLE DEBT

BRISBANE, Calif., January 14, 2013 − InterMune, Inc. (Nasdaq: ITMN) today announced that it plans to offer, subject to market and other conditions, $85.0 million aggregate principal amount of convertible senior notes due 2017 and 12,500,000 shares of its common stock in concurrent underwritten public offerings. InterMune expects to grant the underwriters 30-day options to purchase up to an additional $12.75 million aggregate principal amount of convertible senior notes and up to an additional 1,875,000 shares of common stock in connection with the offerings.

InterMune intends to use the net proceeds from both offerings to repay at maturity or earlier repurchase InterMune' s outstanding 5.00% convertible senior notes due 2015, as well as to fund the commercialization of Esbriet® (pirfenidone), to fund InterMune' s ASCEND trial and for general corporate purposes, which may include funding research and development, and working capital. InterMune may also use a portion of the net proceeds for capital expenditures or for acquisitions or investments in complementary businesses, products and technologies.

Goldman, Sachs & Co. and J. P. Morgan Securities LLC are acting as joint book-running managers of these proposed offerings. The common stock offering and the convertible senior note offering will be conducted as separate public offerings by means of separate prospectus supplements filed as part of an effective shelf registration statement filed with the Securities and Exchange Commission (SEC) on Form S-3. Neither of these offerings is contingent upon the consummation of the other. Before investing in either offering, interested parties may read the prospectus supplement and the accompanying prospectus for such offering and the other documents InterMune has filed with the SEC, which are incorporated by reference in the prospectus supplements and the accompanying prospectus and provide more complete information about InterMune and the offerings. Copies of the preliminary prospectus supplements and the accompanying prospectus relating to each offering may be obtained, when available, from Goldman, Sachs & Co. (Attn: Prospectus Department, 200 West Street, New York, New York 10282, Fax: 212-902-9316 or Email at prospectus-ny@ny.email.gs.com

or by calling 1-866-471-2526) or J.P. Morgan Securities LLC (c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717 or by calling 866-803-9204). Electronic copies of the prospectus supplements may be obtained by visiting EDGAR on the SEC' s website at http://www.sec.gov/.

This announcement does not constitute an offer to sell or a solicitation of an offer to buy nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. This press release is being issued pursuant to and in accordance with Rule 134 under the Securities Act of 1933, as amended. Any offer, if at all, will be made only by means of a prospectus supplement and the accompanying prospectus, forming a part of the effective registration statement.

About InterMune

InterMune is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and fibrotic diseases.

Forward-Looking Statements

This announcement contains forward-looking statements, including statements relating to InterMune' s expectations regarding the completion, timing and size of the proposed public offerings. These statements are subject to significant risks and uncertainties, actual results could differ materially from those projected and InterMune cautions investors not to place undue reliance on the forward-looking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to market conditions and satisfaction of customary closing conditions related to the public offerings. There can be no assurance that InterMune will be able to complete either one or both of the public offerings on the anticipated terms, or at all. If InterMune is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue one or more of its drug development or discovery research programs. Additional risks and uncertainties relating to InterMune and its business can be found in the "Risk Factors" section of InterMune' s Form 10-K filed with the SEC and quarterly reports on Form 10-Q, and in the prospectus supplements related to the proposed offerings to be filed with the SEC. InterMune undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in InterMune' s expectations.

# # #

Exhibit 99.2

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risk factors described below. If any of these risks actually occur, it may materially harm our business, financial condition, operating results or cash flow. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Risks Related to Our Dependence on Pirfenidone

We are dependent on the commercial success of Esbriet (pirfenidone) for the treatment of IPF in the European Union, other European countries and Canada, and on the regulatory approval of pirfenidone for the treatment of IPF in the United States, which may never occur.

We commenced operations in 1998 and have incurred significant losses to date. Prior to launching commercial sales of Esbriet in Germany in September 2011 and making Esbriet commercially available in Austria, Denmark, Iceland, Luxembourg, Norway and Sweden in the first nine months of 2012, our revenue was limited primarily to sales of Actimmune derived from physicians' prescriptions for the off-label use of Actimmune in the treatment of IPF and from upfront license fees and milestone payments in connection with our collaboration with Roche. On June 19, 2012, we completed the divestiture of our worldwide development and commercialization rights to Actimmune. In October 2010, we sold to Roche all of our worldwide rights to danoprevir and terminated our collaboration with Roche from which we had derived our collaboration revenue. As a result, our future success is currently dependent on the regulatory and commercial success of pirfenidone for the treatment of IPF primarily in the EU and the United States. Effective February 2011, Esbriet (pirfenidone) was granted marketing authorization for commercial use in the 27 EU member states for the treatment of adults with mild to moderate IPF, and Esbriet has since been approved for marketing in Norway, Iceland and, most recently in October 2012, in Canada; however, pirfenidone is still under investigation for the treatment of IPF in the United States and has not been approved by the FDA.

We launched commercial sales of Esbriet in Germany in September 2011 and subsequently in Austria, Belgium, Denmark, France, Iceland, Luxembourg, Norway and Sweden. On January 2, 2013, we began our commercial launch of Esbriet in Canada. Subject to EU country reimbursement timelines, we currently expect to conclude the pricing and reimbursement process in Italy in the first quarter of 2013 and to launch in that country as soon as practicable after the process is successfully concluded and various authorizations are secured. With respect to Spain, considering a Royal Decree introduced in 2012 affecting health care expenditures and pharmaceuticals and the continuing economic challenges of the country, we currently anticipate that a decision regarding pricing and reimbursement of Esbriet in Spain will occur in by mid-2013. Furthermore, we currently plan to conclude the discussions with the authorities in the United Kingdom in March 2013, and, depending on the outcome of such discussions, make Esbriet available in the United Kingdom as soon as practicable thereafter, if appropriate. In addition to launches in the remaining so called "Top 5" EU countries, we expect to launch Esbriet in the Netherlands, Finland and Ireland by mid-2013 assuming that acceptable pricing and reimbursement conditions are negotiated in these countries.

Because we do not currently have a product candidate other than pirfenidone in clinical development, our future success is dependent on the continued development of our commercial operation in Europe to successfully commercialize Esbriet in the EU, obtaining regulatory approval from the FDA to market pirfenidone for the treatment of IPF in the United States, and, if approved by

the FDA, successfully commercializing pirfenidone in the United States. If we do not successfully commercialize Esbriet in the EU and/or receive regulatory approval in the United States for pirfenidone for the treatment of IPF, our ability to generate additional revenue will be jeopardized and, consequently, our business will be seriously harmed. We may not succeed in our commercial efforts in the EU, or, if approved by the FDA, in the United States, or we may never receive regulatory approval in the United States for pirfenidone, any of these will have a material adverse effect on our business and prospects. In the near term, we may experience delays and unforeseen difficulties in the launch of Esbriet in one or more of the European Union member states, including as a result of obtaining unfavorable pricing and/or reimbursement, which could negatively affect our stock price. We may also experience delays in obtaining regulatory approval in the United States for pirfenidone, if it is approved at all and our stock price may be negatively affected.

