FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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INTERMUNE INC
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-Q

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from to

Commission File Number: 0-29801

InterMune, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3296648**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3280 Bayshore Blvd., Brisbane, California 94005
(Address of principal executive offices, including zip code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period than the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

As of October 31, 2011, there were 65,507,633 outstanding shares of common stock, par value $0.001 per share, of InterMune, Inc.

INTERMUNE, INC.

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

INTERMUNE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2011	December 31, 2010
	(Unaudited, in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$183,319	$110,584
Available-for-sale securities	284,861	184,489
Accounts receivable, net of allowances of $38 at September 30, 2011 and $36 at December 31, 2010	2,002	1,710
Inventories	6,359	1,151
Prepaid expenses and other current assets	4,561	3,609
Total current assets	481,102	301,543
Acquired product rights, net	19,500	–
Property and equipment, net	1,174	1,246
Other assets (includes restricted cash of $1,428 at September 30, 2011 and $1,432 at December 31, 2010)	7,673	2,358
Total assets	$509,449	$305,147
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$11,306	$7,994
Accrued compensation	10,076	6,578
Convertible notes - current portion	–	44,300
Other accrued liabilities	11,489	11,189
Total current liabilities	32,871	70,061
Deferred rent	71	238
Convertible notes - noncurrent portion	240,250	85,000
Other long term liabilities	–	548
Commitments and contingencies		
Stockholders' equity:		
Common stock	66	57
Additional paid-in capital	1,139,312	942,375
Accumulated other comprehensive income (loss)	215	(37)
Accumulated deficit	(903,336)	(793,095)
Total stockholders' equity	236,257	149,300
Total liabilities and stockholders' equity	$509,449	$305,147

See accompanying Notes to Condensed Consolidated Financial Statements.

INTERMUNE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Unaudited, in thousands, except per share data)			
Revenue, net				
Actimmune®	$5,111	$4,836	$15,072	$15,174
Esbriet®	118	–	118	–
Collaboration revenue	–	818	2,629	2,454
Total revenue, net	5,229	5,654	17,819	17,628
Costs and expenses:				
Cost of goods sold	1,068	1,291	6,713	5,099
Research and development	17,045	15,623	53,967	50,824
Selling, general and administrative	23,983	10,884	63,294	38,747
Restructuring charges	–	110	–	1,371
Total costs and expenses	42,096	27,908	123,974	96,041
Loss from operations	(36,867)	(22,254)	(106,155)	(78,413)
Other income (expense):				
Interest income	131	99	390	409
Interest expense	(1,281)	(2,100)	(4,154)	(6,279)
Other income (expense)	(227)	(29)	(322)	576
Net loss	$(38,244)	$(24,284)	$(110,241)	$(83,707)
Basic and diluted loss per share:				
Net loss per share	$(0.63)	$(0.44)	$(1.88)	$(1.55)
Shares used in computing basic and diluted net loss per share	60,467	54,933	58,599	53,918

See accompanying Notes to Condensed Consolidated Financial Statements.

INTERMUNE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2011	2010
	(Unaudited, in thousands)	
Cash flows used in operating activities:		
Net loss	$(110,241)	$(83,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	2,179	4,819
Stock-based compensation expense	13,243	7,079
Net realized gains on sales of available for sale securities	(15)	(642)
Deferred rent	(167)	(495)
Other	199	–
Changes in operating assets and liabilities:		
Accounts receivable, net	(292)	1,996
Inventories	(5,208)	783
Other assets	(1,358)	86
Accounts payable and accrued compensation	6,262	666
Other accrued liabilities	300	(9,473)
Deferred collaboration revenue	–	(2,454)
Net cash used in operating activities	(95,098)	(81,342)
Cash flows from investing activities:		
Acquisition of product rights	(20,000)	–
Purchases of property and equipment	(828)	(220)
Purchases of available-for-sale securities	(270,110)	(158,700)
Sales of available-for-sale securities	43,938	9,334
Maturities of available-for-sale securities	125,868	116,297
Net cash used in investing activities	(121,132)	(33,289)
Cash flows from financing activities:		
Proceeds from issuance of common stock in a public offering, net of issuance costs	104,788	106,832
Proceeds from issuance of convertible senior notes, net of issuance costs	150,225	–
Proceeds from issuance of common stock under employee stock benefit plans	33,952	9,384
Net cash provided by financing activities	288,965	116,216
Net (decrease) increase in cash and cash equivalents	72,735	1,585
Cash and cash equivalents at beginning of period	110,584	17,007
Cash and cash equivalents at end of period	$183,319	$18,592
Supplemental disclosure of cash flow information:		
Non-cash financing activities:		
Issuance of common stock in exchange for convertible debt	$44,963	$–

See accompanying Notes to Condensed Consolidated Financial Statements.

INTERMUNE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. ORGANIZATION

Overview

We are a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and fibrotic diseases. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. We have an advanced-stage product candidate in pulmonology, pirfenidone, that was granted marketing authorization effective February 2011 in all 27 member countries of the European Union ("EU") for the treatment of adults with mild to moderate idiopathic pulmonary fibrosis ("IPF"). In September 2011, we launched commercial sales of pirfenidone in Germany under the trade name Esbriet®, and we are continuing to prepare for the commercial launch of Esbriet® in the other countries in the EU. We are also pursuing the registration of pirfenidone to treat IPF in the United States. After reviewing various regulatory and clinical development options and following our discussions with the United States Food and Drug Administration ("FDA"), we commenced an additional pivotal Phase 3 clinical study of pirfenidone in IPF in July 2011, known as the ASCEND trial, which is expected to be completed in mid-2013. The results of the ASCEND trial will supplement the existing Phase 3 clinical study data from our CAPACITY clinical trials to support the registration of pirfenidone to treat IPF in the United States. In addition, we currently have rights to one approved and marketed product, Actimmune, which is approved in the United States and numerous other countries for the treatment of chronic granulomatous disease ("CGD") and severe, malignant osteopetrosis. Previously, we also focused on the field of hepatology, which is concerned with the diagnosis and treatment of disorders of the liver. We have a hepatology portfolio of small molecule compounds that are currently in the pre-clinical research stage. However, in May 2011, we announced that we no longer plan to invest further in the field of hepatology.

In September 2011, we completed a registered underwritten public offering of 4.6 million shares of our common stock and a concurrent registered underwritten public offering of $155.3 million aggregate principal amount of 2.5% convertible senior notes due 2018 ("2018 Notes"). The aggregate net proceeds from our concurrent offerings was approximately $255.0 million, after deducting underwriting discounts and commissions and related offering expenses. We currently intend to use the net proceeds from these offerings to fund the commercial launch of Esbriet in the EU, to fund our ASCEND trial and for general corporate purposes.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that we believe are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2010, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

Principles of consolidation

The consolidated financial statements include the accounts of InterMune and its wholly-owned subsidiaries, InterMune Canada Inc. and InterMune UK Ltd. along with our other subsidiaries located in Germany, France, Switzerland, Spain, and Italy. All inter-company balances and transactions have been eliminated.

Use of estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and

liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

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

Inventory valuation

Inventories are stated at the lower of cost or market. Cost is determined by the specific identification method. Inventories were $6.4 million and $1.2 million at September 30, 2011 and December 31, 2010, respectively, and consisted solely of Actimmune finished goods at December 31, 2010. At September 30, 2011, inventories include approximately $5.3 million of Esbriet inventory comprised of costs incurred for in-process inventory since the date of EU approval and approximately $1.1 million of Actimmune finished goods.

Because of the lead times required to manufacture both Esbriet and Actimmune, we enter into purchase obligations to satisfy our estimated inventory requirements. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current as well as committed purchases. We are also required to make judgments as to the expiration dates of our inventory, since it is not usable beyond its expiration date. As part of our excess inventory assessment for both Esbriet and Actimmune, we also consider the expiration dates of future manufactured quantities under our purchase obligations.

We did not incur any charges for inventory writedowns during the nine months ended September 30, 2011. During the nine months ended September 30, 2010, we charged $0.3 million to cost of goods sold for inventory writedowns resulting from the excess of inventory compared to forecasted inventory requirements. As of September 30, 2011, we had firm commitments to purchase approximately $2.1 million of Actimmune inventory and approximately $4.1 million of Esbriet inventory.

Acquired Product Rights

Initial payments for the acquisition of products that, at the time of acquisition, are already marketed or are approved by the FDA or the European Commission (“EC”) for marketing are capitalized and amortized ratably over the estimated life of the products. At the time of acquisition, the product life is estimated based upon the term of the agreement, the remaining patent life of the product and our assessment of future sales and profitability of the product, which we currently estimate to be 20 years. We assess this estimate regularly during the amortization period and adjust the asset value and/or useful life when appropriate. Initial payments for the acquisition of products that, at the time of acquisition, are under development or are not approved by the FDA or EC for marketing, have not reached technical feasibility and have no foreseeable alternative future uses are expensed as research and development costs.

Revenue recognition and revenue reserves

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

Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Collaboration revenue derived from our 2006 agreement with Roche includes upfront license fees and milestone payments. Nonrefundable upfront license fees that require our continuing involvement in the form of research, development, or other commercialization efforts by us are recognized as revenue ratably over the estimated term of our continuing involvement. Milestone payments received under our collaboration agreements that relate to events that are substantive and at risk at the initiation of the agreement are recognized as revenue when the milestones, as defined in each respective contract, are achieved and collectibility of the milestone is assured.

In December 2010, we entered into a new agreement with Roche that focused on research to identify and develop next-generation protease inhibitors for the treatment of HCV. Under terms of the agreement, Roche funded all research costs related to the programs for the period of July 1, 2010 through June 30, 2011, the effective term of the research program. During 2011, we received $2.6 million from Roche as a reimbursement for research services performed which has been recorded as collaboration revenue. We will also be entitled to receive certain milestones and royalties in connection with the continued development and commercialization by Roche of any licensed compounds resulting from the research program.

Research and development expenses

Research and development ("R&D") expenses include salaries, contractor and consultant fees, external clinical trial expenses performed by contract research organizations ("CRO"), licensing fees, acquired intellectual property with no alternative future use and facility and administrative expense allocations. In addition, we fund R&D at research institutions under agreements that are generally cancelable at our option. Research costs typically consist of applied research and preclinical and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis and the transfer and scale-up of manufacturing at our contract manufacturers. Clinical development costs include the costs of Phase 1, Phase 2 and Phase 3 clinical trials. These costs are a significant component of our research and development expenses.

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

Net loss per share

We compute basic net loss per share by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. We deduct shares subject to repurchase by us from the outstanding shares to arrive at the weighted-average shares outstanding. We compute diluted net loss per share by dividing the net loss for the period by the weighted-average number of common and potential common shares outstanding during the period. We exclude dilutive securities, composed of potential common shares issuable upon the exercise of stock options and common shares issuable on conversion of our convertible notes, from diluted net loss per share because of their anti-dilutive effect.

The securities excluded were as follows (in thousands):

	As of September 30,	
	2011	2010
Options	4,057	5,474
Shares issuable upon conversion of convertible notes	9,384	6,581

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$(38,244)	$(24,284)	$(110,241)	$(83,707)
Basic and diluted net loss per share:				
Weighted-average shares of common stock outstanding	61,375	56,011	59,575	54,733

Less: weighted-average shares subject to repurchase	(908)	(1,078)	(976)	(815)
Weighted-average shares used in computing basic and diluted net loss per share	60,467	54,933	58,599	53,918
Basic and diluted net loss per share	$(0.63)	$(0.44)	$(1.88)	$(1.55)

Stock-Based Compensation

The following table reflects stock-based compensation expense recognized for the three- and nine-month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	$1,359	$1,045	$4,459	$2,225
General and administrative	2,935	2,037	8,784	4,854
Total stock-based compensation expense	$4,294	$3,082	$13,243	$7,079

Under the fair value recognition provisions of Accounting Standards Codification (ASC) Topic 718-10, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period for that portion of the award that is ultimately expected to vest. In order to estimate the value of share-based awards, we use the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility, the expected term of the award and the estimated forfeiture rate.

Recent Accounting Pronouncements

In September 2009, the FASB issued Update No. 2009-13, "Multiple-Deliverable Revenue Arrangements−a consensus of the FASB Emerging Issues Task Force" (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21). The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 was effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The adoption of this update on January 1, 2011 did not have a material impact on our condensed consolidated financial statements as we did not enter into or materially modify any multiple-element arrangements during the three- and nine-months ended September 30, 2011. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from those recognized for our past multiple-element arrangements.

In April 2010, the FASB issued Update No. 2010-17, "Milestone Method of Revenue Recognition – a consensus of the Emerging Issues Task Force." The objective of the update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. It provides criteria for evaluating if the milestone is substantive and clarifies that a vendor can recognize consideration that is contingent upon achievement of a milestone as revenue in the period in which the milestone is achieved, if the milestone meets all the criteria to be considered substantive. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity' s performance or on the occurrence of a specific outcome resulting from the entity' s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. This guidance is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010, which we adopted on a prospective basis on January 1, 2011. The election of the milestone method did not have a material impact on our condensed consolidated financial statements and is not expected to result in different accounting treatment for future substantive milestones earned after the date of this adoption. Non-substantive milestones will continue to be recognized over the remaining performance period.

3. FAIR VALUE

In accordance with portions of ASC Topic No. 820, the following table represents the Company' s fair value hierarchy for its financial assets (cash, cash equivalents and investments, including accrued interest of approximately $0.5 million and $0.8 million, respectively) measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 (in thousands):

September 30, 2011	Level 1	Level 2	Level 3	Total
Money market funds	$136,340	$–	$ –	$136,340
Obligations of government-sponsored enterprises	–	142,062	–	142,062
Commercial paper	–	26,996	–	26,996
Corporate debt securities	–	33,800	–	33,800
Total	$136,340	$202,858	$ –	$339,198

December 31, 2010	Level 1	Level 2	Level 3	Total
Money market funds	$96	$–	$ –	$96
Obligations of government-sponsored enterprises	–	178,907	–	178,907
Commercial paper	–	74,780	–	74,780
Corporate debt securities	–	24,286	–	24,286
Total	$96	$277,973	$ –	$278,069

Level 1 assets have been determined using quoted prices in active markets for identical assets or liabilities. Level 2 assets have been obtained from inputs other than level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

The fair value of our long-term convertible debt is estimated based on quoted prices for those instruments. As of September 30, 2011, the fair value of our $85.0 million 5% convertible senior notes due 2015 ("2015 Notes") was approximately $122.9 million and the fair value of our $155.3 million 2018 Notes was $152.2 million. Our 2015 and 2018 Notes are not marked-to-market and are shown at their original issuance value in the accompanying unaudited Condensed Consolidated Balance Sheet.

4. AVAILABLE-FOR-SALE INVESTMENTS

The following is a summary of our available-for-sale investments as of September 30, 2011 and December 31, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2011				
Obligations of government-sponsored enterprises	$142,007	$ 59	$ (4)	$142,062
Money market funds	136,340	–	–	136,340
Commercial paper	26,996	–	–	26,996
Corporate debt securities	33,836	–	(36)	33,800
Total	$339,179	$ 59	$ (40)	$339,198

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2010				
Obligations of government-sponsored enterprises	$178,925	$ 28	$ (46)	$178,907

Money market funds	96	–	–	96
Commercial paper	74,780	–	–	74,780
Corporate debt securities	24,301	–	(15)	24,286
Total	$278,102	$ 28	$ (61)	$278,069

Realized gains and losses and declines in value, judged to be other than temporary, on available-for-sale securities are included in other income (expense) for the three-months ended September 30, 2011 and 2010. Realized gains were calculated based on the specific identification method and were not material for each of the three- and nine-months ended September 30, 2011 and were approximately $0.6 million for the nine-months ended September 30, 2010, consisting primarily of realized gains from the sale of auction rate securities. Unrealized holding gains and losses on securities classified as available-for-sale are recorded in accumulated other comprehensive income.

