IRONWOOD PHARMACEUTICALS INC
Form 10-Q
November 12, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

o 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: 001-34620

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3404176**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
301 Binney Street **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	(Zip Code)

(617) 621-7722

(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 x No o

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 that the registrant was required to submit and post such files): Yes o No o

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. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 1, 2010, there were 46,560,437 shares of Class A common stock outstanding and 52,274,113 shares of Class B common stock outstanding.

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2010

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PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(unaudited)

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 58,696	$ 122,306
Available-for-sale securities	192,135	
Accounts receivable	372	7
Related party accounts receivable, net	4,677	5,212
Prepaid expenses and other assets	4,569	2,673
Restricted cash	2,833	
Current assets of discontinued operations		1,250
Total current assets	263,282	131,448
Long-term restricted cash	7,647	8,132
Property and equipment, net	33,286	21,754
Other assets	317	21
Long-term assets of discontinued operations		1,096
Total assets	$ 304,532	$ 162,451
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,857	$ 4,754
Accrued research and development costs	5,328	12,401
Accrued expenses	6,573	4,299
Current portion of long-term debt		936
Current portion of capital lease obligations	227	143
Current portion of deferred rent	2,374	180
Current portion of deferred revenue	35,490	32,360
Current liabilities of discontinued operations		1,364
Total current liabilities	55,849	56,437
Long-term debt, net of current portion		827

Capital lease obligations, net of current portion		429		112
Deferred rent, net of current portion		15,772		10,486
Deferred revenue, net of current portion		64,415		93,642
Long-term liabilities of discontinued operations				937
Commitments and contingencies (Note 8)				
Convertible preferred stock, $0.001 par value, no shares authorized at September 30, 2010 and 74,942,226 shares authorized at December 31, 2009, no shares issued and outstanding at September 30, 2010 and 69,904,843 shares issued and outstanding at December 31, 2009 (Notes 3 and 9)				298,350
Stockholders equity (deficit):				
Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding at September 30, 2010, and no shares authorized, issued or outstanding at December 31, 2009				
Class A common stock, $0.001 par value, 500,000,000 and 98,530,700 shares authorized at September 30, 2010 and December 31, 2009, respectively, and 43,347,963 shares issued and outstanding at September 30, 2010 and no shares issued and outstanding at December 31, 2009		44		
Class B common stock, $0.001 par value, 100,000,000 and 98,530,700 shares authorized at September 30, 2010 and December 31, 2009, respectively, 55,315,730 and 7,854,602 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively		55		8
Additional paid-in capital		523,809		12,999
Accumulated deficit		(355,889)		(314,559)
Accumulated other comprehensive income		48		
Total Ironwood Pharmaceuticals, Inc. stockholders equity (deficit)		168,067		(301,552)
Noncontrolling interest				3,212
Total stockholders equity (deficit)		168,067		(298,340)
Total liabilities and stockholders equity (deficit)	$	304,532	$	162,451

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Collaborative arrangements revenue	$ 9,059	$ 15,257	$ 27,085	$ 25,917
Operating expenses:				
Research and development	18,742	18,603	56,188	51,918
General and administrative	6,482	4,941	18,868	13,448
Total operating expenses	25,224	23,544	75,056	65,366
Loss from operations	(16,165)	(8,287)	(47,971)	(39,449)
Other income (expense):				
Interest expense	(81)	(72)	(178)	(256)
Interest and investment income	188	28	445	212
Remeasurement of forward purchase contracts				(100)
Other income (expense), net	107	(44)	267	(144)
Net loss from continuing operations before income tax benefit	(16,058)	(8,331)	(47,704)	(39,593)
Income tax benefit		(153)		(153)
Net loss from continuing operations	(16,058)	(8,178)	(47,704)	(39,440)
Net income (loss) from discontinued operations	9,311	(3,243)	7,495	(9,298)
Net loss	(6,747)	(11,421)	(40,209)	(48,738)
Net (income) loss from discontinued operations attributable to noncontrolling interest	(1,523)	519	(1,121)	1,483
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,270)	$ (10,902)	$ (41,330)	$ (47,255)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted:				
Continuing operations	$ (0.16)	$ (1.15)	$ (0.55)	$ (5.59)
Discontinued operations	0.08	(0.38)	0.07	(1.11)
Net loss per share	$ (0.08)	$ (1.53)	$ (0.48)	$ (6.70)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	97,925,657	7,118,345	86,633,080	7,054,291

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2010	**2009**
Cash flows from operating activities:		
Net loss	$ (40,209)	$ (48,738)
Income (loss) from discontinued operations	7,495	(9,298)
Loss from continuing operations	(47,704)	(39,440)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,245	3,562
Loss on disposal of property and equipment	249	70
Remeasurement of forward purchase contracts		100
Share-based compensation expense	5,136	3,076
Accretion of discount/premium on investment securities	895	181
Changes in assets and liabilities:		
Accounts receivable	170	(976)
Restricted cash	(2,348)	(446)
Prepaid expenses and other current assets	(1,896)	(684)
Other assets	(296)	37
Accounts payable and accrued expenses	3,011	(1,097)
Accrued research and development costs	(7,073)	(3,313)
Deferred revenue	(26,097)	32,083
Deferred rent	7,480	1,323
Net cash used in operating activities from continuing operations	(64,228)	(5,524)
Net cash used in operating activities from discontinued operations	(3,025)	(8,390)
Total net cash used in operating activities	(67,253)	(13,914)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(322,319)	(26,673)
Sales and maturities of available-for-sale securities	129,337	30,857
Proceeds from sale of subsidiary	9,500	
Purchases of property and equipment	(15,090)	(2,748)
Proceeds from the sale of property and equipment		18
Net cash (used in) provided by investing activities from continuing operations	(198,572)	1,454
Net cash provided by (used in) investing activities from discontinued operations	1	(489)
Total net cash (used in) provided by investing activities	(198,571)	965
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs		25,250
Proceeds from initial public offering	203,167	
Proceeds from exercise of stock options and issuance of restricted stock	1,215	77
Proceeds from borrowings		1,079

Payments on borrowings		(1,891)		(927)
Net cash provided by financing activities from continuing operations		202,491		25,479
Net cash (used in) provided by financing activities from discontinued operations		(277)		1,352
Net cash provided by financing activities		202,214		26,831
Net (decrease) increase in cash and cash equivalents		(63,610)		13,882
Cash and cash equivalents, beginning of period		122,306		66,330
Cash and cash equivalents, end of period	$	58,696	$	80,212
Supplemental cash flow disclosures:				
Cash paid for interest (includes cash paid by Microbia)	$	308	$	335
Debt and interest paid by purchaser of subsidiary	$	1,075		
Fair value of forward purchase contract	$		$	6,000
Settlement of forward purchase contract related to Forest agreement	$		$	(8,800)
Purchases under capital leases	$	529	$	

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Ironwood Pharmaceuticals, Inc. (the Company) is an entrepreneurial pharmaceutical company that discovers, develops and intends to commercialize innovative medicines targeting important therapeutic needs. The Company is focused on a portfolio of internally discovered drug candidates that currently includes one Phase 3 drug candidate (linaclotide), one Phase 1/Phase 2 pain drug candidate, and multiple preclinical candidates.

Prior to September 2010, the Company held a majority ownership interest in Microbia, Inc. (formerly known as Microbia Precision Engineering), a subsidiary formed in September 2006. Microbia, Inc. (Microbia) engages in a specialty biochemicals business based on a proprietary strain-development platform. On September 21, 2010, the Company sold its interest in Microbia to DSM Holding Company USA, Inc. (DSM) in exchange for cash proceeds of $9.5 million, the payment of approximately $1.1 million of Microbia debt and interest by DSM and future contingent consideration based on the sale of products incorporating Microbia s technology.

The Company was incorporated in Delaware on January 5, 1998. On April 7, 2008, the Company changed its name from Microbia, Inc. to Ironwood Pharmaceuticals, Inc. The Company currently operates in one reportable business segment, human therapeutics. Prior to September 21, 2010, the Company operated in two reportable business segments, human therapeutics and biomanufacturing (Note 12).

The Company has generated an accumulated deficit as of September 30, 2010 of approximately $355.9 million since inception. In February 2010, the Company completed its initial public offering of Class A common stock and raised a total of approximately $203.2 million in net proceeds (Note 3). At September 30, 2010, the Company believes that based on its current business plan, its unrestricted cash, cash equivalents and available-for-sale securities totaling approximately $250.8 million are sufficient to fund operations through the anticipated commercialization of linaclotide in the U.S.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying condensed consolidated financial statements and the related disclosures as of September 30, 2010 and for the three and nine months ended September 30, 2010 and 2009 are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) and the applicable rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K filed with the SEC on March 30, 2010. The December 31, 2009 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by GAAP for complete financial statements.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly the Company s financial position as of September 30, 2010 and results of its operations for the three and nine months ended September 30, 2010 and 2009, and its cash flows for the nine months ended September 30, 2010 and 2009. The interim results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

Basis of Presentation

In June 2009, the Financial Accounting Standards Board (FASB) issued the FASB Accounting Standards Codification (Codification). The Codification became the single source for all authoritative GAAP recognized by the FASB and is required to be applied to financial statements issued for interim and annual periods ending after September 15, 2009. The Codification does not change GAAP and did not impact the Company s financial position or results of operations.