In addition, we anticipate incurring additional expenses and utilizing significant existing cash resources as we continue our commercialization efforts and commercial launch preparations for Esbriet, conduct our Phase 3 ASCEND trial to support the approval of pirfenidone to treat IPF in the United States and continue to grow our operational capabilities, particularly in the EU. This represents a significant investment in the regulatory and commercial success of pirfenidone, which is uncertain.

We may also fail to develop future product candidates for the reasons stated in "Risks Related to the Development of Our Products and Product Candidates." If this were to occur, we will continue to be dependent on the successful commercialization of pirfenidone, our development costs may increase and our ability to generate revenue could be impaired.

We have initiated the ASCEND Phase 3 clinical trial to support potential FDA approval of pirfenidone for the treatment of IPF, the results of which may fail to demonstrate to the FDA sufficient efficacy of pirfenidone and may have a negative effect on sales of Esbriet in the European Union.

We have evaluated our clinical development options to gain FDA approval of pirfenidone for the treatment of IPF within the United States and initiated an additional Phase 3 clinical trial known as the "ASCEND" trial during the second quarter of 2011. We do not have a Special Protocol Assessment, or SPA, in place with the FDA for the ASCEND trial, and the results of this Phase 3 clinical trial, together with the results of our CAPACITY trials, may not be satisfactory to the FDA to support approval of pirfenidone. The ASCEND trial is a 52 week trial with a forced vital capacity, or FVC, primary endpoint. In our meeting with the FDA in March 2011 relating to our plans for the ASCEND trial, the FDA indicated that it would prefer a trial with a longer duration (72 weeks) if designed with a FVC endpoint. While the FDA indicated that a 52 week trial with a FVC endpoint could support approval, the FDA further indicated that a trial with a FVC endpoint would need to provide supportive evidence of an effect on mortality. Consistent with our prior interactions with the FDA in connection with our CAPACITY clinical trials, the FDA indicated a preference for a mortality endpoint.

Whether data from our ASCEND trial when combined with the data from our CAPACITY trials will be sufficient to obtain FDA approval of pirfenidone for the treatment of IPF will depend on the results from the trial and be the subject of review by the FDA at the time of our anticipated NDA resubmission. If the results of the ASCEND trial are not satisfactory to the FDA to support regulatory approval of pirfenidone in the United States, then we will not be able to sell Esbriet in the United States. Further, the publicity of a failure to obtain FDA approval for pirfenidone may negatively affect the sales of Esbriet in the EU and/or may be considered by EU regulatory agencies when assessing reimbursement for pirfenidone, which may lead to a reduction in the amount of reimbursement amounts in certain countries. Additionally, as in any clinical trial, discovery of unknown problems with pirfenidone in the ASCEND trial could negatively impact the approved safety and efficacy profile and result in possible reduced sales or product withdrawal in the EU. Because of our dependence on the

commercial success of Esbriet in the EU, a negative outcome in the ASCEND trial or a negative regulatory outcome by the FDA could materially and adversely affect our business and prospects. For additional risks related to clinical studies and government regulations, see the risks under "Risks Related to Government Regulation and Approval of Our Products and Product Candidates."

Risks Related to the Commercialization of Our Products and Product Candidates

Our revenue from sales of Esbriet in the European Union is dependent upon the pricing and reimbursement guidelines adopted in each of the various countries in the European Union, which levels may fall well below our current expectations.

We have currently priced Esbriet in Germany and France as well as Austria, Belgium, Denmark, Iceland, Luxembourg, Norway and Sweden and have developed estimates of anticipated pricing in other countries in Europe. These estimates are our expectations, which are based upon the lethal nature of IPF, the lack of any approved therapies for IPF, the Orphan Drug designation of Esbriet, our perception of the overall cost benefit of Esbriet and the current pricing in the EU of therapies with a similar product profile, such as treatments for pulmonary hypertension. However, due to efforts to provide for containment of health care costs, one or more EU countries may not support our estimated level of governmental pricing and reimbursement for Esbriet, particularly in light of the budget crises faced by a number of countries in the EU, which would negatively impact anticipated revenue from Esbriet in the EU. For example, in December 2011, the Institute for Quality and Efficiency in Health Care (the "IQWiG"), a non-profit private foundation established in Germany to provide advisory evaluations of the benefits and costs of medical interventions to Germany's Federal Joint Committee (the "G-BA"), published its report on the benefit assessment of Esbriet concluding that there is no additional benefit of pirfenidone for the treatment of mild to moderate IPF. We subsequently submitted a detailed response to the IQWiG concerning the assumptions and methodology applied by the IQWiG in its assessment, and, in March 2012, the G-BA concluded that Esbriet does provide additional benefit (not quantifiable) for the treatment of mild to moderate IPF. On July 23, 2012, we announced the early conclusion of negotiations for the reimbursement price of Esbriet in Germany such that effective September 15, 2012 and until September 15, 2014, the net ex-factory Esbriet price in Germany will be 26,999 , or approximately $33,000 per patient per year, representing an approximate 11% discount from the current price. Such pricing is subject to the rules of the German Act on the Reform of the Market for Medicinal Products which provide that terms for an orphan drug must be re-evaluated following the drug's costs to the German health system of 50 million Euros in any 12-month period. Therefore, upon the earlier of such re-evaluation or September 15, 2014, the G-BA may lower its reimbursement guidelines with respect to Esbriet necessitating that we lower our pricing of Esbriet, which would also negatively impact anticipated revenue from Esbriet in Germany.