The following is a summary of the amortized cost and estimated fair value of available-for-sale securities at September 30, 2011 by contractual maturity (in thousands):

	September 30, 2011	
	Amortized Cost	Fair Value
Mature in less than one year	$331,459	$331,493
Mature in one to three years	7,720	7,705
Mature in over three years	–	–
Total	$339,179	$339,198

5. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive income (loss). We include in other comprehensive income (loss) changes in unrealized gains and losses on our available-for-sale securities and cumulative foreign currency translation adjustment. The activity in other comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$(38,244)	$(24,284)	$(110,241)	$(83,707)
Cumulative foreign currency translation adjustment	250	–	199	–
Change in unrealized gain (loss) on available-for-sale securities	(61)	(80)	53	(1,440)
Comprehensive loss	$(38,055)	$(24,364)	$(109,989)	$(85,147)

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

	September 30, 2011	December 31, 2010
Cumulative foreign currency translation adjustment	$ 196	$ (3)
Net unrealized gain (loss) on available-for-sale securities	19	(34)
Total accumulated other comprehensive income (loss)	$ 215	$ (37)

6. ACQUIRED PRODUCT RIGHTS

Marnac, Inc./KDL GmbH (Pirfenidone)

In 2002, we licensed from Marnac and its co-licensor, KDL, their worldwide rights (excluding Japan, Korea and Taiwan) to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and future milestone and up to 9% royalty payments. Effective November 2007, we entered into asset purchase agreements with Marnac and KDL whereby we effectively terminated the prior license agreement by purchasing, among other things, the pirfenidone-related assets covered by such prior license agreement. Under the terms of the asset purchase agreements, we made acquisition payments of approximately $13.7 million. We also made a milestone payment of $13.5 million in March 2009 in connection with our decision to proceed with regulatory approval for pirfenidone. In March 2011, we received authorization to market Esbriet (pirfenidone) in the European Union and made a milestone payment of $20.0 million in the aggregate to Marnac and KDL and have capitalized such payment as acquired product rights. A future contingent acquisition payment of up to an additional $20.0 million is required to be made by us only if positive Phase 3 data and product approval in the United States is achieved. The asset purchase agreements do not affect the rights to pirfenidone in Japan, Korea and Taiwan, which rights are licensed by Marnac and KDL to Shionogi & Company LTD

(“Shionogi”). Since the original 2002 license agreement has been effectively terminated as a result of our acquisition of such pirfenidone-related assets from Marnac and KDL, we no longer have milestone or royalty obligations thereunder.

7. CONVERTIBLE DEBT

As of March 1, 2011, the holders of all of our then-outstanding 0.25% convertible senior notes due March 1, 2011 (the "2011 Notes"), approximately $45.0 million in aggregate principal, elected to convert the outstanding 2011 Notes into an aggregate of 2,078,561 shares of our common stock. As a result, no 2011 Notes remain outstanding and we have no further obligations under the indenture governing the 2011 Notes.

In September 2011, the Company issued $155.3 million in 2.50% convertible senior notes due 2018. Interest will accrue from the date of issuance and is payable on September 15 and March 15 of each year commencing on March 15, 2012. The convertible senior notes will mature on September 15, 2018. Holders of convertible notes may surrender their notes, in integral multiples of $1,000 principal amount, for conversion any time prior to the close of business on the second business day immediately preceding the maturity date. The initial conversion rate for each $1,000 aggregate principal amount of convertible senior notes is 31.4465 shares of common stock, equivalent to conversion price of approximately $31.80 per share. Offering expenses and underwriting discounts in the aggregate of approximately $5.0 million related to the sale of the 2018 Notes were recorded in other assets and are being amortized to interest expense using the effective interest method over the term of the 2018 Notes, which is approximately seven years from the date of issuance.

8. STOCKHOLDERS' EQUITY

In September 2011, we completed a public offering of 4.6 million shares of registered common stock, at a price of $24.00 per share, before underwriting discounts. We received net proceeds of approximately $104.8 million after deducting underwriting fees of approximately $5.2 million and other related expenses of approximately $0.4 million.

9. COMMITMENTS AND CONTINGENCIES

Contingent Payments

We may be required to make contingent milestone payments to the owners of our licensed products or the suppliers of our drug compounds in accordance with our license, commercialization and collaboration agreements in the aggregate amount of $42.1 million, as of September 30, 2011, if all of the milestones per the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones. Of the $42.1 million in aggregate milestone payments, a $20.0 million contingent payment would be made by us only if approval in the United States is achieved for pirfenidone. Potential milestone payments of $9.6 million are related to the further development of Actimmune, which we have no current plans to pursue, and therefore we do not expect to pay these amounts. Included in the $42.1 million in future aggregate milestone payments are aggregate milestone payments of $11.3 million payable to Array BioPharma, Inc. and Novartis Corporation, of which Hoffmann-LaRoche Inc. and F.Hoffmann-La Roche Ltd. (collectively, "Roche") has agreed to reimburse us in connection with our sale of danoprevir to Roche.

Class Action Lawsuits

In May 2008, a complaint was filed in the United States District Court for the Northern District of California entitled Deborah Jane Jarrett, Nancy Isenhower, and Jeffrey H. Frankel v. InterMune, Inc., W. Scott Harkonen, and Genentech, Inc., Case No. C-08-02376. Plaintiffs alleged that they were administered Actimmune, and they purported to sue on behalf of a class of consumers and other end-payors of Actimmune. The complaint alleged that the Company fraudulently misrepresented the medical benefits of Actimmune for the treatment of IPF and promoted Actimmune for IPF. The complaint asserted various claims against the Company, including civil RICO, unfair competition, violation of various state consumer protection statutes, and unjust enrichment. The complaint sought various damages in an unspecified amount, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiffs' legal fees and costs, as well as equitable relief. Between June 2008 and September 2008, three additional complaints were filed in the United States District Court for the Northern District of California alleging similar facts. In February 2009, the Court consolidated the four complaints for pretrial purposes.

On September 1, 2010, after two rounds of motions to dismiss, the Court granted defendants' third motions to dismiss, dismissing all remaining claims in all consolidated cases with prejudice and entered judgment accordingly. On October 1, 2010, the remaining plaintiffs in all cases filed notices of appeal, appealing the judgment to the United States Court of Appeals for the Ninth Circuit. On October 10, 2011, the United States Court of Appeals for the Ninth Circuit set an oral argument date of November 29, 2011 for the appeals.

The Company believes it has substantial factual and legal defenses to the claims at issue and intends to defend the actions vigorously. We may enter into discussions regarding settlement of these matters, and may enter into settlement agreements, if we believe settlement is in the best interests of our stockholders. We cannot reasonably estimate the possible loss or range of loss that may arise from these lawsuits.

Indemnity Agreement

On or about March 22, 2000, the Company entered into an Indemnity Agreement with W. Scott Harkonen M.D., who served as the Company' s chief executive officer until June 30, 2003. The Indemnity Agreement obligates the Company to hold harmless and indemnify Dr. Harkonen against expenses (including attorneys' fees), witness fees, damages, judgments, fines and amounts paid in settlement and any other amounts Dr. Harkonen becomes legally obligated to pay because of any claim or claims made against him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative, to which Dr. Harkonen is a party by reason of the fact that he was a director, officer, employee or other agent of the Company. The Indemnity Agreement establishes exceptions to the Company' s indemnification obligation, including but not limited to claims "on account of [Dr. Harkonen' s] conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct," claims "on account of [Dr. Harkonen' s] conduct that is established by a final judgment as constituting a breach of [Dr. Harkonen' s] duty of loyalty to the Corporation or resulting in any personal profit or advantage to which [Dr. Harkonen] was not legally entitled," and claims "for which payment is actually made to [Dr. Harkonen] under a valid and collectible insurance policy." The Indemnity Agreement, however, obligates the Company to advance all expenses, including attorneys' fees, incurred by Dr. Harkonen in connection with such proceedings, subject to an undertaking by Dr. Harkonen to repay said amounts if it shall be determined ultimately that he is not entitled to be indemnified by the Company.

Dr. Harkonen has been named as a defendant in the civil action lawsuits described above and became the target of the investigation by the U.S. Department of Justice regarding the promotion and marketing of Actimmune. On March 18, 2008, a federal grand jury indicted Dr. Harkonen on two felony counts related to alleged improper promotion and marketing of Actimmune during the time Dr. Harkonen was employed by the Company (the "Criminal Action"). The trial in the criminal case resulted in a jury verdict on September 29, 2009, finding Dr. Harkonen guilty of one count of wire fraud related to a press release issued on August 28, 2002, and acquitting him of a second count of a misbranding charge brought under the Federal Food, Drug, and Cosmetic Act. On April 13, 2011, the Court denied Dr. Harkonen' s post-trial motions and sentenced Dr. Harkonen to three years of probation, including six months of home detention, 200 hours of community service and a fine of $20,000. The Court' s Judgment was filed on April 18, 2011. Dr. Harkonen filed a notice of appeal on April 25, 2011. Under the terms of the Indemnity Agreement, the Company has an obligation to indemnify Dr. Harkonen for reasonable legal fees and costs incurred in connection with defending this action, including any appeal by Dr. Harkonen of his recent sentence.

Prior to December 2008, insurers that issued directors and officers ("D&O") liability insurance to the Company had advanced all of Dr. Harkonen' s expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action. Those insurers included National Union Fire Insurance Company of Pittsburgh, PA ("AIG"), Underwriters at Lloyd' s, London ("Lloyd' s"), and Continental Casualty Company ("CNA"). On November 19, 2008, however, the insurer that issued a $5 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by AIG, Lloyd' s and CNA, Arch Specialty Insurance Company ("Arch"), advised the Company that the limits of the underlying coverage were expected to be depleted by approximately December 15, 2008; that Arch "disclaims coverage" based on misstatements and misrepresentations allegedly made by Dr. Harkonen in documents provided in the application for the Arch policy and the underlying Lloyd' s policy; and, based on that disclaimer, Arch would not be advancing any of Dr. Harkonen' s expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action.

As a result of Arch' s disclaimer of coverage and refusal to advance expenses, including attorneys' fees, the Company had, as of approximately December 15, 2008, become obligated to advance such expenses incurred by Dr. Harkonen in the civil action lawsuits and Criminal Action.

On January 13, 2009, the Company submitted to the American Arbitration Association ("AAA") a Demand for Arbitration, InterMune, Inc. v. Arch Specialty Insurance Co., No. 74 194 01128 08 JEMO. Dr. Harkonen also is a party to the Arbitration. The

Demand for Arbitration sought an award compelling Arch to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and the Criminal Action, and to advance other former officers' legal fees and costs incurred in relation to the Department of Justice investigation.

The matter was heard by the arbitration panel and on May 29, 2009, the arbitration panel issued an Interim Arbitration Award granting the Company' s request for a partial award requiring Arch to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and Criminal Action. Arch subsequently advanced such fees and costs, including fees and costs previously paid by the Company. The question whether Arch ultimately will be required to cover the advanced fees and costs or, instead, may recoup those fees and costs as not covered by its policy, has not been determined. Unless and until the arbitration panel rules that such fees and costs are not covered, Arch remains obligated to advance such fees and costs. At this time the Company believes no change to the status of the interim Arbitration Award or to the application of the D&O liability insurance in general has occurred due to the trial court judgment, and therefore the Company has not recorded any accrued liabilities associated with this matter.

In late 2009, Arch advised the Company that Arch had exhausted the $5.0 million limit of liability of the Arch D&O insurance policy, and that defense cost invoices submitted to Arch collectively exceed the Arch policy' s limit. The Company therefore advised the insurer that issued a $5.0 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by Arch, Old Republic Insurance Company ("Old Republic"), that the limits of the underlying coverage had been depleted, and the Company submitted invoices for legal services rendered on behalf of Dr. Harkonen and other individuals who were targets of the U.S. Department of Justice' s investigation to Old Republic for payment. Old Republic agreed to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and Criminal Action, but declined to reimburse the Company for payments made on behalf of other individuals who were targets of the U.S. Department of Justice' s investigation. In mid-2010, Old Republic advised the Company that Dr. Harkonen' s defense fees and costs had exhausted the $5 million limit of the Old Republic insurance policy as of the second quarter of 2010. There is no additional insurance coverage available to cover the cost of Dr. Harkonen' s continuing defense. Defense fees and costs incurred over and above this final $5 million of insurance coverage therefore are, in the absence of any available insurance, to be advanced by the Company pursuant to the terms of the Indemnity Agreement. We expect amounts to be paid by the Company to continue into the future until the Criminal Action is finally adjudicated, however we are unable to predict what our total liability could be with any degree of certainty.

10. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION

We have determined that, in accordance with ASC Topic No. 280, we operate in one segment, because operating results are reported only on an aggregate basis to our chief operating decision makers. We currently market Actimmune in the United States for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis and also market Esbriet in Germany for the treatment of adults with mild to moderate IPF.

Our net revenue by region for the three- and nine-months ended September 30, 2011 and 2010, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
United States	$5,086	$4,788	$14,827	$15,047
Europe and other	143	866	2,992	2,581
Total net revenue	$5,229	$5,654	$17,819	$17,628

Our revenue and trade receivables are concentrated with a few customers. We perform credit evaluations on our customers' financial condition and limit the amount of credit extended. However, we generally do not require collateral on accounts receivable. Concentrations of credit risk, with respect to accounts receivable, exist to the extent of amounts presented in the financial statements. Three customers represented 46%, 25% and 17%, respectively, of total trade accounts receivable at September 30, 2011, and three customers represented 37%, 33% and 11%, respectively, of total accounts receivable at December 31, 2010. No other customer represented more than 10% of accounts receivable at September 30, 2011 or December 31, 2010.

Revenue from customers representing 10% or more of total product revenue during the nine month periods ended September 30, 2011 and 2010, was as follows:

Customer	Nine Months Ended September 30, 2011		2010	
CuraScript, Inc.	34	%	36	%
Nova Factor	22	%	25	%
Caremark	21	%	18	%
McKesson	11	%	7	%

Item 2. Management' s Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

This Quarterly Report on Form 10-Q (the Report) contains certain information regarding our financial projections, plans and strategies that are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements involve substantial risks and uncertainty. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "plan," "could," "should," "continue" or the negative of such terms or similar words or expressions. These forward-looking statements may also use different phrases.

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

- product and product candidate development;
- the market or markets for our products or product candidates;
- the ability of our products to treat patients in our markets;
- the ability to achieve certain pricing and reimbursement levels for our product in various countries in the European Union and elsewhere;
- timing and expectations of our clinical trials and when our products or product candidates may be marketed;
- opportunities to establish development or commercial alliances;
- commercial launch preparations, including the timing of launches in the various European Union jurisdictions and the implementation of the infrastructure required for the commercial launches;
- the scope and enforceability of our intellectual property rights, including the anticipated durations of patent protection and marketing exclusivity in the European Union, United States and other jurisdictions, and including claims that we or our collaborators may infringe third party intellectual property rights or otherwise be required to pay license fees and or royalties under such third party rights;
- governmental regulation and approval;
- requirement of additional funding to complete research and development and commercialize products;
- liquidity and sufficiency of our cash resources;
- future revenue, including those from product sales and collaborations, adequacy of revenue reserve levels, future expenses, future financial performance and trends;
- our future research and development expenses and other expenses; and
- our operational and legal risks.