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Principles of Consolidation

During 2006, the Company formed Microbia as a 100% wholly owned subsidiary of the Company. In September 2006, Microbia sold additional equity interests to a third party, which reduced the Company s ownership interest in Microbia to 85% (Note 13). The accompanying condensed consolidated financial statements of Ironwood Pharmaceuticals, Inc. include the assets, liabilities, revenue, and expenses of Microbia, over which the Company exercised control until September 21, 2010, when the Company sold its interest in Microbia to DSM. The Company recorded noncontrolling interest in its condensed consolidated statements of operations for the ownership interest of the minority owners of Microbia. All intercompany transactions and balances are eliminated in consolidation.

Sale of Subsidiary and Discontinued Operations

As a result of the sale of its interest in Microbia, the Company ceased to have any financial interest in Microbia. The Company maintains no further investment in Microbia and has recorded a gain on the sale of Microbia (deconsolidation) in its statements of operations based on current accounting guidance as the difference between the sum of the fair value of the consideration received, the carrying value of the noncontrolling interest in the subsidiary at the date of sale, the fair value of the retained noncontrolling interest (which was zero) and the carrying amount of Microbia s assets and liabilities. The consideration received includes $9.5 million in cash as well as DSM s payment of Microbia s approximately $1.1 million in debt and interest immediately prior to the sale. The gain on sale of Microbia (deconsolidation) is included in income from discontinued operations in the Company s statements of operations.

The calculation of the gain on the sale of Microbia (deconsolidation) is calculated as follows (in thousands):

Consideration received	$	10,575
Carrying value of noncontrolling interest		1,400
		11,975
Net liabilities of Microbia		187
Gain on sale of Microbia (deconsolidation)	$	12,162

The net liabilities of Microbia on September 21, 2010, prior to the sale, consisted of the following (in thousands):

Assets		
Prepaid expenses and other assets	$	52
Restricted cash		30
Property and equipment, net		648
Total assets		730
Liabilities		
Accounts payable	$	193
Accrued expenses		724
Total liabilities		917
Net liabilities	$	187

Additionally, in accordance with the applicable accounting standards, the Company considered if the operations and cash flows of Microbia have been eliminated from the ongoing operations of the Company and if the Company will have any significant continuing involvement in the operations of Microbia after the sale in order to determine whether or not to present Microbia as discontinued operations in the financial statements. As part of this evaluation, the Company considered the impact of the cash flows from the future contingent consideration, a royalty on future sales of products incorporating Microbia s technology, that was included in the agreement with DSM. In accordance with the applicable accounting standards, the cash flows from the future contingent

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

consideration are indirect cash flows, as Ironwood has no continuing involvement with Microbia after the sale, and as such, they represent a passive royalty interest, and therefore the cash flows are considered to be eliminated from the ongoing operations. As a result, Microbia meets the requirements for presentation as discontinued operations and accordingly, the Company has classified the assets, liabilities, operations, and cash flows of Microbia as discontinued operations for all periods presented prior to the sale. The Company has elected as its accounting policy to account for the future contingent consideration, if any, as a gain contingency as the proceeds have not been received and the receipt of royalty income is uncertain. As a result, proceeds will only be recorded in future earnings as they are earned. As of September 30, 2010, no amounts have been recorded for the contingent consideration in the Company s financial statements.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company s management evaluates its estimates, including those related to revenue recognition, available-for-sale securities, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, valuation of forward purchase contracts, research and development, contingencies, and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investment instruments with an original maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds and U.S. government sponsored securities. The carrying amount of cash equivalents approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately $45.1 million and $120.6 million at September 30, 2010 and December 31, 2009, respectively.

Available-for-Sale Securities

The Company classifies all short-term investments with an original maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for the amortization of premiums and accretion of discounts to maturity. Such

amortization is included in interest and investment income. Realized gains and losses, and declines in value judged to be other than temporary on available-for-sale securities, are included in interest and investment income.

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and investment income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no other-than-temporary impairments for the three and nine months ended September 30, 2010.

Concentrations of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, restricted cash, available-for-sale securities, and accounts receivable. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company s available-for-sale investments potentially subject the Company to concentrations of credit risk. The Company has adopted an investment policy which limits the amounts the Company may invest in any one type of investment, and requires all investments held by the Company to be A+ rated, thereby reducing credit risk concentration.

Accounts receivable primarily consist of amounts due under the collaboration agreement with Forest Laboratories, Inc. (Forest) and license agreements with Almirall, S.A. (Almirall) and Astellas Pharma Inc. (Astellas) (Note 5) for which the

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Company does not obtain collateral. Effective September 1, 2009, Forest became a related party when the Company sold to Forest 2,083,333 shares of the Company s Series G convertible preferred stock and effective November 2, 2009, Almirall became a related party when the Company sold to them 681,819 shares of its Series I convertible preferred stock.

Forest accounted for approximately 60% of the Company s revenue from continuing operations for the three and nine months ended September 30, 2010, and approximately 83% for the three and nine months ended September 30, 2009. Almirall accounted for approximately 29% and 31% of the Company s revenue from continuing operations for the three and nine months ended September 30, 2010, respectively, and approximately 17% for the three and nine months ended September 30, 2009. Astellas accounted for approximately 11% and 9% of the Company s revenue from continuing operations for the three and nine months ended September 30, 2010, respectively. Tate & Lyle Investments, Ltd. (T&L) accounted for approximately 0% and 98% of the Company s revenue from discontinued operations for the three and nine months ended September 30, 2010, respectively, and 100% for the three and nine months ended September 30, 2009. For the three and nine months ended September 30, 2010 and 2009, no additional customers accounted for more than 10% of the Company s revenue from continuing operations.

At September 30, 2010 and December 31, 2009, accounts receivable from Forest, net of any payables due Forest, accounted for approximately 90% and 94%, respectively, of the Company s total accounts receivable. At September 30, 2010 and December 31, 2009, Almirall accounted for approximately 3% and 6%, respectively, of the Company s total accounts receivable. At September 30, 2010 and December 31, 2009, Astellas accounted for approximately 7% and 0%, respectively, of the Company s total accounts receivable.

Revenue Recognition

The Company s revenue is generated primarily through collaborative research and development and licensing agreements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, up-front license fees; milestone payments; sale of drug substance to its collaborators; and royalties on product sales. In addition, prior to September 2010, the Company generated services revenue through agreements that generally provided for fees for research and development services rendered.

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, services have been rendered or delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. The Company evaluates revenue from agreements that have multiple elements and accounts for the components as separate elements when the following criteria are met:

- the delivered items have value to the customer on a stand-alone basis;

- there is objective and reliable evidence of fair value of the undelivered items; and

- if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within the Company s control.

Collaborative Arrangements Revenue

Up-front License Fees

The Company recognizes revenues from nonrefundable, up-front license fees for which the separation criteria were not met due to continuing involvement in the performance of research and development services on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term.

Milestones

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required.

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance.

In those circumstances where a substantive milestone is achieved, collection of the related receivable is reasonably assured and the Company has remaining obligations to perform under the collaboration arrangement, the Company recognizes as revenue on the date the milestone is achieved an amount equal to the applicable percentage of the performance period that has elapsed as of the date the milestone is achieved, with the balance being deferred and recognized on a straight-line basis over the remaining period of performance.

Payments received or reasonably assured after performance obligations are fully satisfied are recognized as earned.

Services Revenue

The Company recognized services revenue when there was persuasive evidence that an arrangement existed, services had been rendered or delivery had occurred, the price was fixed and determinable, and collection was reasonably assured. Revenue from research and development services rendered was recognized as services were performed. As a result of the sale of the Company s interest in Microbia in September 2010, services revenue is included in net income (loss) from discontinued operations.

The Company receives research and development funding under the Forest collaboration agreement and considers the factors or indicators within this arrangement to determine whether reporting such funding on a gross or net basis is appropriate. The Company records revenue transactions gross in the condensed consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership. The Company produces clinical materials for its collaborators and is reimbursed for its costs to produce such clinical materials. The Company recognizes revenue on clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator.

For certain of the Company s arrangements, particularly the Company s license agreement with Almirall, it is required that taxes be withheld on payments made to the Company. The Company has adopted a policy to recognize revenue net of these tax withholdings.

Research and Development Costs

The Company expenses research and development costs to operations as incurred. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed.