In addition, in April 2012, the Transparency Commission of the French National Health Authority, the French agency responsible for assessing medicinal products and advising the health authorities on whether those products provide sufficient benefit to be covered by French National Health Insurance, issued a favorable opinion for the reimbursement of Esbriet® by French National Health Insurance. The Transparency Commission noted that no other treatment provided evidence of a clinical benefit in IPF and considering all available information, Esbriet was granted an Amélioration du Service Medical Rendu ("ASMR") rating of level IV. ASMR is a rating of added clinical value in comparison with existing therapies. The Transparency Commission focused on the risk/benefit ratio for assessing the actual medical benefit (SMR), and rated it as "Low." In general the recommended reimbursement rate by France's National Social Security for a product with "Low" SMR rating is 15%. However, diseases requiring a long-term, expensive treatment may be classified as ALD (Affection de Longue Duree–Long Term Diseases) in France. With respect to ALD, patients are fully reimbursed by the National Social Security for most costs related to these diseases (hospitalizations, lab tests, medicines, etc.), regardless of the SMR rating for such medicines (as long as it is not a SMR rating of "Insufficient"). The ALD program covers more than 100 specific diseases, reported either in an explicit list of 30 disease

categories or in an additional ‘‘catch all’’ category for other serious, expensive diseases lasting more than six months. Examples of the broad disease categories are cancers, cystic fibrosis and multiple sclerosis. The official list of illnesses classified as ALD is reviewed annually by the government and the determination of whether a patient in France has an ALD will be made by the patient’ s physician in collaboration with the health authority. Most orphan diseases are directly or indirectly recognized as ALD. IPF is not included on the explicit list of the 30 diseases classified as ALD. We expect that IPF will fall into the ALD ‘‘catch all’’ category for other serious, expensive diseases lasting more than six months. If the criteria for the ‘‘catch all’’ category changes and/or if IPF does not qualify as an ALD, IPF patients may not be fully reimbursed for the use of Esbriet for the treatment of IPF which may lead to decrease in Esbriet utilization and negatively impact our ability to generate revenue from Esbriet sales in France.

In November 2012, the National Institute for Health and Clinical Excellence (‘‘NICE’’), a special health authority of the English National Health Service (‘‘NHS’’) responsible for providing guidance to the NHS in England and Wales on the standards of care that local providers are expected to deliver, issued its provisional recommendations on the use of Esbriet for the treatment of IPF. NICE’ s provisional recommendation was not to recommend pirfenidone for use on the NHS in England and Wales. A final review of Esbriet by NICE is expected to occur in March 2013, and, if NICE decides to support the reimbursement of Esbriet, we currently expect to launch in the UK as soon as practicable thereafter.

Finally, while we were awarded reimbursement in Sweden, it was limited to the sub-population of patients with a predicted FVC lower than 80%. While we deem these restrictions in Sweden as limiting only modestly the overall business potential of Esbriet in Europe and worthwhile considering the favorable price achieved, they may result in the pursuit by other European countries of a similar approach and a higher loss of Esbriet volume than anticipated, which would negatively impact revenue from Esbriet in such countries.

An unfavorable outcome following the pricing and reimbursement review period in any country in the EU may result in lower than expected pricing and reimbursement guidelines in such country as well as the other countries in the EU, which would adversely impact the anticipated revenue from Esbriet in the EU.

Expansion of our commercial infrastructure in the European Union is a significant undertaking that requires substantial financial and managerial resources, and we may not be successful in our efforts. We may also continue to encounter unexpected or unforeseen delays in establishing a commercial infrastructure in the European Union, which may negatively impact our timing of and ability to launch our commercial efforts for Esbriet.

Effective February 2011, the European Commission granted marketing authorization for Esbriet (pirfenidone) in adults for the treatment of mild to moderate IPF. The approval authorizes marketing of Esbriet in all 27 EU member states. We launched commercial sales of Esbriet in Germany in September 2011 and subsequently in Austria, Belgium, Denmark, France, Iceland, Luxembourg, Norway and Sweden. On January 2, 2013, we began our commercial launch of Esbriet in Canada. Subject to EU country reimbursement timelines, we currently expect to conclude the pricing and reimbursement process in Italy in the first quarter of 2013 and to launch Esbriet in that country as soon as practicable after the process is successfully concluded and various authorizations are secured. With respect to Spain, considering a Royal Decree introduced in 2012 affecting health care expenditures and pharmaceuticals and the continuing economic challenges of the country, we currently anticipate that a decision regarding pricing and reimbursement of Esbriet in Spain will occur in by mid-2013. Furthermore, we currently plan to conclude the discussions with the authorities in the United Kingdom in March 2013, and, depending on the outcome of such discussions, make Esbriet available in the

United Kingdom as soon as practicable thereafter, if appropriate. In addition to launches in the remaining so called ‘‘Top 5’’ EU countries, we expect to launch Esbriet in the Netherlands, Finland and Ireland by mid-2013 assuming that acceptable pricing and reimbursement conditions are negotiated in these countries. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. To support our anticipated marketing efforts in Europe, we are currently working to expand our commercial infrastructure within the EU, including an increase to our employee headcount in that region and the establishment of our European headquarters in Muttenz, Switzerland. Further, in December 2010, we transferred all of our non-U.S. rights to research, develop and commercialize pirfenidone for IPF to our wholly-owned Swiss subsidiary, InterMune International AG. However, in order to successfully launch our commercial operations, we will need to increase the number of our managerial, operational, financial and other employees in the EU, which will require additional financial resources and require significant management attention. We may not be successful in establishing a commercial operation in the EU (including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy), the effect of which will have a negative outcome on our ability to commercialize Esbriet and generate revenue from the sale of Esbriet.

Additionally, we may encounter further unexpected or unforeseen delays in establishing our commercial operations that delay the launch of our commercial operations in one or more EU member states. These further delays may further increase the cost of and the resources required for successful commercialization of Esbriet in the EU. Given our limited commercial history, we do not have significant experience in a commercial launch of this size.

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

The development of our products and product candidates is an expensive process, and we anticipate that the annual cost of treatment for 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, including Esbriet in the EU, will depend on many factors, including, but not limited to:

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

In addition, we still are only in the early stages of commercialization of Esbriet in Germany and have only just begun our commercial sales in Austria, Belgium, Canada, Denmark, France, Iceland, Luxembourg, Norway and Sweden and continue to have limited information with regard to the market acceptance of Esbriet. As a result, we may have to revise our estimates regarding the acceptance of Esbriet under our current pricing structure, reevaluate and/or change the current pricing for Esbriet. For more information, please see the risk factor above titled ‘‘Our revenue from sales of Esbriet in the European Union is dependent upon the pricing and reimbursement guidelines adopted in each of the various countries in the European Union, which levels may fall well below our current expectations.’’

The pricing and profitability of our products may be subject to control by the government and other third-party payors, and if third-party payors do not provide coverage or reimburse patients for Esbriet or our other current or future products, our revenue and prospects for profitability will suffer.

The pricing and profitability of our products may be subject to control by the government and other third-party payors. In many foreign markets, the pricing and/or profitability of prescription pharmaceuticals are subject to governmental control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls, such as the omnibus healthcare reform legislation recently adopted by the U.S. government. As a result, our ability to successfully commercialize Esbriet or other product candidates for particular diseases, is highly dependent on the extent to which coverage and reimbursement for such products is available from:

- private health insurers, including managed care organizations;
- governmental payors, such as state-run payors in the EU, as well as federal programs/payors such as Medicaid, the U.S. Public Health Service Agency and Veterans' Administration; and
- other third-party payors.