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

Critical Accounting Policies

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

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimate that are reasonably likely to occur periodically, could materially change the financial statements. We believe there have been no significant changes during the three month period ended September 30, 2011 to the items that we disclosed as our critical accounting policies and estimates under Part II, Item 7, "Management' s Discussion and Analysis of Financial Condition and Results of Operations," in our Annual Report on Form 10-K for the year ended December 31, 2010.

Company Overview

We are a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and fibrotic diseases. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. We have an advanced-stage product candidate in pulmonology, pirfenidone, that was granted marketing authorization effective February 2011 in all 27 member countries of the EU for the treatment of adults with mild to moderate IPF. In September 2011, we launched commercial sales of pirfenidone in Germany under the trade name Esbriet®, and we are continuing to prepare for the commercial launch of Esbriet® in the other countries in the EU. We are also pursuing the registration of pirfenidone to treat IPF in the United States. After reviewing various regulatory and clinical development options and following our discussions with the FDA, we commenced an additional pivotal Phase 3 clinical study of pirfenidone in IPF in July 2011, known as the ASCEND trial, which is expected to be completed in mid-2013. The results of the ASCEND trial will supplement the existing Phase 3 clinical study data from our CAPACITY clinical trials to support the registration of pirfenidone to treat IPF in the United States. In addition, we currently have rights to one approved and marketed product, Actimmune, which is approved in the United States and numerous other countries for the treatment of chronic granulomatous disease ("CGD") and severe, malignant osteopetrosis. Previously, we also focused on the field of hepatology, which is concerned with the diagnosis and treatment of disorders of the liver. We have a hepatology portfolio of small molecule compounds that are currently in the pre-clinical research stage. However, in May 2011, we announced that we no longer plan to invest further in the field of hepatology.

Pirfenidone, a treatment for IPF, a progressive and fatal lung disease, has completed the global Phase 3 CAPACITY clinical development program. In 2004, both the FDA and the European Medicines Agency ("EMA") granted orphan drug status to pirfenidone

for the treatment of IPF. In March 2010, we filed a Marketing Authorisation Application ("MAA") with the EMA seeking approval of pirfenidone for the treatment of patients with mild to moderate IPF. In December 2010, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA adopted a positive opinion recommending the granting of our MAA for pirfenidone within the European Union. We received notification of ratification of the CHMP opinion by the European Commission in March 2011, which authorizes the marketing of Esbriet (pirfenidone) in all 27 member states of the European Union effective February 28, 2011.

To support our anticipated marketing efforts for Esbriet in Europe, we are currently working to expand our commercial infrastructure within the European Union, including an increase to our employee headcount in that region. In December 2010, we announced several additions to our senior leadership team in support of our commercialization of Esbriet as well as the establishment of our European headquarters in Reinach, Switzerland. Since that time we have grown our European organization substantially, including the appointment of General Managers in Germany, France, Italy, Spain and the U.K. In addition, we have completed the hiring of our commercial and medical teams in Germany in connection with the commercial launch of Esbriet in Germany.

In September 2011, we completed a registered underwritten public offering of 4.6 million shares of our common stock and our concurrent registered underwritten public offering of $155.3 million aggregate principal amount of the 2018 Notes. The aggregate net proceeds from our concurrent offerings was approximately $255.0 million, after deducting underwriting discounts and commissions and related offering expenses. We currently intend to use the net proceeds from these offerings to fund the commercial launch of Esbriet in the EU, to fund our ASCEND trial and for general corporate purposes.

In January 2010, the FDA accepted our New Drug Application ("NDA") for pirfenidone for the treatment of patients with mild to moderate IPF and granted priority review status for our NDA. In March 2010, the Pulmonary-Allergy Drugs Advisory Committee ("PADAC") of the FDA voted 9-3 in favor of recommending approval of the Company' s NDA for pirfenidone to reduce decline in lung function in patients with IPF. However, in May 2010, we received a Complete Response Letter from the FDA requesting that we conduct an additional clinical trial to provide additional evidence of the efficacy of pirfenidone to reduce decline in lung function in patients with IPF. After reviewing various regulatory and clinical development options to gain approval of pirfenidone for commercial use within the United States, in January 2011 we reported that, as recommended by the FDA in its Complete Response Letter, we planned to conduct a new Phase 3 clinical study that, if successful, would demonstrate a clinically meaningful effect on forced vital capacity in patients with mild to moderate IPF. In March 2011, we met with the FDA to discuss our plans and proposed trial design for a Phase 3 clinical study, including our proposal to conduct a 52 week study, known as the ASCEND trial. In July 2011, we announced that the first patient had been enrolled in the ASCEND trial. The results from this trial are currently expected in mid-2013.

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. We have established wholly-owned subsidiaries in various countries, primarily to support our expected commercialization of Esbriet in Europe including subsidiaries in the U.K., Germany, France, Switzerland, Spain, Italy and Canada.

Previously, our second area of therapeutic focus was in hepatology, primarily to expand treatment options for patients suffering from chronic hepatitis C virus ("HCV") infection. From October 2006 to October 2010, we collaborated with Hoffmann-LaRoche Inc. and F.Hoffmann-La Roche Ltd. (collectively, "Roche") on the research and development of HCV protease inhibitors , including our compound danoprevir (formerly known as ITMN-191), as a treatment for HCV infection. In October 2010, we sold our worldwide development and commercialization rights to danoprevir to Roche for $175.0 million in cash. In connection with this transaction, our October 2006 collaboration agreement with Roche was terminated. Our remaining hepatology portfolio includes drug discovery and preclinical development of second generation HCV protease inhibitors and NS5A inhibitors. In December 2010, we entered into a new agreement with Roche pursuant to which we continued to conduct research in small molecule protease inhibitors for the treatment of HCV infection. This research program with Roche expired on June 30, 2011. While we will be entitled to receive certain milestones and royalties in connection with the continued development and commercialization by Roche of any licensed compounds resulting from the research program, we will no longer plan on any further investments in the field of hepatology.

Results of Operations

Revenue

Total revenue was $5.2 million and $5.7 million for the three-month periods ended September 30, 2011 and 2010, respectively, representing a decrease of 8%. This decrease was attributable to a decrease in collaboration revenue in 2011, which had been comprised of the reimbursement from Roche for research services performed by us on behalf of Roche. This agreement ended on June 30, 2011. Collaboration revenue in 2010 consists of the amortization of previously deferred revenue earned under the prior collaboration agreement with Roche. This decrease was offset by an increase in sales of Actimmune of approximately $0.3 million, or 6%. Total

revenue was $17.8 million and $17.6 million for the nine-month periods ended September 30, 2011 and 2010, respectively, representing an increase of 1%. This increase was attributable to an increase in collaboration revenue in 2011, as well as the launch of Esbriet in September 2011 in Germany.

Cost of goods sold

Cost of goods sold included product manufacturing costs, royalties, distribution costs and inventory write-downs. Cost of goods sold were $1.1 million and $1.3 million for the three-month periods ended September 30, 2011 and 2010, respectively. Gross margin for our products was 80% and 73% for these periods in 2011 and 2010, respectively. For the nine months ended September 30, 2011, cost of goods sold were $6.7 million compared with $5.1 million for the same period last year. Gross margin for our products was 56% and 66% for these periods in 2011 and 2010, respectively. The decline in gross margin for the nine-month period ended September 30, 2011 compared with the same period in 2010 is the result of a one-time $2.0 million royalty payment made to Roche for reaching specified Actimmune sales targets in mid-2011. This decline was partially offset by a $0.3 million charge we recorded in the first nine months of 2010 related to excess Actimmune inventories. No such charge was recorded in the first nine months of 2011.

Research and development expenses

Research and development expenses were $17.0 million and $15.6 million for the three-month periods ended September 30, 2011 and 2010, respectively, representing an increase of $1.4 million, or 9%. Research and development expenses were $54.0 million and $50.8 million for the nine-month periods ended September 30, 2011 and 2010, respectively, representing an increase of $3.1 million, or 6%. The increase in spending for the three-month period ended September 30, 2011 compared with the same period in 2010 is primarily a result of the initiation of the ASCEND trial. The increase in spending for the nine-month period ended September 30, 2011 compared with the same period in 2010 reflects the initiation of the ASCEND trial and an increase in stock compensation expense of approximately $2.2 million related to awards tied to the European Commission' s decision to grant marketing authorization for Esbriet, partially offset by decreased expenses associated with the discontinuation of investment in the HCV Portfolio following the divestiture of danoprevir in October 2010.

The following tables list our current product development programs and the research and development expenses recognized in connection with each program during the indicated periods. The category title "Programs-Non specific" is comprised of facilities and personnel costs that are not allocated to a specific development program or discontinued programs and $4.5 million and $2.2 million of stock-based compensation in 2011 and 2010, respectively. Our management reviews each of these program categories in evaluating our business. For a discussion of the risks and uncertainties associated with developing our products, as well as the risks and uncertainties associated with potential commercialization of our product candidates, see the Risk Factors below including those under the headings "Risks Related to the Development of Our Products and Product Candidates."

The following chart shows the status of our product development programs as of September 30, 2011:

	Preclinical	Phase I	Phase II	Phase III
Pulmonology and Fibrosis				
Pirfenidone–Idiopathic pulmonary fibrosis				X *
Hepatology**				
Next generation protease inhibitors	X			
NS5A inhibitors	X			

* Granted marketing authorization for Esbriet in the European Union effective February 2011.

** No further investments in hepatology are planned.

Our development program expenses for the nine-month periods ended September 30, 2011 and 2010 were as follows (in thousands):

	Nine Months Ended September 30,	
Development Program	2011	2010
Pulmonology	$34,271	$22,588

Hepatology	2,668	12,050
Programs − Non-specific	17,028	16,186
Total	$53,967	$50,824

Historically, the largest component of our total operating expense was our ongoing investment in research and development and, in particular, the clinical development of our product pipeline. The process of conducting the clinical research necessary to obtain regulatory approval from the FDA and regulatory authorities in other countries is costly and time consuming. Current FDA requirements for a new human drug to be marketed in the United States include the following (and the requirements are similar in countries outside of the United States):

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

In light of the factors mentioned above, we consider the management and development of our pre-clinical and clinical pipelines to be crucial to our long-term success. The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Due to these factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs. In addition, due to these same factors and others, we are unable to reasonably estimate the efforts needed and, therefore, the costs we will incur to complete any of our projects or the estimated time to complete such projects. We are also unable to provide costs incurred for specific research and development projects within each major development program as well as the cumulative costs incurred to date given that we do not maintain specific financial records to this level of detail. However, a substantial majority of our resources have been invested in our pirfenidone project and, prior to our divesture, former danoprevir project in order to advance them into Phase 3 and Phase 2 clinical development, respectively. The remaining projects within our hepatology research programs are in the preclinical development stage and, as of mid-2011, will not receive any further investment going forward.

The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and overall safety and efficacy profile as ultimately decided upon by the FDA. Due to these factors, we believe it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs. In addition, due to these same factors and others, we are unable to reasonably estimate the efforts needed and, therefore, the costs we will incur to complete any of our projects or the estimated time to complete such projects.

Selling, general and administrative expenses

Selling, general and administrative expenses were $24.0 million for the three-month period ended September 30, 2011 and $10.9 million for the same period in 2010, an increase of $13.1 million, or 120%. For the nine-month periods ended September 30, 2011 and 2010, selling, general and administrative expenses were $63.3 million and $38.7 million, respectively, representing an increase of $24.5 million, or 63%. The increased spending for the three-month period ended September 30, 2011 compared with the same period in 2010 is attributable to the expansion of our European infrastructure, including employee headcount. The increased spending for the nine-months ended September 30, 2011 compared with the same period in 2010 is attributable to the reasons noted above and to legal costs associated with the global prosecution of our intellectual property portfolio for Esbriet, other regulatory and corporate matters, as well as in connection with our indemnification obligations to Dr. Harkonen. Additionally, we incurred $8.8 million of stock-based compensation expense during the nine-month period ended September 30, 2011 compared with $4.9 million during the nine-month period ended September 30, 2010. This increase is related to the vesting of awards tied to the European Commission' s decision to grant marketing authorization for Esbriet.

Restructuring charges

In connection with the Complete Response Letter we received from the FDA requesting an additional clinical trial to support the efficacy of pirfenidone, we announced a reduction in force in May 2010. We incurred approximately $1.4 million of restructuring charges during the first nine months of fiscal year 2010, consisting of severance payments to terminated employees.

Interest income

Interest income was $0.1 million for each of the three-month periods ended September 30, 2011 and September 30, 2010. Interest income was $0.4 million for each of the nine-month periods ended September 30, 2011 and September 30, 2010. Amounts recorded reflect our conservative investment portfolio of cash and short-term investments.

Interest expense

Interest expense decreased to $1.3 million in the three-month period ended September 30, 2011, compared with $2.1 million for the three-month period ended September 30, 2010 and decreased to $4.1 million in the nine-month period ended September 30, 2011 from $6.3 million in the same period of 2010. The declines reflect a decline in the amortization of the debt discount on our 0.25% convertible notes due and converted on March 1, 2011. As a result, debt discount amortization was approximately $0.7 million in 2011, compared to $2.8 million recorded in the first nine months of 2010.

Liquidity and Capital Resources

At September 30, 2011, we had available cash, cash equivalents and available-for-sale securities of $468.2 million compared to $295.1 million at December 31, 2010. The increase of $173.1 million was primarily driven by the proceeds from our concurrent debt and equity public offerings of $255.0 million completed in September 2011, net of issuance and transaction costs. This increase was partially offset by the use of cash for our operations as well as the aggregate milestone payment of $20.0 million to Marnac and KDL in connection with our receipt of the marketing authorization for Esbriet in the European Union.

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

Operating Activities

Cash used in operating activities was $95.1 million during the nine-month period ended September 30, 2011, comprised primarily of a net loss of $110.2 million and an increase in inventories of $5.2 million. The increase in inventories reflects our purchases of the active ingredient in Esbriet in connection with our commercial launch in the European Union and specifically the commercial launch in Germany in September 2011. This was partially offset by an increase in accounts payable and accrued compensation of $6.3 million. Details concerning the loss from operations can be found above in this Report under the heading “Results of Operations.”

Investing Activities

Cash used in investing activities was $121.1 million during the nine-month period ended September 30, 2011, comprised primarily of purchases of short-term investments totaling $270.1 million and the aggregate payment of $20.0 million to Marnac and KDL in connection with our receipt of the marketing authorization for Esbriet in the European Union, partially offset by $169.8 million of short-term investment sales and maturities.

Financing Activities

Cash provided by financing activities of $289.0 million for the nine-month period ended September 30, 2011 was due to the proceeds from our concurrent debt and equity public offerings of $255.0 million completed in September 2011, as well as approximately $34.0 million received from the exercise of stock options by our employees.