Research and development expenses comprise costs incurred in performing research and development activities, including salaries and benefits, share-based compensation expense, laboratory supplies and other direct expenses, facilities expenses, overhead expenses, contractual services, including clinical trial and related clinical manufacturing expenses, and other outside expenses. As a result of the sale of the Company s interest in Microbia in September 2010, costs of revenue related to the Microbia services contracts and costs associated with Microbia s research and development activities are included in net income (loss) from discontinued operations.

The Company has entered into a collaboration agreement in which it shares research and development expenses with a collaborator. The Company records the expenses for such work as research and development expense. Because the collaboration arrangement is a cost-sharing arrangement, the Company concluded that when there is a period during the collaboration arrangement during which the Company receives payments from the collaborator, the Company records the payments by the collaborator for their share of the development effort as a reduction of research and development expense.

Share-Based Compensation

Share-based compensation is recognized as an expense in the financial statements based on the grant date fair value. Compensation expense recognized relates to stock awards, restricted stock and stock options granted, modified, repurchased or cancelled on or after January 1, 2006. Stock options granted to employees prior to that time continue to be accounted for using the

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

intrinsic value method. Under the intrinsic value method, compensation associated with share-based awards to employees was determined as the difference, if any, between the fair value of the underlying common stock on the date compensation was measured, generally the grant date, and the price an employee must pay to exercise the award. For awards that vest based on service conditions, the Company uses the straight-line method to allocate compensation expense to reporting periods. The grant date fair value of options granted is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility, expected term and the fair value of the underlying common stock, among others.

The Company records the expense for stock option grants subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

The Company records the expense of services rendered by non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model. The fair value of unvested non-employee awards are remeasured at each reporting period and expensed over the vesting term of the underlying stock options.

Noncontrolling Interest

Noncontrolling interest represents the noncontrolling stockholder s proportionate share of equity and net income or net loss of the Company s former consolidated subsidiary, Microbia. On September 21, 2010, the Company sold its interest in Microbia, resulting in the deconsolidation of its former subsidiary bringing the noncontrolling interest balance to zero. Immediately prior to the sale, the Company converted certain intercompany debt and payables into an additional investment in Microbia, which resulted in an approximately $2.9 million decrease in the noncontrolling interest. The noncontrolling stockholder s proportionate share of the equity in Microbia of approximately $3.2 million as of December 31, 2009 is reflected as noncontrolling interest in the Company s condensed consolidated balance sheets as a component of stockholders equity (deficit).

The proportionate share of the net loss attributable to noncontrolling interest is reflected in the accompanying condensed consolidated statements of operations. The following table is a roll-forward of the noncontrolling interest (in thousands):

Balance at December 31, 2009	$	3,212
Net income from discontinued operations attributable to noncontrolling interest		1,121

Change in noncontrolling interest due to additional investment by Company in subsidiary	(2,933)
Sale of subsidiary (deconsolidation)	(1,400)
Balance at September 30, 2010	$

Net Loss Per Share

The Company calculates basic and diluted net loss per common share by dividing the net loss by the weighted average number of common shares outstanding during the period. The Company has excluded all shares that are subject to repurchase by the Company from the weighted average number of common shares outstanding. The Company s potentially dilutive shares, which include convertible preferred stock, outstanding common stock options and unvested shares of restricted stock, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive. The Company presents the net loss per share attributable to both continued and discontinued operations. The loss attributable to the noncontrolling interest is included in the net income (loss) per share from discontinued operations.

Income Taxes

The Company provides for income taxes under the liability method. Deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The Company is currently evaluating the impact the sale of Microbia will have on its tax attributes.

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Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has considered the Company s history of operating losses and concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. Accordingly, the deferred tax assets have been fully reserved at September 30, 2010 and December 31, 2009. Management reevaluates the positive and negative evidence on a quarterly basis.

The Company accounts for uncertain tax positions recognized in the condensed consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. There were no income tax provisions or benefits for the three and nine months ended September 30, 2010 given the Company s continued net operating loss position. In the three and nine months ended September 30, 2009, the Company recognized an income tax benefit of approximately $0.2 million related to a refundable research and development tax credit.

The statute of limitations for assessment by the Internal Revenue Service (IRS) and state tax authorities is open for tax years ending December 31, 2006, 2007 and 2008, although carryforward attributes that were generated prior to tax year 2006 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. The Company does not have any federal or state audits currently in progress.

Impairment of Long-Lived Assets

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset s value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. There were no indicators of impairment at September 30, 2010.

Comprehensive Income (Loss)

All components of comprehensive income (loss) are required to be disclosed in the condensed consolidated financial statements. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances from non-owner sources and currently consists of net loss and changes in unrealized gains and losses on available-for-sale securities. Comprehensive loss from operations was calculated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,270)	$ (10,902)	$ (41,330)	$ (47,255)
Unrealized gain (loss) on investments	4		48	(21)
Comprehensive loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,266)	$ (10,902)	$ (41,282)	$ (47,276)

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company s chief operating decision-maker in deciding how to allocate resources and in assessing performance.

Prior to the sale of its interest in Microbia in September 2010, the Company had two reportable business segments: human therapeutics and biomanufacturing (Note 12). Revenue from the Company s human therapeutics segment is presented in the condensed consolidated statements of operations as collaborative arrangements revenue. Revenue from the Company s biomanufacturing segment is presented as a component of the net income (loss) from discontinued operations.

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New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

Recently Issued Accounting Standards

In April 2010, the FASB issued Accounting Standards Update ASU No. 2010-17, *Revenue Recognition Milestone Method* (ASU 2010-017). ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This ASU is effective on a prospective basis for research and development milestones achieved in fiscal years, beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require the Company to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. As the Company plans to implement ASU No. 2010-17 prospectively, the effect of this guidance will be limited to future transactions.

In October 2009, the FASB issued ASU No. 2009-13, *Multiple- Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification Subtopic 605-25 (previously included within EITF 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The consensus to ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and allows for retrospective application. The Company is currently evaluating the potential impact of this standard on its financial position and results of operations.

3. Initial Public Offering

In February 2010, the Company completed its initial public offering of Class A common stock pursuant to a registration statement that was declared effective on February 2, 2010. The Company sold 19,166,667 shares of its Class A common stock, which included 2,500,000 shares of the Company s Class A common stock sold pursuant to an over-allotment option granted to the underwriters, at a price to the public of $11.25 per share. As a result of the initial public offering, the Company raised a total of $215.6 million in gross proceeds, and approximately $203.2 million in net proceeds after deducting underwriting discounts and commissions of $10.5 million and offering expenses of $1.9 million. Costs directly associated with the Company s initial public offering were capitalized and recorded as deferred offering costs prior to the closing of the initial public offering. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital.

Upon the closing of the initial public offering, 69,904,843 shares outstanding of the Company s convertible preferred stock automatically converted into 70,391,620 shares of its Class B common stock.

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4. Net Loss Per Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Numerator:				
Net loss from continuing operations	$ (16,058)	$ (8,178)	$ (47,704)	$ (39,440)
Net income (loss) from discontinued operations	9,311	(3,243)	7,495	(9,298)
Less: net (income) loss from discontinued operations attributable to noncontrolling interest	(1,523)	519	(1,121)	1,483
Net income (loss) from discontinued operations attributable to Ironwood Pharmaceuticals, Inc.	7,788	(2,724)	6,374	(7,815)
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,270)	$ (10,902)	$ (41,330)	$ (47,255)
Denominator:				
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	97,925,657	7,118,345	86,633,080	7,054,291
Net loss per share associated with continuing operations	$ (0.16)	$ (1.15)	$ (0.55)	$ (5.59)
Net income (loss) per share associated with discontinued operations attributable to Ironwood Pharmaceuticals, Inc.	$ 0.08	$ (0.38)	$ 0.07	$ (1.11)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	$ (0.08)	$ (1.53)	$ (0.48)	$ (6.70)

The net loss attributable to noncontrolling interest is reflected in the net loss from discontinued operations for purposes of segregating the earnings per share calculation between continuing and discontinued operations.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of September 30, 2010 and 2009, as they would be anti-dilutive:

	At September 30,	
	2010	2009
Convertible preferred stock		69,223,024
Options to purchase common stock	14,580,846	14,094,470

Shares subject to repurchase	311,841	505,839
	14,892,687	83,823,333

5. Collaboration and License Agreements

Forest Laboratories, Inc.