The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. If governmental and other third-party payors do not provide adequate coverage and reimbursement levels for Esbriet, or our other current or future products, market acceptance of our products will be reduced, and our sales will suffer. For example, on July 23, 2012, we announced the early conclusion of negotiations for the reimbursement price of Esbriet® (pirfenidone) in Germany such that effective September 15, 2012 and until September 15, 2014, the net ex-factory Esbriet price in Germany will be 26,999 , or approximately $33,000 per patient per year, representing an approximate 11% discount from the current price. Such pricing is subject to the rules of the German Act on the Reform of the Market for Medicinal Products which provide that terms for an orphan drug must be re-evaluated following the drug's costs to the German health system of 50 million Euros in any 12-month period. Therefore, upon the earlier of such re-evaluation or September 15, 2014, the G-BA may lower its reimbursement guidelines with respect to Esbriet necessitating that we lower our pricing of Esbriet, which would also negatively impact revenue from Esbriet in Germany. Although we cannot predict the full effects on our business of the implementation of the healthcare reform bill in the United States, it is possible that this legislation or other similar legislation will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. These new and any future cost-control initiatives could decrease the price that we would receive for Esbriet, if approved for use in the United States, or any other products that we may develop in the future, which would reduce our revenue and potential profitability.

If we are found to have breached our agreement with Shionogi or if it is otherwise determined that we are obligated to make royalty payments on sales of Esbriet in the European Union to Shionogi, our expenses associated with sales of Esbriet in the European Union will increase and our ability to generate net income from Esbriet sales will be adversely affected.

On July 5, 2012, Shionogi filed a complaint against us in the United States District Court for the Northern District of California. Shionogi's complaint alleges principally that we breached our May 2004 agreement with Shionogi (as amended) governing the exchange and use of certain documents and information relating to the parties' respective clinical trials of pirfenidone. The complaint alleges that we breached the agreement by utilizing certain of Shionogi's information in our MAA and other submissions for pirfenidone with the EMA and then failing to pay royalties to Shionogi on net sales of

pirfenidone (Esbriet®) in the European Union. In the alternative, the complaint alleges that, if we did not use Shionogi' s information in a way that would trigger a royalty obligation under the agreement, we had an obligation to do so as an exclusive licensee. Shionogi is seeking, among other things, unspecified monetary damages and a declaration that we are obligated to pay royalties to Shionogi for all sales of pirfenidone (Esbriet®) in the European Union. While we disagree that we owe any such royalties and intend to defend our position vigorously, an unfavorable outcome in the litigation or in any negotiations with Shionogi could require that we pay royalties or make other payments to Shionogi, which would increase our expenses associated with sales of Esbriet in the EU and adversely affect our ability to generate net income.

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

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

- are more effective;
- have fewer or less severe adverse side effects;
- are better tolerated;
- have better patient compliance;
- receive better reimbursement terms;
- are more accepted by physicians;
- are more adaptable to various modes of dosing;
- have better distribution channels;
- are easier to administer; or
- are less expensive, including but not limited to a generic version of pirfenidone.

Even if we are successful in developing effective drugs, our products may not compete effectively with our competitors' current or future products. We expect that Esbriet may compete in the EU and, if approved by the FDA in the U.S., may compete with other products that are being developed for the treatment of IPF, including possible generic versions of pirfenidone in the U.S., EU and potentially other markets following the expiration of, or in the absence of market exclusivity. Pirfenidone has no composition of matter patent protection. Unless we have (i) Orphan Drug designation, (ii) data exclusivity protection or (iii) other types of patent protection in a particular jurisdiction, we may face competition from a lower cost generic version of pirfenidone in such a jurisdiction. In addition, there are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products, some of which may target the same indications as our product candidates. For example, in December 2010, Gilead entered into an agreement to acquire Arresto gaining Gilead access to Arresto' s Phase 1 humanized monoclonal antibody compound, AB0024, currently in clinical development for the treatment of IPF. Additionally, Boehringer Ingelheim, or BI, has recently presented phase 2 data for BIBF-1120, a triple kinase inhibitor that has showed some potential efficacy at high doses in IPF. BI has publicly posted its Phase 3 trial design for BIBF-1120 in IPF and patient enrollment in its trial is complete. Furthermore, there are seven products in various stages of phase 2 development for IPF, including CC-4047 and CC-930 from Celgene, CNTO-888 from Janssen (J&J), FG-3019 from Fibrogen, GC-1008 from Sanofi, QAX-576 from Novartis and STX-100 from Biogen Idec (acquirer of Stromedix)). Finally, the PANTHER trial, sponsored by the National Institutes of Health and evaluating NAC (N-acetylcysteine) (a generic drug) versus placebo, is underway and completed its

enrollment. If the results of such trial is positive, NAC, especially given that it is a generic drug, may create strong competition, especially in Europe, and create pressure on volume and prices of our Esbriet franchise. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do.

Risks Related to the Development of Our Products and Product Candidates

Drug 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 the treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety and efficacy of that product for the intended indication applied for in the NDA or respective regulatory file. Drug 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 clinical trials, even after promising results in earlier preclinical or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. For example, in March 2007, we terminated our development of Actimmune for patients with IPF as a result of our decision to discontinue the INSPIRE trial on the recommendation of the study' s independent DMC. For specific risks related to the pirfenidone development program, please see the risk factor titled ‘‘If our clinical trials fail to demonstrate to the FDA and foreign regulatory authorities that any of our products or product candidates are safe and effective for the treatment of particular diseases, the FDA and foreign regulatory authorities may require us to conduct additional clinical trials or may not grant us marketing approval for such products or product candidates for those diseases’’ below.

We do not know whether future clinical trials will be initiated, or will be completed on schedule, or at all.

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

- patients do not enroll in clinical trials at the rate we expect;
- the FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- we may not be able to identify or develop a product candidate that can be successful for clinical development;
- patients experience adverse side effects or unsafe toxicity levels;
- patients withdraw or die during a clinical trial for a variety of reasons, including adverse events associated with the advanced stage of their disease and medical problems that may or may not be related to our products or product candidates;
- the interim results of the clinical trial are inconclusive or negative;
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

- our contract laboratories fail to follow good laboratory practices; or
- sufficient quantities of the trial drug are not available.

In particular, we experienced a delay in the completion of our enrollment in our ASCEND clinical trial resulting from slower than anticipated patient enrollment. Our development costs will further increase if we have further material delays in our current clinical trials for pirfenidone or if we need to perform more or larger clinical trials than as may be initially planned for future product candidates. If there are any significant delays for any of our other current or planned clinical trials, our business, financial condition, financial results and the commercial prospects for our products and product candidates will be harmed, and our prospects for profitability will be impaired.

In addition, delays or discontinuations of our clinical trials could require us to cease development efforts of a product candidate in part or altogether, which will harm our business or financial condition and the commercial prospects for such product and product candidate.