We expect to incur net losses in the near term and incur additional expenses and utilize significant existing cash resources as we continue our preparations for the commercial launches of Esbriet in other countries in the European Union, conduct the new 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 European Union. We believe that our existing cash, cash equivalents and available-for-sale securities, together with anticipated cash flows from sales of Esbriet and Actimmune 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. This forward-looking statement involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under "Part II Item 1A. Risk Factors." This forward-looking statement is also based upon our current plans and assumptions, which may change, and our capital requirements, which may increase in future periods. Our future capital requirements will depend on many factors, including, but not limited to:

- capital requirements related to the commercial launch of Esbriet in Germany and preparations for commercial launch in other countries in the European Union, including the expansion of our commercial infrastructure and related personnel and facility expenses;
- our ability to obtain certain pricing and reimbursement levels for Esbriet in various EU countries and elsewhere;
- the adoption by European heath care professionals of Esbriet as first line therapy for the treatment of IPF;
- the financial requirements of our Phase 3 ASCEND clinical study of pirfenidone;
- sales of Esbriet and Actimmune;
- our ability to partner our programs or products;
- the progress of our research and development efforts;
- the initiation, scope and results of preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory reviews;
- determinations as to the commercial potential of our product candidates in development;
- the pace of expansion of administrative expenses;
- the status of competitive products and competitive barriers to entry;
- the establishment and maintenance of manufacturing capacity through third-party manufacturing agreements;
- the establishment of collaborative relationships with other companies;
- the payments of annual interest on our long-term debt; and
- the timing and size of the payments we may receive in connection with compounds licensed to third parties.

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

Off-Balance Sheet Arrangements

With the exception of standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Recent Accounting Pronouncements

In September 2009, the FASB issued Update No. 2009-13, "Multiple-Deliverable Revenue Arrangements−a consensus of the FASB Emerging Issues Task Force" (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, "Revenue Arrangements with

Multiple Deliverables" (EITF 00-21). The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 was effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The adoption of this update on January 1, 2011 did not have a material impact on our condensed consolidated financial statements as we did not enter into or materially modify any multiple-element arrangements during the three- and nine-months ended September 30, 2011. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from those recognized for our past multiple-element arrangements.

In April 2010, the FASB issued Update No. 2010-17, "Milestone Method of Revenue Recognition – a consensus of the Emerging Issues Task Force." The objective of the update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. It provides criteria for evaluating if the milestone is substantive and clarifies that a vendor can recognize consideration that is contingent upon achievement of a milestone as revenue in the period in which the milestone is achieved, if the milestone meets all the criteria to be considered substantive. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity' s performance or on the occurrence of a specific outcome resulting from the entity' s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. This guidance is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010, which we adopted on a prospective basis on January 1, 2011. The election of the milestone method did not have a material impact on our condensed consolidated financial statements and is not expected to result in different accounting treatment for future substantive milestones earned after the date of this adoption. Non-substantive milestones will continue to be recognized over the remaining performance period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short-term and long-term investments in a variety of securities, including obligations of U.S. government-sponsored enterprises, corporate notes and bonds, commercial paper, and money market funds. These securities are classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income. Substantially all investments mature within approximately two years from the date of purchase. Our holdings of the securities of any one issuer, except obligations of U.S. government-sponsored enterprises, do not exceed 10% of the portfolio. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We do not utilize derivative financial instruments to manage our interest rate risks.

The table below presents the original principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as of September 30, 2011 by effective maturity (in millions, except percentages):

	2011	2012	2013	2014	2015 and Beyond	Total	Fair Value at September 30, 2011
Assets:							
Available-for-sale securities	$214.3	$120.2	$5.1	–	–	$339.6	$ 339.2
Average interest rate	0.1 %	0.4 %	1.4%	–	–	0.2 %	–
Liabilities:							
5.0% convertible senior notes due 2015	–	–	–	–	$85.0	$85.0	$ 122.9
Average interest rate	–	–	–	–	5.0 %	5.0 %	–
2.5% convertible senior notes due 2018					$155.3	$155.3	$ 152.2
Average interest rate					2.5 %	2.5 %	–

Foreign Currency Market Risk

We have had obligations denominated in euros for the purchase of Actimmune inventory and presently have obligations in euros, Swiss francs and British pounds related to our expansion efforts currently underway in the European Union. We regularly evaluate the cost-benefit of entering into foreign currency forward contracts to partially mitigate our currency exposure, but have no foreign currency hedge agreements outstanding as of September 30, 2011.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

As of the end of the period covered by this Report, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, or "disclosure controls." This controls evaluation was performed under the supervision and with the participation of management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Disclosure controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Report, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or the Commission. Disclosure controls are also designed to reasonably ensure that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Based upon the controls evaluation, our CEO and CFO have concluded that, as a result of the matters discussed below with respect to our internal control over financial reporting, our disclosure controls were effective at the reasonable assurance level as of the end of the period covered by this Report.

Internal Control Over Financial Reporting

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

Management assessed our internal control over financial reporting as of September 30, 2011, the end of the period covered by this report. As a result of this assessment, management has concluded that our internal control over financial reporting was effective as of September 30, 2011. In making our assessment of internal control over financial reporting, we used the criteria issued in the report Internal Control-Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission.

Changes in Internal Control Over Financial Reporting

There have been no changes to our internal control over financial reporting during the three months ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

CEO and CFO Certifications

Attached as exhibits to this Report, there are "Certifications" of the CEO and the CFO required by Rule 13a-14(a) of the Securities Exchange Act of 1934, or the Rule 13a-14(a) Certifications. This Controls and Procedures section of the Report includes the information concerning the controls evaluation referred to in the Rule 13a-14(a) Certifications and it should be read in conjunction with the Rule 13a-14(a) Certifications for a more complete understanding of the topics presented.

Limitations on the Effectiveness of Controls

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

Class Action Lawsuits

In May 2008, a complaint was filed in the United States District Court for the Northern District of California entitled Deborah Jane Jarrett, Nancy Isenhower, and Jeffrey H. Frankel v. InterMune, Inc., W. Scott Harkonen, and Genentech, Inc., Case No. C-08-02376. Plaintiffs alleged that they were administered Actimmune, and they purported to sue on behalf of a class of consumers and other end-payors of Actimmune. The complaint alleged that the Company fraudulently misrepresented the medical benefits of Actimmune for the treatment of IPF and promoted Actimmune for IPF. The complaint asserted various claims against the Company, including civil RICO, unfair competition, violation of various state consumer protection statutes, and unjust enrichment. The complaint sought various damages in an unspecified amount, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiffs' legal fees and costs, as well as equitable relief. Between June 2008 and September 2008, three additional complaints were filed in the United States District Court for the Northern District of California alleging similar facts. In February 2009, the Court consolidated the four complaints for pretrial purposes.

On September 1, 2010, after two rounds of motions to dismiss, the Court granted defendants' third motions to dismiss, dismissing all remaining claims in all consolidated cases with prejudice and entered judgment accordingly. On October 1, 2010, the remaining plaintiffs in all cases filed notices of appeal, appealing the judgment to the United States Court of Appeals for the Ninth Circuit. On October 10, 2011, the United States Court of Appeals for the Ninth Circuit set an oral argument date of November 29, 2011 for the appeals.

The Company believes it has substantial factual and legal defenses to the claims at issue and intends to defend the actions vigorously. We may enter into discussions regarding settlement of these matters, and may enter into settlement agreements, if we believe settlement is in the best interests of our stockholders. We cannot reasonably estimate the possible loss or range of loss that may arise from these lawsuits.

Indemnity Agreement

On or about March 22, 2000, the Company entered into an Indemnity Agreement with W. Scott Harkonen M.D., who served as the Company' s chief executive officer until June 30, 2003. The Indemnity Agreement obligates the Company to hold harmless and indemnify Dr. Harkonen against expenses (including attorneys' fees), witness fees, damages, judgments, fines and amounts paid in

settlement and any other amounts Dr. Harkonen becomes legally obligated to pay because of any claim or claims made against him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative, to which Dr. Harkonen is a party by reason of the fact that he was a director, officer, employee or other agent of the Company. The Indemnity Agreement establishes exceptions to the Company' s indemnification obligation, including but not limited to claims "on account of [Dr. Harkonen' s] conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct," claims "on account of [Dr. Harkonen' s] conduct that is established by a final judgment as constituting a breach of [Dr. Harkonen' s] duty of loyalty to the Corporation or resulting in any personal profit or advantage to which [Dr. Harkonen] was not legally entitled," and claims "for which payment is actually made to [Dr. Harkonen] under a valid and collectible insurance policy." The Indemnity Agreement, however, obligates the Company to advance all expenses, including attorneys' fees, incurred by Dr. Harkonen in connection with such proceedings, subject to an undertaking by Dr. Harkonen to repay said amounts if it shall be determined ultimately that he is not entitled to be indemnified by the Company.

Dr. Harkonen has been named as a defendant in the civil action lawsuits described above and became the target of the investigation by the U.S. Department of Justice regarding the promotion and marketing of Actimmune. On March 18, 2008, a federal grand jury indicted Dr. Harkonen on two felony counts related to alleged improper promotion and marketing of Actimmune during the time Dr. Harkonen was employed by the Company (the "Criminal Action"). The trial in the criminal case resulted in a jury verdict on September 29, 2009, finding Dr. Harkonen guilty of one count of wire fraud related to a press release issued on August 28, 2002, and acquitting him of a second count of a misbranding charge brought under the Federal Food, Drug, and Cosmetic Act. On April 13, 2011, the Court denied Dr. Harkonen' s post-trial motions and sentenced Dr. Harkonen to three years of probation, including six months of home detention, 200 hours of community service and a fine of $20,000. The Court' s Judgment was filed on April 18, 2011. Dr. Harkonen filed a notice of appeal on April 25, 2011. Under the terms of the Indemnity Agreement, the Company has an obligation to indemnify Dr. Harkonen for reasonable legal fees and costs incurred in connection with defending this action, including any appeal by Dr. Harkonen of his recent sentence.

Prior to December 2008, insurers that issued directors & officers ("D&O") liability insurance to the Company had advanced all of Dr. Harkonen' s expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action. Those insurers included National Union Fire Insurance Company of Pittsburgh, PA ("AIG"), Underwriters at Lloyd' s, London ("Lloyd' s"), and Continental Casualty Company ("CNA"). On November 19, 2008, however, the insurer that issued a $5 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by AIG, Lloyd' s and CNA, Arch Specialty Insurance Company ("Arch"), advised the Company that the limits of the underlying coverage were expected to be depleted by approximately December 15, 2008; that Arch "disclaims coverage" based on misstatements and misrepresentations allegedly made by Dr. Harkonen in documents provided in the application for the Arch policy and the underlying Lloyd' s policy; and, based on that disclaimer, Arch would not be advancing any of Dr. Harkonen' s expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action.

As a result of Arch' s disclaimer of coverage and refusal to advance expenses, including attorneys' fees, the Company had, as of approximately December 15, 2008, become obligated to advance such expenses incurred by Dr. Harkonen in the civil action lawsuits and Criminal Action.

On January 13, 2009, the Company submitted to the American Arbitration Association ("AAA") a Demand for Arbitration, InterMune, Inc. v. Arch Specialty Insurance Co., No. 74 194 01128 08 JEMO. Dr. Harkonen also is a party to the Arbitration. The Demand for Arbitration sought an award compelling Arch to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and the Criminal Action, and to advance other former officers' legal fees and costs incurred in relation to the Department of Justice investigation.

The matter was heard by the arbitration panel and on May 29, 2009, the arbitration panel issued an Interim Arbitration Award granting the Company' s request for a partial award requiring Arch to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and Criminal Action. Arch subsequently advanced such fees and costs, including fees and costs previously paid by the Company. The question whether Arch ultimately will be required to cover the advanced fees and costs or, instead, may recoup those fees and costs as not covered by its policy, has not been determined. Unless and until the arbitration panel rules that such fees and costs are not covered, Arch remains obligated to advance such fees and costs. At this time the Company believes no change to the status of the interim Arbitration Award or to the application of the D&O liability insurance in general has occurred due to the trial court judgment, and therefore the Company has not recorded any accrued liabilities associated with this matter.

In late 2009, Arch advised the Company that Arch had exhausted the $5.0 million limit of liability of the Arch D&O insurance policy, and that defense cost invoices submitted to Arch collectively exceed the Arch policy' s limit. The Company therefore advised the insurer that issued a $5.0 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by Arch, Old Republic Insurance Company ("Old Republic"), that the limits of the underlying coverage had been depleted, and the Company submitted invoices for legal services rendered on behalf of Dr. Harkonen and other individuals who were targets of the U.S. Department of Justice' s investigation to Old Republic for payment. Old Republic agreed to advance Dr. Harkonen' s legal fees and costs incurred in the civil action lawsuits and Criminal Action, but declined to reimburse the Company for payments made on behalf of other individuals who were targets of the U.S. Department of Justice' s investigation. In mid-2010, Old Republic advised the Company that Dr. Harkonen' s defense fees and costs had exhausted the $5 million limit of the Old Republic insurance policy as of the second

quarter of 2010. There is no additional insurance coverage available to cover the cost of Dr. Harkonen' s continuing defense. Defense fees and costs incurred over and above this final $5 million of insurance coverage therefore are, in the absence of any available insurance, to be advanced by the Company pursuant to the terms of the Indemnity Agreement. We expect amounts to be paid by the Company to continue into the future until the Criminal Action is finally adjudicated, however we are unable to predict what our total liability could be with any degree of certainty.

Item 1A. Risk Factors.

An investment in our common stock is risky. Stockholders and potential purchasers of shares of our stock should carefully consider the following risk factors, in addition to other information in this Report. We are identifying these risk factors as important factors that may have a material adverse effect on our business, financial condition or results of operations or could cause our results to differ materially from those contained in any written or oral forward-looking statements made by or on behalf of InterMune. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. We are relying upon the safe harbor for all forward-looking statements in this Report, and any such statements made by or on behalf of InterMune are qualified by reference to the following cautionary statements, as well as to those set forth elsewhere in this Report.

Risks Related to Our Dependence on Pirfenidone

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

We commenced operations in 1998 and have incurred significant losses to date. Our revenue has been limited primarily to sales of Actimmune derived from physicians' prescriptions for the off-label use of Actimmune in the treatment of IPF and from upfront license fees and milestone payments in connection with our collaboration with Roche. In March 2007, we discontinued our development of Actimmune for treatment of IPF. In October 2010, we sold to Roche all of our worldwide rights to danoprevir for $175.0 million in cash, 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. In March 2011, Esbriet (pirfenidone) was granted marketing authorization for commercial use in the EU for the treatment in adults of mild to moderate IPF; however, pirfenidone is still under investigation for the treatment of IPF in the United States and has not been approved by the FDA. In September 2011, we launched commercial sales of Esbriet in Germany and we currently anticipate commercial launches in other countries in the EU beginning in the first half of 2012. Because we do not currently have a product candidate other than pirfenidone in clinical development, our future success is dependent on building a commercial operation in Europe to successfully commercialize Esbriet in the EU, obtaining regulatory approval from the FDA for the use of pirfenidone for the treatment of IPF in the U.S. 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 in the launch of Esbriet in one or more of the European Member states, which could negatively affect our stock price. We may also experience delays in 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 launch Esbriet in Germany, continue our preparations for the commercial launch of Esbriet in other countries in the EU, conduct the new 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 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 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, endpoint. In our meeting with the FDA in March 2011 related to our plans for the ASCEND trial, the FDA indicated that it would prefer a trial with a longer duration (72 week) 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 trial, the FDA indicated a preference for a mortality endpoint.

Whether data from our ASCEND trial will be sufficient for FDA approval 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, and sales of Esbriet in the EU may be negatively affected. 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 in light of the debt crisis currently being experienced in Europe.