In September 2007, the Company entered into a collaboration agreement with Forest to jointly develop and commercialize linaclotide, a drug candidate for the treatment of irritable bowel syndrome with constipation (IBS-C), chronic constipation (CC) and other lower gastrointestinal conditions, in North America. Under the terms of this collaboration agreement, the Company shares equally with Forest all development costs, as well as potential future profits and losses from the development and sale of linaclotide in the United States. The Company will receive royalties from Forest for sales in Canada and Mexico. The Company retained the rights to commercialize linaclotide outside of North America. Forest made non-refundable, up-front payments totaling $70.0 million to the Company in order to obtain rights to linaclotide in North America. Because of the Company s continuing involvement in the development program, the Company is recognizing the up-front license fee as revenue on a straight-line basis over five years, which is

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the Company s estimate of the period over which linaclotide will be jointly developed under the collaboration. The collaboration agreement also includes contingent milestone payments, as well as a contingent equity investment based on the achievement of specific clinical and commercial milestones. These payments, including the up-front license fee, could total up to $330.0 million, of which $125.0 million has already been received, if certain development and sales milestones are achieved for linaclotide. In September 2008, the Company achieved a clinical milestone which triggered a $10.0 million milestone payment from Forest. At September 30, 2010, approximately $27.4 million and $3.9 million of the up-front license fee and milestone payment, respectively, remain deferred and are being recognized on a straight-line basis over the remaining estimated development period.

The collaboration agreement included a contingent equity investment, in the form of a forward purchase contract, which required Forest to purchase 2,083,333 shares of the Company s convertible preferred stock, when a specific clinical milestone was met, at a price of $12.00 per share. The Company evaluated this financial instrument and determined that because the Company may be required to settle the instrument by transferring assets to Forest due to deemed liquidation provisions of the preferred stock, it should be considered an asset or liability, which is required to be carried at fair value. The changes in fair value are recorded as other income or expense.

The Company valued the contingent equity investment at September 12, 2007 at $9.0 million, which represented the value of the premium that Forest would pay for shares of the Company s stock should the milestone be achieved. The $9.0 million was recorded as an asset and incremental deferred revenue at the inception of the arrangement. The $9.0 million of incremental deferred revenue is being recognized as revenue on a straight-line basis over the period of the Company s continuing involvement, which was estimated to be five years from the inception of the arrangement. At September 30, 2010, approximately $3.5 million of the incremental deferred revenue remains deferred and is being recognized on a straight-line basis over the remaining estimated development period.

For the three and nine months ended September 30, 2009, the Company recorded an increase of approximately $0.4 million and $0.1 million, respectively, in the fair value of the forward purchase contract related to this remeasurement.

On July 22, 2009, the Company achieved the clinical milestone under the Forest collaboration agreement, triggering the equity investment. As a result, the Company remeasured the fair value of the contingent equity investment as of July 22, 2009 using assumptions as of that date. The resulting final fair value of the contingent equity investment was $8.8 million. The increase in the fair value of the contingent equity investment was recorded to other income (expense) at that time and the Company reclassified the forward purchase contract as a reduction to convertible preferred stock. The Company issued the 2,083,333 shares to Forest on September 1, 2009. Additionally, the achievement of the clinical milestone triggered a $20.0 million milestone payment from Forest that was received on August 20, 2009, of which approximately $7.8 million remains deferred at September 30, 2010 and is being recognized on a straight-line basis over the remaining estimated development period.

The Company recognized in revenue from the Forest collaboration agreement approximately $5.5 million and $16.4 million during the three and nine months ended September 30, 2010, respectively, and approximately $12.6 million and $21.5 million during the three and nine months ended September 30, 2009, respectively.

Further, because the Company shares development costs equally with Forest, payments from Forest with respect to research and development costs incurred by the Company are recorded as a reduction to expense, and not as revenue. As a result of the cost-sharing arrangements under the collaboration, the Company offset approximately $4.5 million and $12.6 million during the three and nine months ended September 30, 2010 and approximately $5.4 million and $10.2 million during the three and nine months ended September 30, 2009, respectively, against research and development expense.

Almirall, S.A.

In April 2009, the Company entered into a license agreement with Almirall for European rights to develop and commercialize linaclotide for the treatment of IBS-C, CC and other lower gastrointestinal conditions. Under the terms of the license agreement, Almirall is responsible for the expenses associated with the development and commercialization of linaclotide in the European territory. The license agreement requires the Company to participate on a joint development committee over linaclotide s development period. The Company will receive escalating royalties from the sales of linaclotide in the European territory. In May 2009, the Company received a $38.0 million payment from Almirall representing a $40.0 million non-refundable up-front payment net of foreign withholding taxes. The Company elected to record the non-refundable up-front payment on a net basis. Because of the Company s continuing involvement in the development program, the Company is recognizing the up-front license fee

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as revenue on a straight-line basis over fifty months, which is the Company s estimate of the period over which linaclotide will be developed under the license agreement for the European territory. At September 30, 2010, approximately $25.1 million of the up-front license fee remains deferred. The license agreement also includes contingent milestone payments, as well as a contingent equity investment based on the achievement of specific clinical and sales milestones. These payments could total up to $55.0 million, including the contingent equity investment discussed below, of which $15.0 million has already been received, if certain development and sales milestones are achieved for linaclotide.

The license agreement included a contingent equity investment, in the form of a forward purchase contract, which required Almirall to purchase 681,819 shares of the Company s convertible preferred stock, when a specific clinical milestone was met, at a price of $22.00 per share. The Company evaluated this financial instrument and determined that because the Company may be required to settle the instrument by transferring assets to Almirall, it should be considered an asset or liability. The contingent equity investment was valued at inception at its fair value. The Company valued the contingent equity investment at April 30, 2009 at $6.0 million, which represented the value of the premium that Almirall would pay for shares of the Company s stock should the milestone be achieved. The $6.0 million was recorded as an asset and incremental deferred revenue at the inception of the arrangement. The $6.0 million of incremental deferred revenue is being recognized as revenue on a straight-line basis over the period of the Company s continuing involvement, which is estimated to be fifty months. At September 30, 2010, approximately $4.0 million of the incremental deferred revenue remains deferred.

At September 30, 2009, the Company remeasured the fair value of the contingent equity investment using current assumptions resulting in a fair value of $5.8 million. For the three and nine months ended September 30, 2009, the Company recorded a decrease of approximately $0.4 million and a decrease of approximately $0.2 million, respectively, in the fair value of the forward purchase contract related to this remeasurement.

On November 2, 2009, the Company achieved the clinical milestone under the Almirall license agreement, triggering the equity investment. As a result, the Company remeasured the fair value of the contingent equity investment as of November 2, 2009 using assumptions as of that date. The resulting final fair value of the contingent equity investment was $6.5 million. The increase in the fair value of the contingent equity investment was recorded to other income (expense) at that time, and the Company reclassified the forward purchase contract as a reduction to convertible preferred stock. On November 13, 2009, the Company received $15.0 million from Almirall for the purchase of 681,819 shares of convertible preferred stock.

The Company recognized approximately $2.6 million and $8.3 million in revenue from the Almirall license agreement during the three and nine months ended September 30, 2010, respectively, including approximately $0 and $0.4 million, respectively, from the sale of clinical materials to Almirall. During both the three and nine months ended September 30, 2009 the Company recognized approximately $2.6 million and $4.4 million, respectively, in revenue from the Almirall license agreement.

Astellas Pharma Inc.

On November 9, 2009, the Company entered into a license agreement with Astellas. Astellas has the right to develop and commercialize linaclotide for the treatment of IBS-C, CC and other lower gastrointestinal conditions in Japan, South Korea, Taiwan, Thailand, Philippines, and Indonesia. Under the terms of the agreement, Astellas paid the Company an up-front licensing fee of $30.0 million on November 16, 2009. The license agreement requires the Company to participate on a joint development committee over linaclotide s development period. The agreement includes additional development milestone payments that could total up to $45.0 million. In addition, the Company will receive escalating royalties on linaclotide sales should Astellas receive approval to market and sell linaclotide in the Asian market. Astellas will be responsible for activities relating to regulatory approval and commercialization. Because of the Company s continuing involvement in the development program, the Company is recognizing the up-front license fee as revenue on a straight-line basis over 115 months, which is the Company s estimate of the period over which linaclotide will be developed under the license agreement for the Asian market. At September 30, 2010, approximately $28.2 million of the up-front license fee remains deferred. During the three and nine months ended September 30, 2010, the Company recognized approximately $1.0 million and $2.4 million, respectively, in revenue from the Astellas license agreement, including approximately $0.2 million and $0.6 million, respectively, from the sale of clinical materials to Astellas.

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6. Fair Value of Financial Instruments

The table below presents information about the Company s assets that are measured at fair value on a recurring basis as of September 30, 2010 and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability.

The Company s investment portfolio includes many fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company applied other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare evaluations. In addition, model processes were used to assess interest rate impact and develop prepayment scenarios. These models take into consideration relevant credit information, perceived market movements, sector news and economic events. The inputs into these models may include benchmark yields, reported trades, broker-dealer quotes, issuer spreads and other relevant data.