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

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

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with evidence gathered in preclinical and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Our failure to adequately demonstrate the safety and effectiveness of any of our products or product candidates for the treatment of particular diseases may delay or prevent our receipt of the FDA' s and foreign regulatory authorities' approval and, ultimately, may prevent commercialization of our products and product candidates for those diseases. The FDA and foreign regulatory authorities have substantial discretion in deciding whether, based on the benefits and risks in a particular disease, any of our products or product candidates should be granted approval for the treatment of that particular disease. Even if we believe that a clinical trial or trials has demonstrated the safety and statistically significant efficacy of any of our products or product candidates for the treatment of a disease, the results may not be satisfactory to the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted by the FDA and foreign regulatory authorities, including their advisory committees, in different ways, which could delay, limit or prevent regulatory approval. In addition, even if advisory committees to the FDA recommend approval of our product candidates, such recommendations are non-binding and the FDA may not approve our NDA for the product candidates. For example, nine of the twelve members of the Pulmonary-Allergy Drugs Advisory Committee, or PADAC, of the FDA recommended approval of pirfenidone to reduce decline in lung function in patients with IPF. However, notwithstanding the PADAC approval recommendation, we subsequently received a Complete Response Letter from the FDA requesting an additional clinical trial to support the efficacy of pirfenidone. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our products or product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

Our CAPACITY trials were conducted without a SPA with the FDA. The FDA' s SPA process creates a written agreement between the sponsoring company and the FDA regarding clinical study design and other clinical study issues that can be used to support approval of a product candidate. We did not obtain a SPA agreement with the FDA and therefore there was no assurance that the results would provide a sufficient basis in the view of the FDA for the FDA to grant regulatory approval of a new drug application for pirfenidone for the treatment of IPF. In addition, while the FDA will consider and approve NDAs based on various endpoints, the FDA had indicated that mortality is the ideal endpoint for IPF clinical trials. We designed and conducted CAPACITY 1 and CAPACITY 2 based on FVC change as the primary endpoint, as opposed to mortality. The FDA had advised us that they were uncertain as to what would constitute a clinically meaningful treatment effect of pirfenidone on this endpoint and reviewed the effect of pirfenidone not only based on FVC change but also based on the totality of the data, including the effect of pirfenidone on all of the specified efficacy endpoints as well as the safety data to help determine the risk-benefit profile of pirfenidone in IPF patients. The primary endpoint of FVC change was met with statistical significance in CAPACITY 2 but not in CAPACITY 1. Therefore, we did not replicate the efficacy of pirfenidone for the treatment of IPF in a second pivotal study. Moreover, because the data base for the Shionogi Phase 3 study was not included in our NDA, the FDA did not consider this study to support the efficacy of pirfenidone. Rather the adequacy of our application to support the efficacy of pirfenidone for the treatment of IPF was determined by the FDA during the review of our NDA. While in our view the totality of the data from CAPACITY 1 and CAPACITY 2 support the efficacy and safety of pirfenidone in IPF, the FDA disagreed with our view and decided that such data does not adequately support approval of our NDA filing and issued to us a Complete Response Letter on May 4, 2010 requesting an additional clinical trial to support the efficacy of pirfenidone in IPF. We began a new Phase 3 clinical study, the ASCEND trial, during the second quarter of 2011. We did not obtain a SPA agreement with the FDA with respect to the ASCEND trial. The results of this Phase 3 clinical trial may not be satisfactory to the FDA to receive regulatory approval. For additional information related to the risk of the new Phase 3 clinical study, please see the risk factor under the caption "Risks Related to Our Dependence on Pirfenidone–We have initiated the ASCEND Phase 3 clinical trial to support potential FDA approval of pirfenidone for the treatment of IPF, the results of which may fail to demonstrate to the FDA sufficient efficacy of pirfenidone and may have a negative effect on sales of Esbriet in the European Union."

We are subject to extensive and rigorous governmental regulation, including the requirement of FDA or other regulatory approval before our products and product candidates may be lawfully marketed.

Both before and after the approval or our product candidates and product, we, our product candidates, our product, our operations, our facilities, our suppliers, and our contract manufacturers, contract research organizations, and contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the FDA, or an institutional review board, may suspend or terminate human clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Any failure to receive the marketing approvals necessary to commercialize our product candidates could harm our business.

The regulatory review and approval process of governmental authorities is lengthy, expensive and uncertain, and regulatory standards may change during the development of a particular product candidate. We are not permitted to market our product candidates in the United States or other countries until we have received requisite regulatory approvals. The FDA review process typically takes significant time to complete and approval is never guaranteed. If a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, impose restricted distribution programs, require expedited reporting of certain adverse events, or require costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the product. Markets outside of the United States such as the EU also have requirements for approval of drug candidates with which we must comply prior to marketing. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of any of our products or product candidates, once obtained, may be withdrawn.

The FDA has increased its attention to product safety concerns in light of recent high profile safety issues with certain drug products, in the United States. Moreover, heightened Congressional scrutiny on the adequacy of the FDA' s drug approval process and the agency' s efforts to assure the safety of marketed drugs has resulted in proposed agency initiatives and new legislation addressing drug safety issues. If adopted, any new legislation or agency initiatives could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. These restrictions or requirements could require us to conduct costly studies.

In addition, we, our suppliers, our operations, our facilities, our contract manufacturers, our contract research organizations, and our contract testing laboratories are required to comply with extensive FDA requirements both before and after approval of our products. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our product candidates and our products. Also, quality control and manufacturing procedures must continue to conform to current Good Manufacturing Practices, or cGMP, regulations after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. In addition, discovery of safety issues may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

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

If we market a future product in the United States, we will be subject to various federal and state laws pertaining to health care "fraud and abuse" including anti-kickback laws and false claims laws. Subject to certain exceptions, the anti-kickback laws make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify "safe harbors" or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for

payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of Medicaid rebate information and other information affecting federal and state and third-party payment for our products, and the sale and marketing of our products, could become subject to scrutiny under these laws. In addition, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their ‘‘off-label’’ promotion of drugs.

We are subject to similar laws in foreign countries where we conduct business. For example, within the EU, the control of unlawful marketing activities is a matter of national law in each of the member states. The member states of the EU closely monitor perceived unlawful marketing activity by companies. We could face civil, criminal and administrative sanctions if any member state determines that we have breached our obligations under its national laws. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected.

We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws by us or our agents or distributors could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure by us or our agents or distributors to comply with these laws, rules and regulations could delay our expansion and could adversely affect our business.