We have currently priced Esbriet in Germany, and developed estimates of anticipated pricing in other countries in the EU, 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, in light of the budget crises faced by a number of countries in the EU and efforts to provide for containment of health care costs, one or more EU countries may not support this level of governmental pricing and reimbursement for Esbriet, which would negatively impact 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 encounter unexpected or unforeseen delays in establishing a commercial infrastructure in the European Union, which may negatively impact our ability to launch our commercial efforts for Esbriet and the timing of such launch.

In March 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. In September 2011, we launched commercial sales of Esbriet in Germany and based on anticipated EU member country reimbursement timelines, we currently plan to launch Esbriet in the remaining so-called "Top 5" EU countries as follows: France, Spain and Italy in the first half of 2012 and in the United Kingdom in the third quarter of 2012. We also plan to launch Esbriet in all or substantially all of the 10 most important pharmaceutical markets in the EU by the end of 2012. 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 we recently announced the establishment of our European headquarters in Reinach, 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 expand the number of our managerial, operational, financial and other employees in the EU, which will require additional financial resources and divert management' s 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 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 delays may 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 have only just begun our commercial sales of Esbriet in Germany and 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.

If third-party payors do not provide coverage or reimburse patients for Esbriet, Actimmune or our other current or future products, our revenue and prospects for profitability will suffer.

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.

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

Often, third-party payors make the decision to reimburse an off-label prescription based on whether that product has a compendia listing. A drug compendia is produced by a compendia body, such as the United States Pharmacopoeia Drug Information, that lists approved indications that a product has received from the FDA. The compendia bodies also evaluate all of the clinical evidence to determine whether an off-label use of a product should be listed in the compendia as medically appropriate. A compendia listing of an

off-label use is a condition typically required by third-party payors, such as Medicare and private payors, to cover that use. Applications for a compendia listing are often based upon the publication of certain data in peer reviewed journals whose publication is often outside the applicant' s control. We do not have a compendia listing for Actimmune and we do not intend to seek to achieve acceptance by a compendia body for Actimmune for the treatment of IPF. As a result, additional third-party payors may decide to deny reimbursement for Actimmune for the treatment of IPF and fewer physicians may prescribe Actimmune for such treatment. If either of these were to occur, sales of Actimmune would decline and our revenue would suffer.

Some third-party payors have denied coverage for Actimmune for the treatment of IPF for a variety of reasons, including the cost of Actimmune, the fact that IPF is not an FDA-approved indication for Actimmune or a third-party payor' s assessment that a particular patient' s case of IPF has advanced to a stage at which treatment with Actimmune would not have a significant effect. We believe that approximately 60-70% of the patients who seek coverage for Actimmune for the treatment of IPF from private third-party payors are able to obtain coverage. While coverage trends have not changed significantly in the last few years, major health plans could further restrict coverage or adopt a policy of no coverage since we have discontinued the INSPIRE trial and have no further development plans for Actimmune for the treatment of IPF.

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

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

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

not provide us with accurate or timely information regarding their inventories, the number of patients who are using Actimmune or Actimmune complaints;

not effectively sell or support Actimmune;

reduce their efforts or discontinue to sell or support Actimmune;

not devote the resources necessary to sell Actimmune in the volumes and within the time frames that we expect;

be unable to satisfy financial obligations to us or others; or

cease operations.

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

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. Actelion has begun enrolling patients with IPF in a new exploratory study with macitentan, a tissue-targeting endothelin receptor antagonist. In January 2009, Gilead initiated a Phase 3 clinical study of ambrisentan for the treatment of IPF that was halted due to lack of efficacy in December 2010. However, 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. 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 has begun. Additionally, Pfizer Inc. is studying sildenafil in advanced IPF patients to potentially improve exercise tolerance. This trial is in Phase 3 development. 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. While we no longer plan on further investments in the field of hepatology, our collaboration agreement with Roche on NS3 protease inhibitors entitles us to receive certain milestones and royalties in connection with the continued development and commercialization by Roche of any licensed compounds resulting from the HCV research program completed under the agreement. Given this competitive landscape in the HCV field, there can be no assurance that any of the protease inhibitor compounds licensed by Roche will continue to be developed or commercialized by Roche and therefore we may not realize any economic benefit from these compounds. 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. 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.

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

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

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, 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. We do not intend to conduct further development of Actimmune for the treatment of

IPF. In addition, we reported that our exploratory Phase 2 clinical trial evaluating Actimmune for the potential treatment of advanced liver fibrosis caused by HCV in patients who have failed standard antiviral therapy failed to meet its primary endpoint. As a result, we do not intend to conduct further development of Actimmune for the treatment of liver fibrosis. 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:

- we may not be able to identify or develop a product candidate that can be successful for clinical development;
- the FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients experience adverse side effects 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.

Our development costs will increase if we have material delays in our current clinical trial 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.

Preclinical development is a long, expensive and uncertain process, and we may choose not to develop a particular product candidate, or we may terminate one or more preclinical development programs.

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

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

If 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.

Our CAPACITY trials were conducted without a Special Protocol Assessment, or 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 an 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 an 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."

In addition, in the course of its review of an NDA, MAA or other regulatory application for any of our compounds, the FDA, EMA or other regulatory authorities may conduct audits of the practices and procedures of a company and its suppliers and contractors concerning manufacturing, clinical study conduct, non-clinical studies and several other areas. If the FDA, EMA and/or other regulatory authorities conduct an audit relating to an NDA, MAA or regulatory application submitted by us and finds a significant deficiency in any of these or other areas, the FDA, EMA or other regulatory authorities could delay or not approve our NDA, MAA or regulatory application. As in the case of the FDA issuing to us a Complete Response Letter on our NDA for pirfenidone for IPF, 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.

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, which includes the need to conduct nonclinical studies and clinical trials of each product candidate, 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. For example, securing FDA approval requires the submission of an NDA to the FDA. The approval application must include extensive nonclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each indication. The approval application must also include significant information regarding the chemistry, manufacturing and controls for the product. 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. For example, with respect to our NDA for pirfenidone for IPF in the United States, we received a Complete Response Letter from the FDA requesting an additional clinical trial to support the efficacy of pirfenidone. 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.

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

The FDA and foreign regulatory authorities may impose significant restrictions on the use or marketing of our products or impose additional requirements for post-approval studies. Later discovery of previously unknown problems with any of our products or their manufacture may result in further restrictions, including withdrawal of the product from the market. In this regard, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of inspectional observations." While we believe that all of these observations are being appropriately corrected, failure to correct any deficiency could result in manufacturing delays. Our existing approvals, and any new approval for any other disease that we target, if granted, could be withdrawn for failure to comply with regulatory requirements or to meet our post-approval commitments. For example, we have ongoing Phase 4 post-marketing commitments to the FDA relating to Actimmune for the treatment of osteopetrosis, including a registry and drug interaction study. The failure to adequately address these ongoing Phase 4 commitments could result in a regulatory action or restriction, such as withdrawal of the relevant product' s approval by the FDA. If approval for a disease is withdrawn, we could no longer market the affected product for that disease. In addition, governmental authorities could seize our inventory of such product, force us to recall

any product already in the market, or subject us to criminal or civil penalties, if we fail to comply with FDA or other governmental regulations.

For a description of restrictions relating to the off-label promotion of our products, please see the risk factor titled, "If we fail to comply or have in the past failed to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, we could be subject to regulatory enforcement action by the FDA or other governmental authorities as well as follow-on actions filed by consumers and other end-payors, which actions could result in substantial fines, sanctions and damage awards against us, any of which could harm our business" below.

If we fail to comply or have in the past failed to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, we could be subject to regulatory enforcement action by the FDA or other governmental authorities as well as follow-on actions filed by consumers and other end-payors, which actions could result in substantial fines, sanctions and damage awards against us, any of which could harm our business.

The FDA has authority to regulate advertising and promotional labeling for our products under the Federal Food, Drug, and Cosmetic Act and implementing regulations. In general, that authority requires advertising and promotional labeling to be truthful and not misleading, and consistent with the information in the product' s approved label, including that a product may be marketed only for the approved indications. Physicians may prescribe commercially available drugs for uses that are not described in the product' s labeling and that differ from those uses tested by us and approved by the FDA. Such off-label uses are common across medical specialties. For example, even though the FDA has not approved the use of Actimmune for the treatment of IPF, we are aware that physicians are prescribing, and have prescribed in the past, Actimmune for the treatment of IPF. Substantially all of our Actimmune revenue is derived from physicians' prescriptions for off-label use for IPF. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA and other governmental agencies do, however, restrict manufacturers' communications on the subject of off-label use. Companies may not promote FDA-approved drugs for off-label uses. Accordingly, we may not promote Actimmune for the treatment of IPF. The FDA and other governmental authorities actively enforce regulations prohibiting promotion of off-label uses. The federal government has levied large civil and criminal fines against manufacturers for alleged improper promotion, including us in October 2006 in connection with our reaching a comprehensive settlement with the government to resolve all claims as related to our promotional activities with respect to Actimmune. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which certain promotional conduct is changed or curtailed. We are aware of many instances, including our own experience as it relates to Actimmune, in which the Office of the Inspector General of the FDA has sought and secured criminal penalties and/or a corporate integrity agreement against pharmaceutical manufacturers requiring payment of substantial fines and monitoring of certain promotional activities to ensure compliance with FDA regulations. We engage in medical education activities that are subject to scrutiny under the FDA' s regulations relating to off-label promotion. While we believe we are currently in compliance with these regulations, the regulations are subject to varying interpretations, which are evolving.

If the FDA or any other governmental agency initiates an enforcement action against us and it is determined that we violated prohibitions relating to off-label promotion in connection with past or future activities, we could be subject to civil and/or criminal fines and sanctions such as those noted above in this risk factor, any of which would have an adverse effect on our revenue, business and financial prospects. As a follow-on to such governmental enforcement actions, consumers and other end-payors of the product may initiate action against us claiming, among other things, fraudulent misrepresentation, civil RICO, unfair competition, violation of various state consumer protection statutes, and unjust enrichment. For example, as a follow-on to the subpoena we received from the U.S. Department of Justice with respect to our promotional and marketing activities in connection with Actimmune and the resulting settlement we reached with the government in October 2006, we have had various class action suits filed against us by consumers and other end-payors of Actimmune. If the plaintiffs in such follow-on actions are successful, we could be subject to various damages, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiffs' legal fees and costs, any of which would also have an adverse effect on our revenue, business and financial prospects.

In addition, some of the agreements pursuant to which we license our products, including our license agreement relating to Actimmune, contain provisions requiring us to comply with applicable laws and regulations, including the FDA' s restriction on the promotion of FDA-approved drugs for off-label uses. As a result, if it were determined that we violated the FDA' s rules relating to off-

label promotion in connection with our marketing of Actimmune, we may be in material breach of our license agreement for Actimmune. If we failed to cure a material breach of this license agreement, we could lose our rights to certain therapeutic uses for Actimmune under the agreement.

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

The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. 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. Although we cannot predict the full effects on our business of the implementation of the healthcare reform bill, 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 Actimmune or any other products that we may develop in the future, which would reduce our revenue and potential profitability.

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

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

In addition, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their "off-label" promotion of drugs. For information regarding allegations with respect to "off-label" promotion by us, please see the risk factor titled "If we fail to comply or have in the past failed to comply with FDA or other government regulations prohibiting the promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, we could be subject to regulatory enforcement action by the FDA or other governmental authorities as well as follow-on actions filed by consumers and other end-payors, which actions could result in substantial fines, sanctions and damage awards against us, any of which could harm our business" above.

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

Risks Related to Manufacturing and Our Dependence on Third Parties

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

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

- It may not be technically feasible to scale up an existing manufacturing process to meet demand or such scale-up may take longer than anticipated; and

Failure to comply with strictly enforced good manufacturing practices regulations and similar foreign standards may result in delays in product approval or withdrawal of an approved product from the market. For example, the FDA has conducted routine inspections of our manufacturing contractors, and some were issued a standard "notice of observations." Failure to correct any deficiency could result in manufacturing delays.

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

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

We do not have the resources, facilities or experience to manufacture any of our products or product candidates ourselves. Completion of our clinical trials and commercialization of our products requires access to, or development of, manufacturing facilities that meet FDA standards to manufacture a sufficient supply of our products. The FDA, 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 Actimmune for commercial purposes. We have a long-term supply contract with BI for Actimmune, 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 products 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. For example, our current supply agreement with BI for Actimmune is set to expire

at the end of December 2012. If we are unable to negotiate an extension of this supply agreement with BI before it expires, we would need to secure a replacement manufacturer and negotiate acceptable terms with such replacement manufacturer. If we are unable to do so in a timely basis, or at all, we may experience a stock-out as well as lose our ability to maintain our regulatory approvals for Actimmune.

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 in the United States 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 in the U.S. 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 products and product candidates, and those third parties may not perform satisfactorily.

If our third-party contractors do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in or prevented from obtaining regulatory approvals for our products and product candidates, and may not be able to successfully commercialize our products and product candidates for targeted diseases. We do not have the ability to independently conduct clinical trials for all of our products and product candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to perform this function. 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 interferon gamma-1b, 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.

Within the next few years various patents relating to interferon gamma-1b will expire and we will lose our ability to rely upon the intellectual property we currently own to prevent others from marketing interferon gamma-1b in the United States, which may impair our ability to generate revenue.

We have licensed certain patents relating to interferon gamma-1b, the active ingredient in Actimmune, from Genentech (a wholly-owned subsidiary of Roche). A U.S. patent relating to the composition of interferon gamma-1b expires in 2014. Other material U.S. patents relating to interferon gamma-1b expire between 2009 and 2013. We also previously purchased certain patents relating to interferon gamma analogs from Amgen Inc. in 2002 including two U.S. patents issued on August 30, 2005 that will expire on August 30, 2022. When these various patents expire, we will be unable to use these patents to try to block others from marketing interferon gamma-1b in the United States and, as a result, sales of Actimmune may decline and our ability to generate revenue may decrease.

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. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years from the date of approval. The orphan drug rules are similar in the EU and marketing exclusivity is for a period of ten years from the date of approval. Qualification to maintain Orphan Drug status is generally monitored by the regulatory authorities during the Orphan Drug exclusivity period. 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.

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. The FDA and the EMA granted pirfenidone orphan drug designation for the treatment of IPF in 2004, which we currently anticipate will provide us seven and ten years of market exclusivity in the U.S. and EU, respectively, for the use of pirfenidone for the treatment of IPF from the date that pirfenidone is approved. 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 or 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. 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. 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.

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 prove to 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 use of pirfenidone for the treatment in adults of mild to moderate IPF.

We have three granted patents, two allowed patent applications, and a number of other 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 pirfenidone in IPF patients, 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, and a granted patent relating to the titration of the dosing of Esbriet at the initiation of therapy, which expires in late 2027. We also have two allowed patent applications relating to the safe usage of pirfenidone with respect to fluvoxamine and smoking that are currently expected to extend exclusivity of pirfenidone for the treatment in adults of mild to moderate IPF until 2030. We also have eight issued patents in the United States relating to the formulation or safe and/or effective use of pirfenidone in IPF patients. 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 license agreement with Genentech, we may lose our ability to develop and market Actimmune.

We license certain patents and trade secrets relating to Actimmune from Genentech. If we breach this agreement with Genentech, they may be able to terminate the respective license, and we would have no further rights to utilize the licensed patents or trade secrets to develop and market Actimmune, which could adversely affect our revenue and financial prospects.