The Company has classified assets measured at fair value on a recurring basis as follows (in thousands):

		Fair Value Measurements at Reporting Date Using		
Description	**September 30, 2010**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds (included in cash and cash equivalents)	$ 35,148	$ 35,148	$	$
U.S. government-sponsored entities (included in cash and cash equivalents)	9,997		9,997	
U.S. government-sponsored entities	129,532		129,532	
U.S. Treasury securities	62,603	62,603		
Total	$ 237,280	$ 97,751	$ 139,529	$

Cash, cash equivalents, accounts receivable, prepaid expenses and other current assets, restricted cash, accounts payable, accrued expenses and the current portion of capital lease obligations at September 30, 2010 and December 31, 2009, and the current portion of long-term debt at

December 31, 2009 are carried at amounts that approximate fair value due to their short-term maturities.

Capital lease obligations at September 30, 2010 and December 31, 2009 and long-term debt at December 31, 2009 approximate fair value as they bear interest at a rate approximating a market interest rate.

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7. Available-for-Sale Investments

The following is a summary of available-for-sale securities at September 30, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2010:				
U.S. government-sponsored entities	$ 129,505	$ 30	$ (3)	$ 129,532
U.S. Treasury securities	62,582	21		62,603
Total	$ 192,087	$ 51	$ (3)	$ 192,135

The Company did not have any available-for-sale securities at December 31, 2009.

The contractual maturities of all securities held at September 30, 2010 are one year or less. There were four investments in an unrealized loss position having an aggregate fair value of approximately $15.7 million at September 30, 2010. The Company reviews its investments for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment s carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and considers whether evidence indicating the cost of the investment is recoverable outweighs evidence to the contrary.

The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. Gross realized gains and losses on the sales of investments have not been material to the Company s consolidated results of operations.

8. Commitments and Contingencies

The Company leases various facilities and equipment under leases that expire at varying dates through 2016. Certain of these leases contain renewal options, and require the Company to pay operating costs, including property taxes, insurance, and maintenance.

On February 9, 2010, the Company entered into a Second Lease Amendment for its 301 Binney Street facility. Under the amended lease, the Company, effective as of February 9, 2010, leased an additional 50,000-60,000 square feet of the 301 Binney Street facility, comprised of (a) an initial phase of at least 30,000 square feet (the Initial Phase), with rent for such space in the Initial Phase commencing July 1, 2010, and (b) a second phase of up to an additional 30,000 square feet (for total additional space of no less than 50,000 square feet and no more than 60,000 square feet) (the Second Phase), with rent for such space in the Second Phase commencing no later than July 1, 2011. The Company signed a Third Lease Amendment, effective as of July 1, 2010, that defines the Initial Phase as 35,444 rentable square feet. The final square footage of the Second Phase will be mutually agreed upon based on actual constructed space. The rent for the space in the Initial Phase is $42.00 per rentable square foot per year, and the rent for the space in the Second Phase will be $42.50 per rentable square foot per year. The base rent for the additional space in each of the Initial Phase and the Second Phase will increase annually by $0.50 per rentable square foot. Under the terms of the Second Lease Amendment, the landlord will provide the Company with a finish work allowance of $55.00 per rentable square foot of additional space rented in the Initial Phase and the Second Phase. The Amendment does not change the January 31, 2016 expiration date of the original lease. As a result of the Second Amendment, the Company increased its letter of credit by approximately $2.1 million and disposed of leasehold improvements resulting in a loss of approximately $0.2 million. In conjunction with the Second Amendment, the Company elected not to renew its lease of approximately 39,000 square feet of space at its 320 Bent Street facility when the lease expires in December 2010.

On November 3, 2009, Microbia amended its facility lease to include an early termination option. In consideration for an up-front payment of approximately $0.3 million, the landlord gave Microbia an option to terminate the lease, which was exercised on January 18, 2010. As a result, the lease would have terminated on September 30, 2010 had the Company not sold its interest in Microbia. Under the terms of the amended lease, the landlord agreed to defer the monthly base rent for the seven months beginning March 2010 and ending September 2010. Additionally, Microbia may have been required to issue a warrant to the landlord, which would have been exercisable into shares of Microbia common stock. The number of shares issuable would have been determined at

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the time of issuance in accordance with the terms of the warrant and the price per share would have been the fair value of Microbia s common stock at that time. The Company calculated the fair value of the warrant at September 21, 2010 and December 31, 2009, which was *de minimus*. As a result of the sale of Microbia, all common stock and warrants of Microbia were cancelled, as such, no warrants will be issued.

As a result of the sale of the Company s interest in Microbia to DSM, Microbia will not incur approximately $0.8 million of contingent restructuring costs related to its November 2009 restructuring, which would have been incurred if Microbia implemented an additional reduction in force prior to the earlier of November 5, 2010 or the date that Microbia closed on a new round of financing.

In June 2010, the Company entered into a commercial supply agreement with a contract manufacturing organization for the purchase of a portion of the linaclotide active pharmaceutical ingredient (API) that will be used to seek regulatory approval of linaclotide in the United States, Canada and/or Mexico, and, pending any such approval, that will be commercialized in such country. The commercial supply agreement contains minimum purchase requirements that commence with the commercial launch of linaclotide and that are dependent upon forecasted commercial requirements. Since, at this time, linaclotide has not yet been approved for commercialization and future commercial demand for linaclotide is unknown, the Company cannot estimate our future minimum purchase requirements under the commercial supply agreement.

In September 2010, the Company repaid all outstanding principal and interest under its loan and security agreement with a financing company which was used to finance the purchase of laboratory and other equipment. The Company incurred pre-payment fees of approximately $67,000 in conjunction with the repayment of debt of which approximately $31,000 is included in net income (loss) from discontinued operations and the remainder is included in interest expense in the statements of operations.

9. Stockholders Equity (Deficit)

Common Stock

At September 30, 2010, the Company is authorized to issue 675,000,000 shares of stock, of which 600,000,000 shares have been authorized for the issuance of common stock, with a par value of $0.001 per share, which consist of Class A common stock and Class B common stock, and 75,000,000 shares have been authorized for the issuance of preferred stock, with a par value of $0.001 per share.

All shares of common stock that were outstanding immediately prior to the initial public offering were shares of Class B common stock and all shares of common stock sold in the initial public offering were shares of Class A common stock. Prior to the closing of the Company s initial public offering, the Company had outstanding nine series of convertible preferred stock with various rights and preferences. In conjunction with the closing of the Company s initial public offering, all of the Company s 69,904,843 outstanding convertible preferred shares automatically converted on a one-for-one basis, except for Series C convertible preferred stock, which converted on a one-for-1.076 basis, into 70,391,620 shares of Class B common stock. At September 30, 2010, the Company had no preferred shares outstanding.

Restricted Stock

In 2009, the Company sold an aggregate of 515,549 shares of common stock to independent members of the Board of Directors under restricted stock agreements in accordance with the terms of the Company s 2005 Stock Incentive Plan (2005 Plan) and the Company s director compensation program. 115,549 shares of restricted common stock sold in 2009 vested on December 31, 2009 and the remainder vest ratably over four years beginning in January 2010. In the event that a member of the Board of Directors ceases to serve on the Company s Board prior to December 31, 2013, the member shall forfeit all unvested shares in accordance with the terms of the restricted stock agreement.

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A summary of the unvested shares of restricted stock as of September 30, 2010 is presented below:

	Shares		Weighted Average Grant Date Fair Value
Unvested at December 31, 2009	400,000	$	5.67
Granted		$	
Vested	(67,500)	$	5.69
Forfeited	(40,000)	$	5.48
Unvested at September 30, 2010	292,500	$	5.69

10. Stock Option Plans

The Company has several share-based compensation plans. Under the 1998 Amended and Restated Stock Option Plan (1998 Plan), options to purchase 3,405,000 shares of common stock were available for grant to employees, directors, and consultants of the Company. The options were granted under the 1998 Plan at fair market value on the grant date, generally vest over a period of four years, and expire ten years from the grant date. There are no shares available for future grant under this plan, as it expired in accordance with its terms in 2008. At September 30, 2010 and December 31, 2009, options for 328,346 and 550,633 shares, respectively, were outstanding under the 1998 Plan.

Under the Company s 2002 Stock Incentive Plan (2002 Plan) and 2005 Plan, stock awards may be granted to employees, officers, directors, consultants, or advisors of the Company. The 2002 Plan and 2005 Plan provide for the granting of stock options, restricted stock, restricted stock units, and other share-based awards. At September 30, 2010, 4,700,000 shares of common stock are reserved for issuance under the 2002 Plan and 12,200,000 shares are reserved under the 2005 Plan. The 2002 Plan allows for the transfer of unused shares from the 1998 Plan. At September 30, 2010, there were 61,831 shares available for future grant under the 2002 Plan and 23,657 shares available for future grant under the 2005 Plan.