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

Risks Related to Manufacturing and Our Dependence on Third Parties

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

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

- It may not be technically feasible to scale up an existing manufacturing process to meet demand or such scale-up may take longer than anticipated; and
- Failure to comply with strictly enforced good manufacturing practices regulations and similar foreign standards may result in delays in product approval or withdrawal of an approved product from the market. For example, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard ‘‘notice of observations.’’ Failure to correct any deficiency could result in manufacturing delays.

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

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

We do not have the resources, facilities or experience to manufacture our product or any of our product candidates ourselves. Completion of our clinical trials and commercialization of our products requires access to, or development of, manufacturing facilities that meet FDA standards to manufacture a sufficient supply of our products. The FDA, the EU and foreign regulatory authorities must approve facilities that manufacture our products for commercial purposes, as well as the manufacturing processes and specifications for the product. We depend on third parties for the manufacture of our product candidates for preclinical and clinical purposes, and we rely on third parties with FDA-approved manufacturing facilities for the manufacture of Esbriet for commercial purposes. We have a long-term supply contract with Signa C.V. and ACIC Fine Chemicals Inc. for Esbriet active pharmaceutical ingredient and a contract with Catalent for the manufacture of the drug product for Esbriet. However, if we do not perform our obligations under these agreements, these agreements may be terminated.

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

- If market demand for our products is less than our purchase obligations to our manufacturers, we may incur substantial penalties and substantial inventory write-offs.
- Manufacturers of our product and our product candidates are subject to ongoing periodic inspections by the EU, FDA and other regulatory authorities for compliance with strictly enforced good manufacturing practices regulations and similar foreign standards, and we do not have control over our third-party manufacturers' compliance with these regulations and standards.
- When we need to change third party manufacturers of a particular pharmaceutical product, the EU, FDA and foreign regulatory authorities must approve the new manufacturers' facilities and processes prior to our use or sale of products it manufactures for us. This requires demonstrated compatibility of product, process and testing and compliance inspections. Delays in transferring manufacturing technology between third parties could delay clinical trials, regulatory submissions and commercialization of our product candidates.
- Our manufacturers might not be able or may refuse to fulfill our commercial or clinical trial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market or clinical trial demands. For example, our current long-term supply contract with Signa C.V. and ACIC Fine Chemicals Inc. for the active pharmaceutical ingredient for Esbriet does not impose any obligation on Signa C.V. or ACIC Fine Chemicals Inc. to reserve a minimum annual capacity for the production of such ingredient, which could impair our ability to obtain product from them in a timely fashion.
- We may not have intellectual property rights, or may have to share intellectual property rights, to any improvements in the manufacturing processes or new manufacturing processes for our products.
- Our product costs may increase if our manufacturers pass their increasing costs of manufacture on to us.
- If third-party manufacturers do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain or maintain regulatory approvals for our products and product candidates and we may experience stock-outs. This would adversely

impact our ability to successfully commercialize our products and product candidates. Furthermore, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all.

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

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

A disruption in our ability to ship Esbriet from our packaging facilities to our distributor in the European Union or a disruption in our distribution channels in the European Union could result in significant product delays and adversely affect our results.

We currently ship Esbriet from packaging facilities to our distributor in the EU. A disruption in our ability to ship Esbriet to our distributor in the EU or a disruption in our distribution channels in the EU for any reason, including as a result of a natural disaster, terrorism or failure of our commercial carrier, could result in product delivery delays. If this were to occur, we may be unable to satisfy customer orders on a timely basis, if at all. A significant disruptive event to our ability to distribute Esbriet could adversely affect our ability to generate revenue from Esbriet and materially affect our business and results of operations.

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

If our third-party contractors do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in or prevented from obtaining regulatory approvals for our products and product candidates, and may not be able to successfully commercialize our products and product candidates for targeted diseases. We do not have the ability to independently conduct clinical trials for all of our products and product candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to perform this function. For example, we use contract research organizations to conduct our new Phase 3 ASCEND trial for pirfenidone. Our ability to monitor and audit the performance of these third parties is limited. If these third parties do not perform satisfactorily, our clinical trials may be extended or delayed, resulting in potentially substantial cost increases to us and other adverse impacts on our product development efforts. We may not be able to locate any necessary acceptable replacements or enter into favorable agreements with them, if at all.

Risks Related to Our Intellectual Property Rights

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

Our commercial success will depend in part on obtaining and maintaining patent protection on our products and product candidates and successfully defending these patents against third-party challenges. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No

consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. In addition, each country has its own rules regarding the allowability and enforceability of certain types of patents and therefore there can be no assurance that our patents applications will be granted or that our issued patents will be enforceable in any given jurisdiction. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights.

Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners may be costly and time consuming and could harm our business. Litigation may be necessary in some instances to determine the validity, enforceability, scope and infringement of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

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.

For example, the pirfenidone molecule itself has no composition of matter patent protection in the United States or elsewhere. We must therefore rely primarily on the protection afforded by formulation and method of use patents relating to the use of pirfenidone for the treatment in adults of mild to moderate IPF. While many countries such as the United States permit method of use patents relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving and may be unfavorably interpreted to prevent us from patenting some or all of our pending patent applications. There are some countries that currently do not allow such method of use patents, or that significantly limit the types of uses that are patentable.

In the EU, patents are subject to a post-grant opposition period, and enforcement of patents is on a country-by-country basis subject to varying, complex and evolving national requirements and standards. Competitors could challenge the validity of our patent claims and challenge whether their product actually infringes those claims. Such challenges would involve complex legal and factual questions and entail considerable costs and investment of effort.

Others have filed and in the future may file patent applications covering uses and formulations of pirfenidone, or other products in our development program. If a third party has been or is in the future issued a patent that blocked our ability to commercialize any of our products, alone or in combination,

for any or all of the diseases that we are targeting, we would be prevented from commercializing that product or combination of products for that disease or diseases unless we obtained a license from the patent holder. We may not be able to obtain such a license to a blocking patent on commercially reasonable terms, if at all. If we cannot obtain, maintain and protect the necessary proprietary rights for the development and commercialization of our products or product candidates, our business and financial prospects will be impaired.

The pirfenidone molecule itself has no composition of matter patent protection in the United States or elsewhere, and may only be protected for the treatment of IPF by orphan drug designation in the United States and European Union.

The pirfenidone molecule itself has no composition of matter patent protection in the United States or elsewhere. In the EU we have been granted orphan drug designation for pirfenidone for the treatment of IPF by the EMA, which provides for ten years of market exclusivity until March 2021. The exclusivity period afforded by orphan drug designation in the United States begins on first NDA approval for this product in IPF and ends seven years thereafter. Therefore, we may not have the ability to prevent others from commercializing pirfenidone for (i) IPF after the orphan drug designation exclusivity period ends, (ii) uses of pirfenidone covered by other patents held by third parties or (iii) other uses of pirfenidone in the public domain for which there is no patent protection. We are relying on exclusivity granted from orphan drug designation in IPF to protect pirfenidone from competitors in this indication and, following expiration of orphan drug protection in the EU, and if approved for commercial use by the FDA, in the United States, we must rely primarily on the protection afforded by formulation and method of use patents relating to the safe and/or effective use of pirfenidone for IPF. We cannot provide any assurance that we will be able to maintain this orphan drug designation. Furthermore, although pirfenidone has received orphan drug marketing exclusivity for the treatment of patients with IPF, the FDA and/or the EMA can still approve different drugs for use in treating the same indication or disease, which would create a more competitive market for us and our revenues will be diminished.