If we breach our license agreement with Shionogi, we may lose our ability to develop and commercialize pirfenidone in other jurisdictions.

In February 2010, we entered into an agreement with Shionogi whereby we have the ability to obtain 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 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.

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. For example, if Genentech fails to maintain the intellectual property rights related to Actimmune licensed to us, we may lose our rights to develop and market certain therapeutic uses for Actimmune and may be forced to incur substantial additional costs to maintain or protect our intellectual property rights or to compel Genentech to do so.

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

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 $903.3 million at September 30, 2011. We expect to incur substantial additional net losses prior to achieving profitability, if ever. The extent of our future net losses and the timing of our profitability are highly uncertain, and we may never achieve profitable operations. We are planning to expand the number of diseases for which our products may be marketed, and this expansion will require significant expenditures. To date, we have generated revenue primarily through the sale of Actimmune. However, Actimmune sales have decreased in recent periods and we expect this trend to continue into the future. 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.

Revenue from the sale of Actimmune has been declining and is expected to decline further.

Physicians may choose not to prescribe Actimmune or provide fewer patient referrals for Actimmune for the treatment of IPF for a variety of reasons, some of which are because:

- Actimmune is not approved by the FDA for the treatment of IPF, and we therefore are unable to market or promote Actimmune for the treatment of IPF;
- in our initial and Phase 3 INSPIRE clinical trials, Actimmune failed to meet the primary and secondary endpoints;
- physicians prefer to enroll their patients in clinical trials for the treatment of IPF;
- Actimmune does not have a drug compendia listing, often a criterion used by third-party payors to decide whether or not to reimburse off-label prescriptions;
- physicians' patients are unable to receive or lose reimbursement from a third-party reimbursement organization;
- physicians are not confident that Actimmune has a clinically significant treatment effect for IPF; or
- a competing product shows a clinically significant treatment effect for IPF.

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, along with anticipated cash flows from our sales of Esbriet and Actimmune, will be sufficient to fund our operating expenses, debt obligations and capital requirements under our current business plan through at least the next twelve 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 to allocate those 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.

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 base many of our operating decisions on anticipated revenue trends and competitive market conditions, which are difficult to predict. We acquire inventories and enter into non-cancelable purchase obligations in order to meet demand for our products based on these projections. For the years ended December 31, 2010, 2009 and 2008, we recorded charges of $0.5 million, $0.3 million and $0.7 million, respectively, for excess inventories related to Actimmune from previous years' contractual purchases. We could be required to record additional charges for excess inventories and/or non-cancelable purchase obligations. If demand for Actimmune decreases faster than we anticipate.

In addition, we initiated our commercial launch of Esbriet in Germany in September 2011, and we currently plan to initiate commercial launches in additional countries in the EU beginning in 2012. While we have attempted to forecast demand for Esbriet in Germany and the EU, 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 will 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 or any of our other contractual obligations, Roche has the right to seek indemnification from us for damages it suffers as a result of such breach. 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 we entered into with Roche and its affiliates in connection

with our sale of our worldwide development and commercialization rights to danoprevir. If one or more of our representations and warranties were not true at the time we made them to Roche, we would be in breach of the Asset Purchase Agreement. In the event of a breach by us, Roche has the right to seek indemnification from us for damages suffered by Roche as a result of such breach. The amounts for which we could become liable to Roche 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 October 31, 2011, we had 171 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.

Risks Related to our Securities

Our significant level of indebtedness could limit cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under our outstanding notes.

We have now and will continue to have, a significant amount of indebtedness. As of September 30, 2011, we had $85.0 million of outstanding indebtedness under our 2015 Notes and $155.3 million indebtedness under our 2018 Notes. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our business, results of operations and financial condition, including:

increasing our vulnerability to adverse economic and industry conditions;

limiting our ability to obtain additional financing;

requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes;

limiting our flexibility in planning for, or reacting to, changes in our business;

dilution experienced by our existing stockholders as a result of the conversion of our 2015 notes into shares of common stock; and

placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

As of September 30, 2011, our annual debt service obligation on our 2015 and 2018 Notes was $8.1 million. We cannot assure you that we will continue to maintain sufficient cash reserves or that our business will continue to generate cash flow from operations at levels sufficient to permit us to pay principal, premium, if any, and interest on our indebtedness, or that our cash needs will not increase. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our outstanding notes or any indebtedness which we may incur in the future, we would be in default, which would permit the holders of the affected notes or other indebtedness to accelerate the maturity of such notes or other indebtedness and could cause defaults under the company' s other notes and indebtedness. Any default under our notes or any indebtedness which we may incur in the future could have a material adverse effect on our business, results of operations and financial condition.

We may fail to meet our publicly announced financial guidance or other expectations about our business, which would cause our stock to decline in value and affect the trading price of our outstanding notes.

There are a number of reasons why we might fail to meet our financial guidance or other expectations about our business, including, but not limited to, the following:

negative developments or setbacks in our application to obtain marketing approval for pirfenidone in the United States, including negative results of the ASCEND trial that we initiated in the second quarter of 2011 and/or a negative response from the FDA to our anticipated NDA resubmission based on data from this trial;

delays or unexpected difficulties in our commercial launch of Esbriet in the EU;

lower than expected pricing and reimbursement levels for Esbriet in the EU;

if only a subset of or no affected patients respond to therapy with any of our products or product candidates;

the actual dose or efficacy of the product for a particular condition may be different than currently anticipated;

negative publicity about the results of our clinical studies, such as the 2007 failure of Actimmune to meet its primary endpoint in the INSPIRE trial and our resulting decision to discontinue the trial, the failure of pirfenidone to meet its primary endpoint and the PFS secondary endpoint in the CAPACITY 1 trial, or those of others with similar or related products may reduce demand for our products and product candidates;

the treatment regimen may be different in duration than currently anticipated;

treatment may be sporadic;

we may not be able to sell a product at the price we expect;

we may not be able to accurately calculate the number of patients using the product;

we may not be able to supply enough product to meet demand;

there may be current and future competitive products that have greater acceptance in the market than our products do;

we may decide to divest a product;

our development activities may proceed faster than planned;

we may decide to change our marketing and educational programs;

clinical trial participation may reduce product sales; or

physicians' prescriptions or patient referrals for Actimmune may decline.

If we fail to meet our revenue and/or expense projections and/or other financial guidance for any reason, our stock could decline in value. The market price of our common stock, as well as the general level of interest rates and our credit quality, will likely significantly affect the trading price of our notes.

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

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

Substantial sales of shares or the issuance of additional stock may negatively impact the market price of our common stock and the trading price of our outstanding notes.

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

We have filed registration statements covering the approximately 8.0 million shares of common stock that are either issuable upon the exercise of outstanding options or reserved for future issuance pursuant to our stock plans as of September 30, 2011.

During the second quarter of 2011, Warburg Pincus Equity Partners, L.P. and certain of its affiliates (collectively, Warburg Pincus) filed documents with the Commission indicating that it had distributed an aggregate of 9,468,728 shares of our common stock to its partners. Jonathan S. Leff, a member of our board of directors, is a managing director of Warburg Pincus LLC and a partner of Warburg Pincus & Co., which are affiliates of Warburg Pincus.

As of September 30, 2011, we had an aggregate of approximately 17.1 million shares of common stock authorized but unissued and not reserved for issuance under our option and compensation plans or under other convertible or derivative instruments. We may issue all of these shares without any action or approval by our stockholders. The issuance of these unreserved shares in connection with acquisitions or otherwise, as well as any shares of our common stock issued in connection with the exercise of stock options, restricted stock units, under convertible or derivative instruments or otherwise would dilute the notional percentage ownership held by the our security holders. In addition, we may issue a substantial number of shares of our common stock upon conversion of our outstanding notes.

At times, the market price of our common stock has fluctuated significantly, and as a result an investment in our stock could decline in value. Future fluctuations in our stock price may also impact the trading price of our outstanding notes and make them more difficult to resell.

The market price of our common stock has been and is likely to continue to be extremely volatile. During the twelve-month period ended September 30, 2011, the closing price of our common stock on The NASDAQ Global Select Market ranged from a high of $51.08 in April 2011 to a low of $12.53 in December 2010. The market price of our common stock could be subject to wide fluctuations in response to a variety of factors, many of which we cannot control, including:

- general economic and political conditions and specific conditions in the biotechnology industry;
- changes in expectations as to our future financial performance, including financial estimates or publication of research reports by securities analysts;
- strategic actions taken by us or our competitors, such as acquisitions or restructurings;
- announcements of new products or technical innovations by us or our competitors;
- actions taken by institutional shareholders; and
- speculation in the press or investment community.

In addition, the stock market in general, and the stock price of companies listed on NASDAQ, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance. Periods of volatility in the market price of a company' s securities frequently results in securities class action and shareholder derivative litigation against that company. This type of litigation can result in substantial costs and a diversion of management' s attention and resources.

Because our outstanding notes are convertible into shares of our common stock, volatility or depressed market prices of our common stock could have a similar effect on the trading price of our outstanding notes. Holders who receive shares of our common stock upon conversion of our notes will also be subject to the risk of volatility and depressed market prices of our common stock.

Provisions of Delaware law, our charter documents and the indentures governing our outstanding notes may impede or discourage a takeover, which could cause the market price of our common stock to decline.

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

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

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

The repurchase rights in our outstanding notes triggered by the occurrence of a fundamental change and the additional shares of our common stock by which the conversion rates are increased in connection with certain make-whole fundamental change transactions could also discourage a potential acquirer.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid any dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance our operations and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. As a result, holders who convert their notes and receive shares of our common stock will not realize a return on their investment unless the market price of our common stock appreciates, which we cannot assure.

Item 6. Exhibits.

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of InterMune.(1)
3.2	Certificate of Ownership and Merger, dated April 26, 2001.(2)
3.3	Amended and Restated Bylaws of InterMune.(3)
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of InterMune.(4)
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of InterMune.(5)
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of InterMune.(6)
3.7	Certificate of Designation of Series A Junior Participating Preferred Stock. (7)
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7.
4.2	Specimen Common Stock Certificate.(1)
4.3	Registration Rights Agreement, dated as of February 17, 2004, among Registrant, Morgan Stanley & Co. Incorporated, Banc of America Securities LLC, Credit Suisse First Boston LLC, Harris Nesbitt Corp. and RBC Capital Markets Corporation.(8)
4.4	Indenture, dated September 19, 2011, between InterMune and The Bank of New York Mellon Trust Company, N.A., as Trustee.(9)
4.5	First Supplemental Indenture, dated September 19, 2011, between InterMune. and The Bank of New York Mellon Trust Company, N.A., as Trustee (including the form of 2.50% convertible senior note due 2018).(9)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).(10)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).(10)
32.1*	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350).(10)
101.INS**	XBRL Instance Document.(10)
101.SCH**	XBRL Taxonomy Extension Schema Document.(10)
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.(10)
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.(10)
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.(10)

(1) Filed as an exhibit to InterMune' s Registration Statement on Form S-1 filed with the Securities and Exchange Commission (the "Commission") on February 2, 2000 (No. 333-96029), as amended by Amendment No. 1 filed with the Commission on February 18, 2000, as amended by Amendment No. 2 filed with the Commission on March 6, 2000, as amended by Amendment No. 3 filed with the Commission on March 22, 2000, as amended by Amendment No. 4 filed with the Commission on March 23, 2000 and as amended by Amendment No. 5 filed with the Commission on March 23, 2000.

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

(3) Filed as an exhibit to InterMune' s Current Report on Form 8-K filed with the Commission on March 24, 2010.

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

(5) Filed as an exhibit to InterMune' s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.

(6) Filed as an exhibit to InterMune' s Registration Statement on Form S-3 filed with the Commission on September 4, 2009 (No. 333-161758).

(7) Filed as an exhibit to InterMune' s Current Report on Form 8-K filed with the Commission on July 18, 2001.

(8) Filed as an exhibit to InterMune' s amended Annual Report on Form 10-K/A (Amendment No. 1) for the year ended December 31, 2003 filed on May 14, 2004.

(9) Filed as an exhibit to InterMune' s Current Report on Form 8-K filed with the Commission on September 19, 2011.

(10) Filed or furnished herewith.

* This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, and are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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 thereunto duly authorized.

InterMune, Inc.

By: /s/ Bruce Tomlinson

Bruce Tomlinson
Vice President, Controller and Principal Accounting Officer

Date: November 7, 2011

INDEX TO EXHIBITS

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* This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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Exhibit 31.1

CERTIFICATIONS

I, Daniel G. Welch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of InterMune, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant' s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant' s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant' s internal control over financial reporting that occurred during the registrant' s most recent fiscal quarter (the registrant' s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant' s internal control over financial reporting; and

5. The registrant' s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant' s auditors and the audit committee of the registrant' s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant' s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant' s internal control over financial reporting.

Date: November 7, 2011

/s/ Daniel G. Welch

Daniel G. Welch
Chairman, Chief Executive Officer and President
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, John C. Hodgman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of InterMune, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant' s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant' s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant' s internal control over financial reporting that occurred during the registrant' s most recent fiscal quarter (the registrant' s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant' s internal control over financial reporting; and

5. The registrant' s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant' s auditors and the audit committee of the registrant' s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant' s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant' s internal control over financial reporting.

Date: November 7, 2011

/s/ John C. Hodgman

John C. Hodgman
Chief Financial Officer and Senior Vice President,
Finance
(principal financial officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the Exchange Act) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Daniel G. Welch, Chief Executive Officer of InterMune, Inc. (the Company), and John C. Hodgman, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company' s Quarterly Report on Form 10-Q for the period ended September 30, 2011, to which this Certification is attached as Exhibit 32.1 (the Periodic Report), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 7th day of November, 2011.

/s/ Daniel G. Welch	/s/ John C. Hodgman
Daniel G. Welch	John C. Hodgman
Chief Executive Officer	Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of InterMune, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Condensed Consolidated Balance Sheets (Parenthetical) (USD $) In Thousands	Sep. 30, 2011	Dec. 31, 2010
Condensed Consolidated Balance Sheets [Abstract]		
Accounts receivable, allowances	$ 38	$ 36
Other assets, restricted cash	$ 1,428	$ 1,432

Condensed Consolidated Statements Of Operations (USD $) In Thousands, except Per Share data	3 Months Ended		9 Months Ended	
	Sep. 30, 2011	Sep. 30, 2010	Sep. 30, 2011	Sep. 30, 2010
Revenue, net				
Actimmune	$ 5,111	$ 4,836	$ 15,072	$ 15,174
Esbriet	118		118	
Collaboration revenue		818	2,629	2,454
Total revenue, net	5,229	5,654	17,819	17,628
Costs and expenses:				
Cost of goods sold	1,068	1,291	6,713	5,099
Research and development	17,045	15,623	53,967	50,824
Selling, general and administrative	23,983	10,884	63,294	38,747
Restructuring charges		110		1,371
Total costs and expenses	42,096	27,908	123,974	96,041
Loss from operations	(36,867)	(22,254)	(106,155)	(78,413)
Other income (expense):				
Interest income	131	99	390	409
Interest expense	(1,281)	(2,100)	(4,154)	(6,279)
Other income (expense)	(227)	(29)	(322)	576
Net loss	$ (38,244)	$ (24,284)	$ (110,241)	$ (83,707)
Basic and diluted loss per share:				
Net loss per share	$ (0.63)	$ (0.44)	$ (1.88)	$ (1.55)
Shares used in computing basic and diluted net loss per share	60,467	54,933	58,599	53,918

Document And Entity Information	9 Months Ended	
	Sep. 30, 2011	Oct. 31, 2011
Document And Entity Information [Abstract]		
Document Type	10-Q	
Amendment Flag	false	
Document Period End Date	Sep. 30, 2011	
Document Fiscal Year Focus	2011	
Document Fiscal Period Focus	Q3	
Entity Registrant Name	INTERMUNE INC	
Entity Central Index Key	0001087432	
Current Fiscal Year End Date	--12-31	
Entity Filer Category	Accelerated Filer	
Entity Common Stock, Shares Outstanding		65,507,633

Convertible Debt	9 Months Ended Sep. 30, 2011
Convertible Debt [Abstract]	
Convertible Debt	

7. CONVERTIBLE DEBT

As of March 1, 2011, the holders of all of our then-outstanding 0.25% convertible senior notes due March 1, 2011 (the "2011 Notes"), approximately $45.0 million in aggregate principal, elected to convert the outstanding 2011 Notes into an aggregate of 2,078,561 shares of our common stock. As a result, no 2011 Notes remain outstanding and we have no further obligations under the indenture governing the 2011 Notes.