On January 21, 2010, the Company s stockholders approved the 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan) (together with the 2002 Plan and 2005 Plan, the Plans) which became effective upon the closing of the Company s initial public offering. Under the 2010 Plan, stock awards may be granted to employees, officers, directors, or consultants of the Company. There were 6,000,000 shares of common stock initially reserved for issuance under the 2010 Plan. The number of shares available for future grant under the 2010 Plan may be increased on the first day of each fiscal year by an amount equal to the lesser of (i) 6,600,000; (ii) 4% of the number of outstanding shares of common stock on the first day of each fiscal year; and (iii) an amount determined by the Board of Directors. Awards that are returned to the

Company s 1998 Plan, 2002 Plan and 2005 Plan as a result of their expiration, cancellation, termination or repurchase are automatically made available for issuance under the 2010 Plan. At September 30, 2010, there were 5,976,901 shares available for future grant under the 2010 Plan.

On January 21, 2010, the Company s stockholders approved the 2010 Employee Stock Purchase Plan (Purchase Plan) which became effective upon the closing of the Company s initial public offering. The Purchase Plan allows eligible employees the right to purchase shares of common stock at the lower of 85% of the fair market value of a share of common stock on the first or last day of an offering period. Each offering period is six months. There were 400,000 shares of common stock initially reserved for issuance pursuant to the Purchase Plan. The number of shares available for future grant under the Purchase Plan may be increased on the first day of each fiscal year by an amount equal to the lesser of (i) 1,000,000 shares, (ii) 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. At September 30, 2010, there were 400,000 shares available for future grant under the Purchase Plan. The initial offering period began on July 1, 2010 and runs through December 31, 2010. During the three and nine months ending September 30, 2010, $0.1 million of stock compensation expense was recognized in relation to the Purchase Plan.

Each plan, other than the Purchase Plan, provides for the granting of stock awards whereby the Company s Class B common stock is issuable upon exercise of options granted before the closing of the Company s initial public offering and Class A common stock is issuable upon exercise of options granted after the Company s initial public offering. At September 30, 2010, options exercisable into 12,346,540 shares of Class B common stock and 2,234,306 shares of Class A common stock were outstanding.

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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The option price at the date of grant is determined by the Board of Directors and, in the case of incentive stock options, may not be less than the fair market value of the common stock at the date of grant. Due to the absence of an active market for the Company s common stock, prior to the pricing of the Company s initial public offering on February 2, 2010, the Board of Directors was required to determine the fair value of the common stock for consideration in setting exercise prices for the options granted and in valuing the options granted. In determining the fair value, the Board of Directors considered both quantitative and qualitative factors including prices at which the Company sold shares of its convertible preferred stock, the rights, preferences and liquidity of the Company s convertible preferred and common stock, the Company s historical operating and financial performance and the status of its research and product development efforts, achievement of enterprise milestones, including the Company entering into collaboration agreements where third parties agree to purchase shares of the Company s convertible preferred stock at fixed prices sometime in the future, external market conditions affecting the biotechnology industry sector, and financial market conditions and, commencing in 2006, contemporaneous valuations provided by management.

The option exercise period may not extend beyond ten years from the date of grant. The 2002 Plan and 2005 Plan provide that, subject to approval by the Board of Directors, option grantees may have the right to exercise an option prior to vesting. Shares purchased upon the exercise of unvested options will be subject to the same vesting schedule as the underlying options, and are subject to repurchase at the original exercise price by the Company should the employee be terminated or leave the Company prior to becoming fully vested in such shares. At September 30, 2010 and December 31, 2009, there were 19,341 and 34,156 shares, respectively, that had been issued pursuant to the exercise of unvested options that remain unvested and subject to repurchase by the Company. Upon stock option exercise, the Company issues restricted shares and delivers them to the participant. The number of these early-exercised shares is not substantive. The cash paid for the exercise prices is recorded as a liability and was not material to the consolidated financial statements at September 30, 2010 and December 31, 2009. At September 30, 2010, the Company does not hold any treasury shares.

The Company, from time to time, issues certain time-accelerated stock options to certain employees under the Plans. The vesting of these time-accelerated stock options accelerates upon the achievement of certain performance-based milestones, such as the filing of a New Drug Application (NDA) with the Food and Drug Administration (FDA), the first commercial sale of a Company product, the successful completion of an initial public offering, or achieving a specified market capitalization target, among others. If these criteria are not met, such options will vest between six and ten years after the date of grant, and expire at the end of ten years. During the nine months ended September 30, 2010, 52,500 shares vested as a result of milestone or service period achievements, and the Company recorded related share-based compensation of approximately $0.1 million for these options. In the three months ended September 30, 2010, 7,500 shares vested as a result of milestone or service period achievements. At September 30, 2010 and December 31, 2009, there were 2,279,000 and 2,481,500 shares, respectively, issuable under outstanding and unvested time-accelerated options. When achievement of the milestone is not deemed probable, the Company recognizes compensation expense associated with time-accelerated stock options initially over the vesting period of the respective stock option. When deemed probable of achievement, the Company expenses the remaining unrecognized compensation for the respective stock option over the implicit service period.

During 2005, the Company granted to employees options to purchase 97,500 shares of common stock at an exercise price of $0.60 per share, which represented the fair value of the stock at that time. These options are subject to performance-based milestone vesting and expire ten years from the date of grant. The options were deemed to be variable upon grant because the number of shares that will vest were not fixed on the date of grant. The options are therefore remeasured at each reporting period until settlement of the option. During the year ended December 31, 2006,

37,500 shares vested as a result of milestone achievements. In the year ended December 31, 2008, it became probable that the remaining 60,000 unvested options would vest and ultimately vested in February 2009. In April 2010, 30,000 shares were exercised and therefore will no longer be remeasured. For the three and nine months ended September 30, 2010, the Company recorded related share-based compensation expense of approximately $(0.1) million for these options and approximately $0.2 million for the three and nine months ending September 30, 2009.

During 2009, the Company granted to employees options to purchase a total of 1,060,000 shares of common stock subject to performance-based milestone vesting. During the nine months ended September 30, 2010, the Company granted additional options to purchase a total of 57,500 shares of common stock subject to performance-based milestone vesting. The vesting of these stock options will occur upon the achievement of certain performance-based milestones, such as the filing of a second NDA with the FDA, the first commercial sale of a Company product, or achieving a specified sales target. During the three months ended September 30, 2010, the Company did not grant any additional options to purchase shares of common stock subject to performance-based milestone vesting. During the nine months ended September 30, 2010, 5,000 shares vested as a result of milestone achievements and the Company

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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recorded related share-based compensation expense of approximately $31,000 for these options. During the three months ended September 30, 2010, no shares vested as a result of milestone achievements. The Company has concluded that for the remaining shares of common stock subject to performance-based milestone vesting, only one performance-based milestone has become probable of achievement as of September 30, 2010; as such, approximately $77,000 of compensation expense has been recorded related to these options. At September 30, 2010, the unrecognized share-based compensation expense related to these options was approximately $3.9 million.

The Company also grants options to external consultants. No options were granted to external consultants during the three months ended September 30, 2010 or the three months ended September 30, 2009. 25,000 options were granted to external consultants during the nine months ended September 30, 2010.The weighted average grant date fair value per share of these options was $7.22. During the nine months ended September 30, 2009, the Company granted options for the purchase of 37,000 shares to external consultants. The weighted average grant date fair value per share of options granted to external consultants during the nine months ended September 30, 2009 was $2.97. Most grants made to external consultants vest over a period of one year, and the expense related to these options is charged to share-based compensation expense over the vesting period of the options. The amount of share-based compensation expense that may be recognized for outstanding, unvested options as of September 30, 2010 was approximately $0.1 million. The amount of share-based compensation expense that will ultimately be recorded will depend on the remeasurement of the outstanding awards through their vesting date. This remaining compensation expense will be recognized over a weighted average amortization period of 1.4 years at September 30, 2010.

In calculating share-based compensation costs, the Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable. The Company estimates the number of awards that will be forfeited in calculating compensation costs. Such costs are then recognized over the requisite service period of the awards on a straight-line basis.

Determining the fair value of share-based awards using the Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the expected term of the award and expected stock price volatility. The weighted average assumptions used to estimate the fair value of the stock options using the Black-Scholes option-pricing model were as follows for the three and nine months ended September 30, 2010 and 2009:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Expected volatility	57.5%	62.1%	57.7%	62.4%
Expected term (in years)	6.5	6.5	6.5	6.5
Risk-free interest rate	2.3%	3.3%	3.0%	2.7%
Expected dividend yield	%	%	%	%

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Ironwood Pharmaceuticals, Inc.