In addition, other third parties have obtained patents in the United States and elsewhere relating to formulation and methods of use of pirfenidone for the treatment of certain diseases. As a result, it is possible that we could face competition from third party products that have pirfenidone as the active pharmaceutical ingredient. If a third party were to obtain FDA approval in the United States for the use of pirfenidone, or regulatory approval in another jurisdiction, for an indication before we did, such third party would be first to market and could establish the price for pirfenidone in these jurisdictions. This could adversely impact our ability to implement our pricing strategy for the product and may limit our ability to maximize the commercial potential of pirfenidone in the United States and elsewhere. The presence of a lower priced competitive product with the same active pharmaceutical ingredients as our product could lead to use of the competitive product for our anti-fibrotic indications. This could lead to pricing pressure for pirfenidone, which would adversely affect our ability to generate revenue from the sale of pirfenidone for anti-fibrotic indications.

Pirfenidone is the only commercially approved drug approved for the treatment of mild to moderate IPF. There are no other existing approved treatments. Therefore the incidence and prevalence of IPF that currently provide the basis of orphan drug designation in the European Union and the United States could change over time, and it is possible that orphan drug designation could be lost in these markets should the patient population exceed that required to maintain orphan drug status in these countries.

Market exclusivity afforded by orphan drug designation is generally offered as an incentive to drug developers to invest in developing and commercializing products for unique diseases that impact a limited number of patients. With respect to the United States, 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. Qualification to maintain orphan drug status is generally monitored by the regulatory authorities during the orphan drug exclusivity period, currently seven years and ten years from the date of approval in the EU and United States, respectively. IPF is currently a poorly diagnosed disease in these markets. It is possible that with the approval of Esbriet in the EU, and the potential approval of pirfenidone in the United States, that the incidence and prevalence numbers for IPF could change in these markets. Should the incidence and prevalence of IPF patients who are eligible to receive pirfenidone for the treatment of IPF in these markets materially increase, it is possible that the orphan drug designation, and related market exclusivity, in these jurisdictions could be lost.

Following expiration of orphan drug designation in the European Union, and if approved for commercial use by the FDA, in the United States, our current intellectual property portfolio may not be sufficient to protect the continued exclusivity of pirfenidone for the treatment in adults of mild to moderate IPF.

Because the pirfenidone molecule itself has no composition of matter patent protection in the United States or elsewhere, following expiration of orphan drug designation in the EU, and if approved for commercial use by the FDA, in the United States, we must rely primarily on the protection afforded by the formulation and method of use patents relating to the safe and/or effective use of pirfenidone for the treatment in adults of mild to moderate IPF.

We have five granted patents and a number of pending patent applications in Europe relating to Esbriet' s formulation and use in IPF patients, particularly related to the safe and efficacious usage of the product. This collection of patents is expected to provide patent protection in Europe until 2030, and includes a granted patent that relates to the effect of food on the pharmacokinetics and safety of Esbriet, which expires in late 2026, a granted patent which relates to the safe and efficacious usage of Esbriet in patients who develop elevation in liver transaminase levels, which expires in late 2029, a granted patent relating to the titration of the dosing of Esbriet at the initiation of therapy, which expires in late 2027, a granted patent relating to the safe usage of Esbriet with respect to fluvoxamine that expires in 2030, and a granted patent relating to the safe usage of Esbriet with respect to smoking that expires in 2030. We also have nine issued patents in the United States relating to the formulation or safe and/or effective use of Esbriet in IPF patients, and a number of pending U.S. patent applications. In addition we have numerous pending patent applications under active prosecution in other foreign jurisdictions. The laws regarding patentability and enforceability of patents such as ours varies on a country by country basis.

These patents can be challenged by our competitors in various jurisdictions who may argue such patents are invalid or unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Additionally, even if the validity of these patents were upheld in a patent challenge, a court may refuse to stop the other party from practicing the activity at issue on the ground that its activities are not covered by our patents. Any of these outcomes would limit our ability to exclusively market pirfenidone for the treatment in adults of mild to moderate IPF in the EU, and if approved for commercial use by the FDA, in the United States, as well as certain other countries where we have filed for patent protection.

If we breach our agreement with Shionogi, our ability to develop and commercialize pirfenidone in other jurisdictions may be impaired. In addition, Shionogi has demanded that it is entitled to royalty payments on our sales of Esbriet.

In February 2010, we entered into an agreement with Shionogi that gives us an option to exercise a license for access to certain patient level data from the Shionogi Phase 3 clinical trial with pirfenidone in patients with IPF, which we refer to as SP3, to be used, along with other Shionogi clinical study

information, as ‘‘pivotal study data’’ (as defined in the agreement) in connection with our regulatory filings. We did not use SP3 patient level data as pivotal study data in our recently approved MAA or in any other submissions in connection with review of the MAA. Similarly, we did not use SP3 patient level data as pivotal study data in our U.S. NDA or in any other submissions in connection with review of the U.S. NDA. However, going forward, we may elect to use SP3 patient level data as pivotal study data in our regulatory filings in the United States or in other jurisdictions. Should we breach our agreement with Shionogi, we may lose our ability to use Shionogi’ s patient level data in our regulatory filings in the United States or in other jurisdictions, which could adversely affect our ability to obtain regulatory approval of pirfenidone in such jurisdictions. In addition, in March 2012, following discussions with Shionogi, Shionogi demanded that we agree that it is entitled to royalty payments on our sales of Esbriet in Europe, based on Shionogi’ s interpretation of our May 2004 agreement with Shionogi (as amended). On July 5, 2012, Shionogi filed a complaint against us in the United States District Court for the Northern District of California alleging, principally, that we breached that agreement by utilizing certain of Shionogi’ s information in our MAA and other submissions for pirfenidone with the EMA and then failing to pay royalties to Shionogi on net sales of pirfenidone (Esbriet) in the European Union. In the alternative, the complaint alleges that, if we did not use Shionogi’ s information in a way that would trigger a royalty obligation under the agreement, we had an obligation to do so as an exclusive licensee. Shionogi is seeking, among other things, unspecified monetary damages and a declaration that we are obligated to pay royalties to Shionogi on net sales of pirfenidone (Esbriet®) in the European Union. While we disagree that we owe any such royalties and intend to defend our position vigorously, an unfavorable outcome in the litigation with Shionogi could require that we pay royalties or make other payments to Shionogi.