In September 2011, the Company issued $155.3 million in 2.50% convertible senior notes due 2018. Interest will accrue from the date of issuance and is payable on September 15 and March 15 of each year commencing on March 15, 2012. The convertible senior notes will mature on September 15, 2018. Holders of convertible notes may surrender their notes, in integral multiples of $1,000 principal amount, for conversion any time prior to the close of business on the second business day immediately preceding the maturity date. The initial conversion rate for each $1,000 aggregate principal amount of convertible senior notes is 31.4465 shares of common stock, equivalent to conversion price of approximately $31.80 per share. Offering expenses and underwriting discounts in the aggregate of approximately $5.0 million related to the sale of the 2018 Notes were recorded in other assets and are being amortized to interest expense using the effective interest method over the term of the 2018 Notes, which is approximately seven years from the date of issuance.

Fair Value

Fair Value [Abstract]

Fair Value

9 Months Ended
Sep. 30, 2011

3. FAIR VALUE

In accordance with portions of ASC Topic No. 820, the following table represents the Company's fair value hierarchy for its financial assets (cash, cash equivalents and investments, including accrued interest of approximately $0.5 million and $0.8 million, respectively) measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 (in thousands):

September 30, 2011	Level 1	Level 2	Level 3	Total
Money market funds	$136,340	$—	$—	$136,340
Obligations of government-sponsored enterprises	—	142,062	—	142,062
Commercial paper	—	26,996	—	26,996
Corporate debt securities	—	33,800	—	33,800
Total	$136,340	$202,858	$—	$339,198

December 31, 2010	Level 1	Level 2	Level 3	Total
Money market funds	$96	$—	$—	$96
Obligations of government-sponsored enterprises	—	178,907	—	178,907
Commercial paper	—	74,780	—	74,780
Corporate debt securities	—	24,286	—	24,286
Total	$96	$277,973	$—	$278,069

Level 1 assets have been determined using quoted prices in active markets for identical assets or liabilities. Level 2 assets have been obtained from inputs other than level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

The fair value of our long-term convertible debt is estimated based on quoted prices for those instruments. As of September 30, 2011, the fair value of our $85.0 million 5% convertible senior notes due 2015 ("2015 Notes") was approximately $122.9 million and the fair value of our $155.3 million 2018 Notes was $152.2 million. Our 2015 and 2018 Notes are not marked-to-market and are shown at their original issuance value in the accompanying unaudited Condensed Consolidated Balance Sheet.

Commitments And Contingencies	9 Months Ended Sep. 30, 2011
Commitments And Contingencies [Abstract]	
Commitments And Contingencies	

9. COMMITMENTS AND CONTINGENCIES

Contingent Payments

We may be required to make contingent milestone payments to the owners of our licensed products or the suppliers of our drug compounds in accordance with our license, commercialization and collaboration agreements in the aggregate amount of $42.1 million, as of September 30, 2011, if all of the milestones per the agreements are achieved. These milestones include development, regulatory approval, commercialization and sales milestones. Of the $42.1 million in aggregate milestone payments, a $20.0 million contingent payment would be made by us only if approval in the United States is achieved for pirfenidone. Potential milestone payments of $9.6 million are related to the further development of Actimmune, which we have no current plans to pursue, and therefore we do not expect to pay these amounts. Included in the $42.1 million in future aggregate milestone payments are aggregate milestone payments of $11.3 million payable to Array BioPharma, Inc. and Novartis Corporation, of which Hoffmann-LaRoche Inc. and F.Hoffmann-La Roche Ltd. (collectively, "Roche") has agreed to reimburse us in connection with our sale of danoprevir to Roche.

Class Action Lawsuits

In May 2008, a complaint was filed in the United States District Court for the Northern District of California entitled Deborah Jane Jarrett, Nancy Isenhower, and Jeffrey H. Frankel v. InterMune, Inc., W. Scott Harkonen, and Genentech, Inc., Case No. C-08-02376. Plaintiffs alleged that they were administered Actimmune, and they purported to sue on behalf of a class of consumers and other end-payors of Actimmune. The complaint alleged that the Company fraudulently misrepresented the medical benefits of Actimmune for the treatment of IPF and promoted Actimmune for IPF. The complaint asserted various claims against the Company, including civil RICO, unfair competition, violation of various state consumer protection statutes, and unjust enrichment. The complaint sought various damages in an unspecified amount, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiffs' legal fees and costs, as well as equitable relief. Between June 2008 and September 2008, three additional complaints were filed in the United States District Court for the Northern District of California alleging similar facts. In February 2009, the Court consolidated the four complaints for pretrial purposes.

On September 1, 2010, after two rounds of motions to dismiss, the Court granted defendants' third motions to dismiss, dismissing all remaining claims in all consolidated cases with prejudice and entered judgment accordingly. On October 1, 2010, the remaining plaintiffs in all cases filed notices of appeal, appealing the judgment to the United States Court of Appeals for the Ninth Circuit. On October 10, 2011, the United States Court of Appeals for the Ninth Circuit set an oral argument date of November 29, 2011 for the appeals.

The Company believes it has substantial factual and legal defenses to the claims at issue and intends to defend the actions vigorously. We may enter into discussions regarding settlement

of these matters, and may enter into settlement agreements, if we believe settlement is in the best interests of our stockholders. We cannot reasonably estimate the possible loss or range of loss that may arise from these lawsuits.

Indemnity Agreement

On or about March 22, 2000, the Company entered into an Indemnity Agreement with W. Scott Harkonen M.D., who served as the Company's chief executive officer until June 30, 2003. The Indemnity Agreement obligates the Company to hold harmless and indemnify Dr. Harkonen against expenses (including attorneys' fees), witness fees, damages, judgments, fines and amounts paid in settlement and any other amounts Dr. Harkonen becomes legally obligated to pay because of any claim or claims made against him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, arbitrational, administrative or investigative, to which Dr. Harkonen is a party by reason of the fact that he was a director, officer, employee or other agent of the Company. The Indemnity Agreement establishes exceptions to the Company's indemnification obligation, including but not limited to claims "on account of [Dr. Harkonen's] conduct that is established by a final judgment as knowingly fraudulent or deliberately dishonest or that constituted willful misconduct," claims "on account of [Dr. Harkonen's] conduct that is established by a final judgment as constituting a breach of [Dr. Harkonen's] duty of loyalty to the Corporation or resulting in any personal profit or advantage to which [Dr. Harkonen] was not legally entitled," and claims "for which payment is actually made to [Dr. Harkonen] under a valid and collectible insurance policy." The Indemnity Agreement, however, obligates the Company to advance all expenses, including attorneys' fees, incurred by Dr. Harkonen in connection with such proceedings, subject to an undertaking by Dr. Harkonen to repay said amounts if it shall be determined ultimately that he is not entitled to be indemnified by the Company.

Dr. Harkonen has been named as a defendant in the civil action lawsuits described above and became the target of the investigation by the U.S. Department of Justice regarding the promotion and marketing of Actimmune. On March 18, 2008, a federal grand jury indicted Dr. Harkonen on two felony counts related to alleged improper promotion and marketing of Actimmune during the time Dr. Harkonen was employed by the Company (the "Criminal Action"). The trial in the criminal case resulted in a jury verdict on September 29, 2009, finding Dr. Harkonen guilty of one count of wire fraud related to a press release issued on August 28, 2002, and acquitting him of a second count of a misbranding charge brought under the Federal Food, Drug, and Cosmetic Act. On April 13, 2011, the Court denied Dr. Harkonen's post-trial motions and sentenced Dr. Harkonen to three years of probation, including six months of home detention, 200 hours of community service and a fine of $20,000. The Court's Judgment was filed on April 18, 2011. Dr. Harkonen filed a notice of appeal on April 25, 2011. Under the terms of the Indemnity Agreement, the Company has an obligation to indemnify Dr. Harkonen for reasonable legal fees and costs incurred in connection with defending this action, including any appeal by Dr. Harkonen of his recent sentence.

Prior to December 2008, insurers that issued directors and officers ("D&O") liability insurance to the Company had advanced all of Dr. Harkonen's expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action. Those insurers included National Union Fire Insurance Company of Pittsburgh, PA ("AIG"), Underwriters at Lloyd's, London ("Lloyd's"), and Continental Casualty Company ("CNA"). On November 19, 2008, however, the insurer that issued a $5 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by AIG, Lloyd's and CNA, Arch Specialty Insurance Company ("Arch"),

advised the Company that the limits of the underlying coverage were expected to be depleted by approximately December 15, 2008; that Arch "disclaims coverage" based on misstatements and misrepresentations allegedly made by Dr. Harkonen in documents provided in the application for the Arch policy and the underlying Lloyd's policy; and, based on that disclaimer, Arch would not be advancing any of Dr. Harkonen's expenses, including attorneys' fees, incurred in the civil action lawsuits and Criminal Action.

As a result of Arch's disclaimer of coverage and refusal to advance expenses, including attorneys' fees, the Company had, as of approximately December 15, 2008, become obligated to advance such expenses incurred by Dr. Harkonen in the civil action lawsuits and Criminal Action.

On January 13, 2009, the Company submitted to the American Arbitration Association ("AAA") a Demand for Arbitration, InterMune, Inc. v. Arch Specialty Insurance Co., No. 74 194 01128 08 JEMO. Dr. Harkonen also is a party to the Arbitration. The Demand for Arbitration sought an award compelling Arch to advance Dr. Harkonen's legal fees and costs incurred in the civil action lawsuits and the Criminal Action, and to advance other former officers' legal fees and costs incurred in relation to the Department of Justice investigation.

The matter was heard by the arbitration panel and on May 29, 2009, the arbitration panel issued an Interim Arbitration Award granting the Company's request for a partial award requiring Arch to advance Dr. Harkonen's legal fees and costs incurred in the civil action lawsuits and Criminal Action. Arch subsequently advanced such fees and costs, including fees and costs previously paid by the Company. The question whether Arch ultimately will be required to cover the advanced fees and costs or, instead, may recoup those fees and costs as not covered by its policy, has not been determined. Unless and until the arbitration panel rules that such fees and costs are not covered, Arch remains obligated to advance such fees and costs. At this time the Company believes no change to the status of the interim Arbitration Award or to the application of the D&O liability insurance in general has occurred due to the trial court judgment, and therefore the Company has not recorded any accrued liabilities associated with this matter.

In late 2009, Arch advised the Company that Arch had exhausted the $5.0 million limit of liability of the Arch D&O insurance policy, and that defense cost invoices submitted to Arch collectively exceed the Arch policy's limit. The Company therefore advised the insurer that issued a $5.0 million D&O insurance policy providing coverage excess of the monetary limits of coverage provided by Arch, Old Republic Insurance Company ("Old Republic"), that the limits of the underlying coverage had been depleted, and the Company submitted invoices for legal services rendered on behalf of Dr. Harkonen and other individuals who were targets of the U.S. Department of Justice's investigation to Old Republic for payment. Old Republic agreed to advance Dr. Harkonen's legal fees and costs incurred in the civil action lawsuits and Criminal Action, but declined to reimburse the Company for payments made on behalf of other individuals who were targets of the U.S. Department of Justice's investigation. In mid-2010, Old Republic advised the Company that Dr. Harkonen's defense fees and costs had exhausted the $5 million limit of the Old Republic insurance policy as of the second quarter of 2010. There is no additional insurance coverage available to cover the cost of Dr. Harkonen's continuing defense. Defense fees and costs incurred over and above this final $5 million of insurance coverage therefore are, in the absence of any available insurance, to be advanced by the Company pursuant to the terms of the Indemnity Agreement. We expect amounts to be paid by the Company to continue into the future until the Criminal Action is finally adjudicated, however we are unable to predict what our total liability could be with any degree of certainty.

Disclosures About Segments Of An Enterprise And Related Information

Disclosures About Segments Of An Enterprise And Related Information [Abstract]

Disclosures About Segments Of An Enterprise And Related Information

9 Months Ended

Sep. 30, 2011

10. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION

We have determined that, in accordance with ASC Topic No. 280, we operate in one segment, because operating results are reported only on an aggregate basis to our chief operating decision makers. We currently market Actimmune in the United States for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis and also market Esbriet in Germany for the treatment of adults with mild to moderate IPF.

Our net revenue by region for the three- and nine-months ended September 30, 2011 and 2010, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
United States	$5,086	$4,788	$14,827	$15,047
Europe and other	143	866	2,992	2,581
Total net revenue	$5,229	$5,654	$17,819	$17,628

Our revenue and trade receivables are concentrated with a few customers. We perform credit evaluations on our customers' financial condition and limit the amount of credit extended. However, we generally do not require collateral on accounts receivable. Concentrations of credit risk, with respect to accounts receivable, exist to the extent of amounts presented in the financial statements. Three customers represented 46%, 25% and 17%, respectively, of total trade accounts receivable at September 30, 2011, and three customers represented 37%, 33% and 11%, respectively, of total accounts receivable at December 31, 2010. No other customer represented more than 10% of accounts receivable at September 30, 2011 or December 31, 2010.

Revenue from customers representing 10% or more of total product revenue during the nine month periods ended September 30, 2011 and 2010, was as follows:

	Nine Months Ended September 30,	
Customer	2011	2010
CuraScript, Inc.	34 %	36 %
Nova Factor	22 %	25 %
Caremark	21 %	18 %
McKesson	11 %	7 %

Stockholders' Equity

9 Months Ended
Sep. 30, 2011

Stockholders' Equity [Abstract]
Stockholders' Equity

8. STOCKHOLDERS' EQUITY

In September 2011, we completed a public offering of 4.6 million shares of registered common stock, at a price of $24.00 per share, before underwriting discounts. We received net proceeds of approximately $104.8 million after deducting underwriting fees of approximately $5.2 million and other related expenses of approximately $0.4 million.