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The following table summarizes the expense recognized for these share-based compensation arrangements in the condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Ironwood:				
Employee stock options	$ 1,572	$ 1,122	$ 4,437	$ 2,830
Restricted stock awards	121	84	348	84
Non-employee stock options	127	52	185	162
ESPP	55		55	
Stock awards	8		111	
	1,883	1,258	5,136	3,076
Microbia Stock Plan (included in discontinued operations)	14	66	59	175
	$ 1,897	$ 1,324	$ 5,195	$ 3,251

Share-based compensation is reflected in the condensed consolidated statements of operations as follows for the three and nine months ended September 30, 2010 and 2009 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 1,093	$ 622	$ 2,849	$ 1,305
General and administrative	790	636	2,287	1,771
Net income (loss) from discontinued operations	14	66	59	175

At September 30, 2010, there were 6,062,389 shares, available for future grant under the Plans.

The following table summarizes stock option activity under the share-based compensation plans, including performance-based options:

	Shares of Common	Weighted Average	Weighted Average	Aggregate Intrinsic

	Stock Attributable to Options		Exercise Price	Contractual Life (in years)		Value (in thousands)
Outstanding at December 31, 2009	13,691,579	$	2.45	6.24	$	131,459
Granted	2,256,500	$	11.34			
Exercised	(1,281,758)	$	0.95			
Cancelled	(85,475)	$	5.97			
Outstanding at September 30, 2010	14,580,846	$	3.94	6.43	$	93,729
Vested or expected to vest at September 30, 2010	13,276,925	$	3.84	6.33	$	86,538
Exercisable at September 30, 2010(1)	6,910,684	$	1.99	4.91	$	56,784

(1) All stock options granted under the 1998 Plan, 2002 Plan and 2005 Plan contain provisions allowing for the early exercise of such options into restricted stock. The exercisable shares disclosed above represent those that are vested as of September 30, 2010.

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Ironwood Pharmaceuticals, Inc.

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The weighted average grant date fair value per share of options granted to employees during the three and nine months ended September 30, 2010 was $6.04 and $6.58, respectively, and $3.38 and $3.16 during the three and nine months ended September 30, 2009, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2010 was approximately $5.7 million and $14.1 million, respectively, and approximately $0.6 million and $0.8 million during the three and nine months ended September 30, 2009, respectively. Prior to the closing of the Company s initial public offering, the intrinsic value was calculated as the difference between the estimated fair value of the Company s common stock and the exercise price of the option.

The grant date fair value of the options granted to employees during the three and nine months ended September 30, 2010 was approximately $2.2 million and $14.7 million, respectively, and approximately $4.6 million and $9.0 million, respectively during the three and nine months ended September 30, 2009.

As of September 30, 2010, there was approximately $1.5 million and $16.2 million of unrecognized share-based compensation, net of estimated forfeitures, related to restricted stock awards and unvested stock option grants with time-based vesting, respectively, which are expected to be recognized over a weighted average period of 3.45 years. The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures.

11. Related Party Transactions

The Company has and currently obtains legal services from a law firm that is an investor of the Company. The Company paid approximately $96,000 and $196,000 in legal fees to this investor during the three and nine months ended September 30, 2010, respectively, and approximately $4,000 and $8,000 in legal fees to this investor during the three and nine months ended September 30, 2009, respectively.

In September 2009, Forest became a related party when the Company sold to Forest 2,083,333 shares of the Company s convertible preferred stock and in November 2009, Almirall became a related party when the Company sold to Almirall 681,819 shares of the Company s convertible preferred stock (Note 5). Additional related party disclosure related to Microbia and T&L is included in Note 13.

12. Segment Reporting

Prior to the sale of its interest in Microbia in September 2010, the Company had two reportable business segments: human therapeutics and biomanufacturing. The Company has no inter-segment revenues.

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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As a result of the sale of the Company s interest in Microbia the results of the biomanufacturing segment are now presented as discontinued operations in the balance sheets, statements of operations and statements of cash flows. The following table reports revenue and loss from operations for the Company s reportable segments for the three and nine months ended September 30, 2010 and 2009 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue:				
Human therapeutics	$ 9,059	$ 15,257	$ 27,085	$ 25,917
Biomanufacturing (included in discontinued operations)		400	1,985	1,581
Total	$ 9,059	$ 15,657	$ 29,070	$ 27,498
Loss from operations:				
Human therapeutics	$ (16,165)	$ (8,287)	$ (47,971)	$ (39,449)
Biomanufacturing (included in discontinued operations)	(2,790)	(3,201)	(4,531)	(9,186)
Total	$ (18,955)	$ (11,488)	$ (52,502)	$ (48,635)

	September 30, 2010	December 31, 2009
Total assets:		
Human therapeutics	$ 304,532	$ 160,105
Biomanufacturing (included in discontinued operations)		2,346
Total	$ 304,532	$ 162,451

At September 30, 2010 and December 31, 2009, approximately $5.0 million and $5.2 million, respectively, of the Company s accounts receivable related to the human therapeutics segment. At December 31, 2009, approximately $15,000 of accounts receivable related to the Company s biomanufacturing segment was included in current assets of discontinued operations.

13. Microbia, Inc.

Sale of Microbia to DSM

On September 21, 2010, the Company sold its interest in Microbia to DSM in exchange for cash proceeds of $9.5 million, the payment of approximately $1.1 million of Microbia debt and interest by DSM and future contingent consideration based on the sale of products incorporating Microbia s technology.

Tate & Lyle Investments, Ltd.

In September 2006, the Company entered into a collaboration agreement with T&L. The collaboration agreement had a five-year term with a one-year notice of termination. In connection with the execution of the collaboration agreement, the Company also issued T&L 1,823,529 shares of common stock of Microbia, at the aggregate purchase price of approximately $2,000, and issued 7,000,000 shares of convertible preferred stock of Microbia at the aggregate purchase price of $7.0 million. After the sale of stock to T&L, the Company retained an 85% majority ownership interest, and T&L had a 15% noncontrolling interest in Microbia. The Company s ownership interest in Microbia was entirely comprised of convertible preferred stock with the same preferences to that held by T&L. The ownership of the convertible preferred and common stock by T&L is recorded as noncontrolling interest in the consolidated financial statements.

On June 15, 2010, T&L and Microbia entered into an agreement to terminate their collaboration. The terms and conditions of the agreement included an exchange of intellectual property and a one-time payment to Microbia of approximately $1.8 million. All current and future obligations between Microbia and T&L were terminated as a result of this agreement.

Revenue earned from the T&L collaboration agreement totaled approximately $1.9 million during the nine months ended September 30, 2010 and approximately $0.1 million and $1.6 million during the three and nine months ended September 30, 2009, respectively. No revenue was earned from the T&L collaboration agreement during the three months ended September 30, 2010. This

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Ironwood Pharmaceuticals, Inc.

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revenue is included in discontinued operations for all periods presented. Accounts receivable from T&L was approximately $10,000 at December 31, 2009.

Strategic Restructuring Plan

In November 2009, Microbia implemented a strategic restructuring plan that included an immediate reduction of Microbia s workforce by approximately 40% of its existing workforce, and a reduced workweek for an additional 12% of its existing workforce. Microbia took this action to focus on its proprietary strain-development platform and existing service agreements.

In connection with the strategic restructuring plan, Microbia recorded restructuring charges of approximately $1.2 million in the year ended December 31, 2009, relating primarily to one-time termination benefits and asset impairment charges, which are included in net income (loss) from discontinued operations. As of September 21, 2010, Microbia had paid in cash all remaining termination benefits. As a result of the sale of the Company s interest in Microbia to DSM, Microbia will not incur approximately $0.8 million of contingent restructuring costs related to its November 2009 restructuring, which would have been incurred if Microbia implemented an additional reduction in force prior to the earlier of November 5, 2010 or the date that Microbia closed on a new round of financing.

14. Subsequent Events

Milestone

On November 1, 2010, the Company announced positive top-line results in the second confirmatory Phase 3 clinical trial assessing the efficacy and safety of linaclotide in patients with IBS-C. The Company announced the positive top-line results of the first confirmatory Phase 3 clinical trial in September 2010. Based on the positive top-line results from these two clinical trials, Almirall will make a one-time $20 million milestone payment, less applicable taxes, to the Company.

Federal Grant

On October 29, 2010, the Company was notified that it was awarded approximately $978,000 in grants under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act. The total amount awarded is expected to be recognized during the fourth quarter of 2010.

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

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management s discussion and analysis of financial condition and results of operations for the year ended December 31, 2009 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors in Part II, Item 1A of this Quarterly Report on Form 10-Q, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are an entrepreneurial pharmaceutical company that discovers, develops and intends to commercialize innovative medicines targeting important therapeutic needs. To achieve this, we are building a sustainable culture centered on creating and marketing important new drugs. Our experienced team of researchers is focused on a portfolio of internally discovered drug candidates that includes one Phase 3 drug candidate (linaclotide), one Phase 1/Phase 2 pain drug candidate, and multiple preclinical programs. We have pursued a partnering strategy for the commercialization of linaclotide that has enabled us to retain significant control over linaclotide s development and commercialization, share the costs of drug development and commercialization with collaborators whose capabilities complement ours, and retain approximately half of the future long-term value of linaclotide in the major pharmaceutical markets, should linaclotide meet our sales expectations.