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

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

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

We generally do not control the patent prosecution of intellectual property that we license from third parties. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would exercise over intellectual property that we own, and, as a result, we may lose our rights to such intellectual property and incur substantial costs.

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

Patent prosecution may not be appropriate or obtainable for certain of our technologies, and we may instead protect such proprietary information as trade secrets. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors.

These agreements generally provide that all confidential information developed or made known to an individual or company during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees and consultants, our agreements generally provide that all inventions made by the individual while engaged by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors. If our trade secrets become known, we may lose a competitive advantage and our ability to generate revenue may therefore be impaired.

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

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

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

If we continue to incur net losses for an extended period of time, we may be unable to continue our business.

We have incurred net losses since inception, and our accumulated deficit was approximately $1.04 billion at September 30, 2012. We expect to incur substantial additional net losses prior to achieving profitability, if ever. The extent of our future net losses and the timing of our profitability are highly uncertain, and we may never achieve profitable operations. We are planning to expand the number of diseases for which our products may be marketed, and this expansion will require significant expenditures. Through June 2012, we generated revenue primarily through the sale of Actimmune; however, in June 2012, we divested all of our Actimmune assets. We have not generated operating profits to date from our products. If the time required for us to achieve profitability is longer than we anticipate, we may not be able to continue our business.

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

We believe our existing cash, cash equivalents and available-for-sale securities as of September 30, 2012, along with anticipated cash flows from our sales of Esbriet, will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the next 12 months. However, our current plans and assumptions may change, and our capital requirements may increase. 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.

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

Because we are an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, we may choose to delay our research and development efforts for a promising product candidate or we may elect to terminate our programs for and, in certain cases, our licenses to, such product candidates or programs in order to allocate resources to another program, which could cause us to fall behind our initial timetables for development of certain product candidates. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all. If we terminate a preclinical program in which we have invested significant resources, we will have expended resources on a program that will not provide a full return on our investment and missed the opportunity to have allocated those resources to potentially more productive uses.

Due to cash constraints or for strategic business reasons we may decide to take certain actions that reduce our expenses. For example, we sold to Roche our worldwide development and commercialization rights to danoprevir and received $175.0 million from the sale of such rights. On a forward-looking basis we will not incur the expense associated with further investment in danoprevir; however, our rights to share profits from sales of danoprevir in the United States have also been terminated and, as a result, our business and future financial results may be harmed.

Negative conditions in the global markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist of high-grade corporate debt securities, government agency securities and direct government obligation securities. Due to recent credit market and global economic conditions, markets for certain fixed-income securities have been volatile and have experienced limitations in liquidity. If there is insufficient demand for the securities we hold, we may not have liquid access to our investments and may be required to recognize an impairment for those securities should we conclude that such impairment is other-than-temporary. For example, as recently as September 30, 2010 we held in our investment portfolio $4.8 million of auction rate securities that had experienced illiquid market conditions requiring us to previously adjust the carrying-value of these securities. As of December 31, 2010, all of our auction rate securities had been sold or redeemed.

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

We initiated our commercial launch of Esbriet in Germany in September 2011 and subsequently in Austria, Belgium, Canada, Denmark, France, Iceland, Luxembourg, Norway and Sweden and we currently plan to initiate commercial launches in additional countries in the EU in 2013. While we have attempted to forecast demand for Esbriet in Germany, other European countries and Canada, until we have a sufficient history of commercial sales in such jurisdictions, we cannot know with certainty whether our inventory of Esbriet is in excess of or insufficient to meet demand. Further, we have just recently established our sales organization in the EU and we do not yet know if the size of the sales organization is sufficient to successfully commercialize Esbriet, which makes accurately forecasting demand more difficult. If we fail to accurately forecast demand for Esbriet, we may face temporary supply shortages, which would impair our ability to generate revenue from such demand, or excess inventories, which may result in additional charges for such excess inventory.

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. We have product liability risk for all of our product candidates and for all of the clinical trials we conduct, including our discontinued INSPIRE trial. If product liability costs exceed our liability insurance coverage, we may incur substantial liabilities. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. While we believe that our clinical trial and product liability insurance currently provides adequate protection to our business, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

If we materially breach the representations and warranties we made to Roche under the asset purchase agreement for the sale of danoprevir or to Vidara under the asset purchase agreement for the sale of Actimmune, or if we fail to perform any of our other contractual obligations under these agreements, Roche or Vidara, as applicable, has the right to seek indemnification from us for damages it suffers as a result of such breach or failure. These amounts could be significant.

We have agreed to indemnify Roche and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the asset purchase agreement for our sale of our worldwide development and commercialization rights to danoprevir. In addition, we have agreed to indemnify Vidara and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the asset purchase agreement for the sale of our worldwide development and commercialization rights to Actimmune®. If one or more of our representations and warranties were not true at the time we made them to Roche or Vidara, or if we fail to perform any of our other contractual obligations under an agreement, we would be in breach of the applicable asset purchase agreement. In the event of a breach or failure by us to perform, Roche or Vidara, as applicable, has the right to seek indemnification from us for damages suffered by either of them as a result of such breach. The amounts for which we could become liable may be significant.

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

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

standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for significant damages or fines, which may not be covered by or may exceed our insurance coverage.

Insurance coverage is increasingly difficult to obtain or maintain.

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

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

As of September 30, 2012, we had 230 full-time employees, and our success depends on our continued ability to attract, retain and motivate highly qualified management, scientific and commercial personnel, especially in Europe, and on our ability to develop relationships with leading academic scientists. Competition for personnel and academic collaborations is intense. We are highly dependent on our current management and key scientific and technical personnel, including Daniel G. Welch, our Chairman, Chief Executive Officer and President, as well as the other principal members of our management. None of our employees, including members of our management team, has a long-term employment contract, and any of our employees can leave at any time. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. In addition, we may need to hire additional personnel and develop additional academic collaborations if we 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.

Our ability to use our net operating losses and certain other tax attributes may be subject to annual limitations under federal and state tax law that could materially affect our ability to utilize such losses and attributes.

If a corporation undergoes an "ownership change" within the meaning of section 382 of the Internal Revenue Code, or section 382, the corporation's ability to utilize any net operating losses, or NOLs, and certain tax credits and other attributes generated before such an ownership change, is limited. We believe that we have in the past experienced ownership changes within the meaning of section 382 that have resulted in limitations under section 382 (and similar state provisions) on the use of our NOLs and other tax attributes. Future changes in ownership could result in additional ownership changes within the meaning of section 382 that could further limit our ability to utilize our NOLs and certain other tax attributes.