Organization

Organization [Abstract]
Organization

9 Months Ended
Sep. 30, 2011

1. ORGANIZATION

Overview

We are a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and fibrotic diseases. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. We have an advanced-stage product candidate in pulmonology, pirfenidone, that was granted marketing authorization effective February 2011 in all 27 member countries of the European Union ("EU") for the treatment of adults with mild to moderate idiopathic pulmonary fibrosis ("IPF"). In September 2011, we launched commercial sales of pirfenidone in Germany under the trade name Esbriet®, and we are continuing to prepare for the commercial launch of Esbriet® in the other countries in the EU. We are also pursuing the registration of pirfenidone to treat IPF in the United States. After reviewing various regulatory and clinical development options and following our discussions with the United States Food and Drug Administration ("FDA"), we commenced an additional pivotal Phase 3 clinical study of pirfenidone in IPF in July 2011, known as the ASCEND trial, which is expected to be completed in mid-2013. The results of the ASCEND trial will supplement the existing Phase 3 clinical study data from our CAPACITY clinical trials to support the registration of pirfenidone to treat IPF in the United States. In addition, we currently have rights to one approved and marketed product, Actimmune, which is approved in the United States and numerous other countries for the treatment of chronic granulomatous disease ("CGD") and severe, malignant osteopetrosis. Previously, we also focused on the field of hepatology, which is concerned with the diagnosis and treatment of disorders of the liver. We have a hepatology portfolio of small molecule compounds that are currently in the pre-clinical research stage. However, in May 2011, we announced that we no longer plan to invest further in the field of hepatology.

In September 2011, we completed a registered underwritten public offering of 4.6 million shares of our common stock and a concurrent registered underwritten public offering of $155.3 million aggregate principal amount of 2.5% convertible senior notes due 2018 ("2018 Notes"). The aggregate net proceeds from our concurrent offerings was approximately $255.0 million, after deducting underwriting discounts and commissions and related offering expenses. We currently intend to use the net proceeds from these offerings to fund the commercial launch of Esbriet in the EU, to fund our ASCEND trial and for general corporate purposes.

Available-For-Sale Investments

Available-For-Sale Investments [Abstract]

Available-For-Sale Investments

9 Months Ended Sep. 30, 2011

4. AVAILABLE-FOR-SALE INVESTMENTS

The following is a summary of our available-for-sale investments as of September 30, 2011 and December 31, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2011				
Obligations of government-sponsored enterprises	$142,007	$ 59	$ (4)	$142,062
Money market funds	136,340	—	—	136,340
Commercial paper	26,996	—	—	26,996
Corporate debt securities	33,836	—	(36)	33,800
Total	$339,179	$ 59	$ (40)	$339,198

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2010				
Obligations of government-sponsored enterprises	$178,925	$ 28	$ (46)	$178,907
Money market funds	96	—	—	96
Commercial paper	74,780	—	—	74,780
Corporate debt securities	24,301	—	(15)	24,286
Total	$278,102	$ 28	$ (61)	$278,069

Realized gains and losses and declines in value, judged to be other than temporary, on available-for-sale securities are included in other income (expense) for the three-months ended September 30, 2011 and 2010. Realized gains were calculated based on the specific identification method and were not material for each of the three- and nine-months ended September 30, 2011 and were approximately $0.6 million for the nine-months ended September 30, 2010, consisting primarily of realized gains from the sale of auction rate securities. Unrealized holding gains and losses on securities classified as available-for-sale are recorded in accumulated other comprehensive income.

The following is a summary of the amortized cost and estimated fair value of available-for-sale securities at September 30, 2011 by contractual maturity (in thousands):

	September 30, 2011	
	Amortized Cost	Fair Value
Mature in less than one year	$331,459	$331,493
Mature in one to three years	7,720	7,705

Mature in over three years	—	—
Total	$339,179	$339,198

Comprehensive Loss

Comprehensive Loss [Abstract]
Comprehensive Loss

9 Months Ended
Sep. 30, 2011

5. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive income (loss). We include in other comprehensive income (loss) changes in unrealized gains and losses on our available-for-sale securities and cumulative foreign currency translation adjustment. The activity in other comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$(38,244)	$(24,284)	$(110,241)	$(83,707)
Cumulative foreign currency translation adjustment	250	—	199	—
Change in unrealized gain (loss) on available-for-sale securities	(61)	(80)	53	(1,440)
Comprehensive loss	$(38,055)	$(24,364)	$(109,989)	$(85,147)

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

	September 30, 2011	December 31, 2010
Cumulative foreign currency translation adjustment	$ 196	$ (3)
Net unrealized gain (loss) on available-for-sale securities	19	(34)
Total accumulated other comprehensive income (loss)	$ 215	$ (37)

Acquired Product Rights

Acquired Product Rights [Abstract]

Acquired Product Rights

9 Months Ended
Sep. 30, 2011

6. ACQUIRED PRODUCT RIGHTS

Marnac, Inc./KDL GmbH (Pirfenidone)

In 2002, we licensed from Marnac and its co-licensor, KDL, their worldwide rights (excluding Japan, Korea and Taiwan) to develop and commercialize pirfenidone for all fibrotic diseases, including renal, liver and pulmonary fibrosis. Under the agreement terms, we received an exclusive license from Marnac and KDL in exchange for an up-front cash payment of $18.8 million and future milestone and up to 9% royalty payments. Effective November 2007, we entered into asset purchase agreements with Marnac and KDL whereby we effectively terminated the prior license agreement by purchasing, among other things, the pirfenidone-related assets covered by such prior license agreement. Under the terms of the asset purchase agreements, we made acquisition payments of approximately $13.7 million. We also made a milestone payment of $13.5 million in March 2009 in connection with our decision to proceed with regulatory approval for pirfenidone. In March 2011, we received authorization to market Esbriet (pirfenidone) in the European Union and made a milestone payment of $20.0 million in the aggregate to Marnac and KDL and have capitalized such payment as acquired product rights. A future contingent acquisition payment of up to an additional $20.0 million is required to be made by us only if positive Phase 3 data and product approval in the United States is achieved. The asset purchase agreements do not affect the rights to pirfenidone in Japan, Korea and Taiwan, which rights are licensed by Marnac and KDL to Shionogi & Company LTD ("Shionogi"). Since the original 2002 license agreement has been effectively terminated as a result of our acquisition of such pirfenidone-related assets from Marnac and KDL, we no longer have milestone or royalty obligations thereunder.

Condensed Consolidated Statements Of Cash Flows (USD $) In Thousands	9 Months Ended	
	Sep. 30, 2011	Sep. 30, 2010
Cash flows used in operating activities:		
Net loss	$ (110,241)	$ (83,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	2,179	4,819
Stock-based compensation expense	13,243	7,079
Net realized gains on sales of available for sale securities	(15)	(642)
Deferred rent	(167)	(495)
Other	199	
Changes in operating assets and liabilities:		
Accounts receivable, net	(292)	1,996
Inventories	(5,208)	783
Other assets	(1,358)	86
Accounts payable and accrued compensation	6,262	666
Other accrued liabilities	300	(9,473)
Deferred collaboration revenue		(2,454)
Net cash used in operating activities	(95,098)	(81,342)
Cash flows from investing activities:		
Acquisition of product rights	(20,000)	
Purchases of property and equipment	(828)	(220)
Purchases of available-for-sale securities	(270,110)	(158,700)
Sales of available-for-sale securities	43,938	9,334
Maturities of available-for-sale securities	125,868	116,297
Net cash used in investing activities	(121,132)	(33,289)
Cash flows from financing activities:		
Proceeds from issuance of common stock in a public offering, net of issuance costs	104,788	106,832
Proceeds from issuance of convertible senior notes, net of issuance costs	150,225	
Proceeds from issuance of common stock under employee stock benefit plans	33,952	9,384
Net cash provided by financing activities	288,965	116,216
Net (decrease) increase in cash and cash equivalents	72,735	1,585
Cash and cash equivalents at beginning of period	110,584	17,007
Cash and cash equivalents at end of period	183,319	18,592
Supplemental disclosure of cash flow information:		
Issuance of common stock in exchange for convertible debt	$ 44,963	

Summary Of Significant Accounting Policies

9 Months Ended Sep. 30, 2011

Summary Of Significant Accounting Policies [Abstract]
Summary Of Significant Accounting Policies

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that we believe are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2010, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

Principles of consolidation

The consolidated financial statements include the accounts of InterMune and its wholly-owned subsidiaries, InterMune Canada Inc. and InterMune UK Ltd. along with our other subsidiaries located in Germany, France, Switzerland, Spain, and Italy. All inter-company balances and transactions have been eliminated.

Use of estimates

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

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

Inventory valuation

Inventories are stated at the lower of cost or market. Cost is determined by the specific identification method. Inventories were $6.4 million and $1.2 million at September 30, 2011 and December 31, 2010, respectively, and consisted solely of Actimmune finished goods at December 31, 2010. At September 30, 2011, inventories include approximately $5.3 million of Esbriet

inventory comprised of costs incurred for in-process inventory since the date of EU approval and approximately $1.1 million of Actimmune finished goods.

Because of the lead times required to manufacture both Esbriet and Actimmune, we enter into purchase obligations to satisfy our estimated inventory requirements. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current as well as committed purchases. We are also required to make judgments as to the expiration dates of our inventory, since it is not usable beyond its expiration date. As part of our excess inventory assessment for both Esbriet and Actimmune, we also consider the expiration dates of future manufactured quantities under our purchase obligations.

We did not incur any charges for inventory writedowns during the nine months ended September 30, 2011. During the nine months ended September 30, 2010, we charged $0.3 million to cost of goods sold for inventory writedowns resulting from the excess of inventory compared to forecasted inventory requirements. As of September 30, 2011, we had firm commitments to purchase approximately $2.1 million of Actimmune inventory and approximately $4.1 million of Esbriet inventory.

Acquired Product Rights

Initial payments for the acquisition of products that, at the time of acquisition, are already marketed or are approved by the FDA or the European Commission ("EC") for marketing are capitalized and amortized ratably over the estimated life of the products. At the time of acquisition, the product life is estimated based upon the term of the agreement, the remaining patent life of the product and our assessment of future sales and profitability of the product, which we currently estimate to be 20 years. We assess this estimate regularly during the amortization period and adjust the asset value and/or useful life when appropriate. Initial payments for the acquisition of products that, at the time of acquisition, are under development or are not approved by the FDA or EC for marketing, have not reached technical feasibility and have no foreseeable alternative future uses are expensed as research and development costs.

Revenue recognition and revenue reserves

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

Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Collaboration revenue derived from our 2006 agreement with Roche includes upfront license fees and milestone payments. Nonrefundable upfront license fees that require our continuing involvement in the form of research, development, or other commercialization efforts by us are recognized as revenue ratably over the estimated term of our continuing involvement. Milestone payments received under our collaboration agreements that relate to events that are substantive and at risk at the initiation of the agreement are recognized as revenue when the milestones, as defined in each respective contract, are achieved and collectibility of the milestone is assured.

In December 2010, we entered into a new agreement with Roche that focused on research to identify and develop next-generation protease inhibitors for the treatment of HCV. Under terms of the agreement, Roche funded all research costs related to the programs for the period of July 1, 2010 through June 30, 2011, the effective term of the research program. During 2011, we received $2.6 million from Roche as a reimbursement for research services performed which has been recorded as collaboration revenue. We will also be entitled to receive certain milestones and royalties in connection with the continued development and commercialization by Roche of any licensed compounds resulting from the research program.

Research and development expenses

Research and development ("R&D") expenses include salaries, contractor and consultant fees, external clinical trial expenses performed by contract research organizations ("CRO"), licensing fees, acquired intellectual property with no alternative future use and facility and administrative expense allocations. In addition, we fund R&D at research institutions under agreements that are generally cancelable at our option. Research costs typically consist of applied research and preclinical and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis and the transfer and scale-up of manufacturing at our contract manufacturers. Clinical development costs include the costs of Phase 1, Phase 2 and Phase 3 clinical trials. These costs are a significant component of our research and development expenses.

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

Net loss per share

We compute basic net loss per share by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. We deduct shares subject to repurchase by us from the outstanding shares to arrive at the weighted- average shares outstanding. We compute diluted net loss per share by dividing the net loss for the period by the weighted-average number of common and potential common shares outstanding during the period. We exclude dilutive securities, composed of potential common shares issuable upon the

exercise of stock options and common shares issuable on conversion of our convertible notes, from diluted net loss per share because of their anti-dilutive effect.

The securities excluded were as follows (in thousands):

	As of September 30,	
	2011	2010
Options	4,057	5,474
Shares issuable upon conversion of convertible notes	9,384	6,581

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$(38,244)	$(24,284)	$(110,241)	$(83,707)
Basic and diluted net loss per share:				
Weighted-average shares of common stock outstanding	61,375	56,011	59,575	54,733
Less: weighted-average shares subject to repurchase	(908)	(1,078)	(976)	(815)
Weighted-average shares used in computing basic and diluted net loss per share	60,467	54,933	58,599	53,918
Basic and diluted net loss per share	$(0.63)	$(0.44)	$(1.88)	$(1.55)

Stock-Based Compensation

The following table reflects stock-based compensation expense recognized for the three- and nine-month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	$1,359	$1,045	$4,459	$2,225
General and administrative	2,935	2,037	8,784	4,854
Total stock-based compensation expense	$4,294	$3,082	$13,243	$7,079

Under the fair value recognition provisions of Accounting Standards Codification (ASC) Topic 718-10, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period for that portion of the award that is ultimately expected to vest. In order to estimate the value of share-based awards, we use the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility, the expected term of the award and the estimated forfeiture rate.

Recent Accounting Pronouncements

In September 2009, the FASB issued Update No. 2009-13, "Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force" (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21). The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 was effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The adoption of this update on January 1, 2011 did not have a material impact on our condensed consolidated financial statements as we did not enter into or materially modify any multiple-element arrangements during the three- and nine-months ended September 30, 2011. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from those recognized for our past multiple-element arrangements.

In April 2010, the FASB issued Update No. 2010-17, "Milestone Method of Revenue Recognition – a consensus of the Emerging Issues Task Force." The objective of the update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. It provides criteria for evaluating if the milestone is substantive and clarifies that a vendor can recognize consideration that is contingent upon achievement of a milestone as revenue in the period in which the milestone is achieved, if the milestone meets all the criteria to be considered substantive. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. This guidance is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010, which we adopted on a prospective basis on January 1, 2011. The election of the milestone method did not have a material impact on our condensed consolidated financial statements and is not expected to result in different accounting treatment for future substantive milestones earned after the date of this adoption. Non-substantive milestones will continue to be recognized over the remaining performance period.

Condensed Consolidated Balance Sheets (USD $) In Thousands	Sep. 30, 2011	Dec. 31, 2010
ASSETS		
Cash and cash equivalents	$ 183,319	$ 110,584
Available-for-sale securities	284,861	184,489
Accounts receivable, net of allowances of $38 at September 30, 2011 and $36 at December 31, 2010	2,002	1,710
Inventories	6,359	1,151
Prepaid expenses and other current assets	4,561	3,609
Total current assets	481,102	301,543
Acquired product rights, net	19,500	
Property and equipment, net	1,174	1,246
Other assets (includes restricted cash of $1,428 at September 30, 2011 and $1,432 at December 31, 2010)	7,673	2,358
Total assets	509,449	305,147
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	11,306	7,994
Accrued compensation	10,076	6,578
Convertible notes - current portion		44,300
Other accrued liabilities	11,489	11,189
Total current liabilities	32,871	70,061
Deferred rent	71	238
Convertible notes - noncurrent portion	240,250	85,000
Other long term liabilities		548
Commitments and contingencies		
Stockholders' equity:		
Common stock	66	57
Additional paid-in capital	1,139,312	942,375
Accumulated other comprehensive income (loss)	215	(37)
Accumulated deficit	(903,336)	(793,095)
Total stockholders' equity	236,257	149,300
Total liabilities and stockholders' equity	$ 509,449	$ 305,147