We were incorporated in Delaware as Microbia, Inc. (which was the name of our formerly majority-owned subsidiary), on January 5, 1998. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc.

Prior to September 2010, we held a majority ownership interest in Microbia, Inc. (formerly known as Microbia Precision Engineering), a subsidiary formed in September 2006. Microbia, Inc., or Microbia, engages in a specialty biochemicals business based on a proprietary strain-development platform. On September 21, 2010, we sold our interest in Microbia to DSM Holding Company USA, Inc., or DSM, in exchange for cash proceeds of $9.5 million, the payment of approximately $1.1 million of Microbia debt and interest by DSM and future contingent consideration based on the sale of products incorporating Microbia s technology.

We currently operate in one reportable business segment human therapeutics. Our human therapeutics segment consists of the development and commercialization of our product candidates, including linaclotide. Prior to the sale of our interest in Microbia, we also operated in the biomanufacturing segment. Our biomanufacturing segment, which comprised a much smaller part of our business, consisted of our majority ownership interest in Microbia. Our human therapeutics segment represented 100% of our total assets at September 30, 2010 and approximately 99% of our total assets at December 31, 2009 while our biomanufacturing segment represented approximately 1% of our total assets at December 31, 2009. For the three and nine months ended September 30, 2010 and 2009, our biomanufacturing segment is included in net income (loss) from discontinued operations in our financial statements.

To date we have dedicated substantially all of our activities to the research and development of our product candidates. We have not generated any revenue to date from product sales and have incurred significant operating losses since our inception in 1998. We incurred net losses attributable to Ironwood Pharmaceuticals, Inc. of approximately $8.3 million and $41.3 million in the three and nine months ended September 30, 2010, respectively, and approximately $10.9 million and $47.3 million in the three and nine months ended September 30, 2009, respectively. As of September 30, 2010, we had an accumulated deficit of approximately $355.9 million and we expect to incur losses for the foreseeable future.

Financial Overview

Revenue. Revenue to date from our human therapeutics segment is generated primarily through our collaboration agreement with Forest Laboratories, Inc., or Forest, and our license agreements with Almirall, S.A., or Almirall, and Astellas Pharma Inc., or Astellas. The terms of these agreements typically include payment to us of one or more of the following: nonrefundable, up-front license fees; milestone payments; and royalties on product sales. Revenue from our human therapeutics segment is shown in our consolidated statements of operations as collaborative arrangements revenue. Revenue from our biomanufacturing segment was generated by our former subsidiary, Microbia, which had entered into research and development service agreements with various third parties. These agreements generally provided for fees for research and development services rendered. As a result of the sale of our interest in Microbia, revenue from our biomanufacturing segment is included in net income (loss) from discontinued operations. We

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expect our revenue to fluctuate for the foreseeable future as our collaborative arrangements revenue is principally based on the achievement of clinical and commercial milestones.

Research and development expense. Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of compensation, benefits and other employee related expenses, facility costs and third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities. The costs of revenue related to the Microbia services contracts and costs associated with Microbia s research and development activities are included in net income (loss) from discontinued operations. We charge all research and development expenses to operations as incurred. Under our Forest collaboration agreement we are reimbursed for certain research and development expenses and we net these reimbursements against our research and development expenses as incurred.

Our lead product candidate is linaclotide and it represents the largest portion of our research and development expense for our product candidates. Linaclotide is a first-in-class compound currently in Phase 3 clinical development for the treatment of irritable bowel syndrome with constipation, or IBS-C, and chronic constipation, or CC. We recently announced the positive top-line results from each of the two Phase 3 IBS-C clinical trials assessing the safety and efficacy of linaclotide in patients with IBS-C, and in November 2009, we announced that we achieved positive results in each of our Phase 3 CC trials. Our other clinical stage program is IW-6118, an inhibitor of Fatty Acid Amide Hydrolase, or FAAH, being evaluated for the treatment of pain and inflammation. IW-6118 is a novel small molecule inhibitor of FAAH, that decreased inflammation and pain and elevated fatty acid amides in preclinical models. We have an active investigational new drug application, or IND, for IW-6118 and are currently investigating the safety, tolerability, and pharmacokinetic properties of this molecule in Phase 1/Phase 2 studies.

The following table sets forth our research and development expenses related to linaclotide and IW-6118 for the three and nine months ended September 30, 2010 and 2009. We began tracking program expenses for linaclotide in 2004, and research and development program expenses from inception to September 30, 2010 were approximately $117.4 million. We began tracking program expenses for IW-6118 in 2008, and program expenses from inception to September 30, 2010 were approximately $12.6 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs. The expenses for linaclotide include both reimbursements to us by Forest as well as our portion of costs incurred by Forest for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreement. Costs related to facilities, depreciation, share-based compensation and research and development support services are not directly charged to programs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
Linaclotide	$ 5,507	$ 10,543	$ 20,716	$ 25,850
IW-6118	2,156	935	4,716	4,328

The lengthy process of securing Food and Drug Administration, or FDA, approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on linaclotide or IW-6118 prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, linaclotide, IW-6118 or any of our other product candidates will generate revenues and cash flows.

We have multiple product candidates in earlier stages of development, and are pursuing various therapeutic opportunities. We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is typically dependent upon the receipt of clear, positive data. In addition, we are actively engaged in identifying externally-discovered drug candidates at various stages of clinical development and accessing them through in-licensing or acquisition. In evaluating potential assets, we apply the same criteria as those used for investments in internally-discovered assets. To date, we have not in-licensed any drug candidates, but we do expect to do so from time to time.

The majority of our external costs are spent on linaclotide, as costs associated with later stage clinical trials are, in most cases, more significant than those incurred in earlier stages of our pipeline. We expect external costs related to the linaclotide program to begin decreasing as a result of the positive top-line results received from each of the two Phase 3 clinical trials for IBS-C provided that no other clinical trials are necessary to obtain regulatory approval in the U.S. If IW-6118 is successful in early stage clinical trials, we would expect the program s external costs to increase as it progresses through later stage clinical trials. The remainder of our

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research and development expense is not tracked by project as it consists primarily of our internal costs, and it benefits multiple projects that are in earlier stages of development and which typically share resources.

The successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

- The duration of clinical trials may vary substantially according to the type, complexity and novelty of the product candidate.

- The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures.

- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

- The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict.

- The costs, timing and outcome of regulatory review of a product candidate may not be favorable.

- The emergence of competing technologies and products and other adverse market developments may negatively impact us.

As a result of the uncertainties discussed above, we are unable to determine the duration and costs to complete current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate s commercial potential.

We expect our research and development costs to continue to be substantial for the foreseeable future and to increase with respect to our product candidates other than linaclotide as we advance those product candidates through preclinical studies and clinical trials.

General and administrative expense. General and administrative expense consists primarily of compensation, benefits and other employee related expenses for personnel in our administrative, finance, legal, information technology, business development, commercial and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, facility costs and professional fees for accounting and legal services. As a result of our initial public offering, or IPO, in February 2010, we have experienced and will likely continue to experience increases in general and administrative expense relating to operating as a public company. These increases include legal fees, accounting fees, costs associated with implementing and complying with the requirements of the Sarbanes-Oxley Act of 2002 and the Dodd Frank Wall Street Reform and Protection Act of 2010, and directors and officers insurance premiums, as well as fees for investor relations services. We also anticipate substantial increases in expenses related to developing the organization necessary to commercialize linaclotide.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reported periods. These estimates and assumptions, including those related to revenue recognition, available-for-sale securities, impairments of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development expenses, contingencies, and share-based compensation are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. Prior to our IPO, we also evaluated our estimates and judgments regarding the fair value assigned to our common stock. These critical estimates and assumptions are based on our historical experience, our observance of trends in the industry, and various other

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factors that are believed to be reasonable under the circumstances and form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from our estimates under different assumptions or conditions.

During the nine months ended September 30, 2010, there were no significant changes in our critical accounting policies or estimates. See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 30, 2010 for additional information about these critical accounting policies, as well as a description of our other significant accounting policies.

As a result of the sale of our interest in Microbia, we have presented the assets, liabilities, operations, and cash flows of Microbia as discontinued operations for all periods presented prior to the sale.

Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our condensed consolidated financial statements.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
Collaborative arrangements revenue	$ 9,059	$ 15,257	$ 27,085	$ 25,917
Operating expenses:				
Research and development	18,742	18,603	56,188	51,918
General and administrative	6,482	4,941	18,868	13,448
Total operating expenses	25,224	23,544	75,056	65,366
Loss from operations	(16,165)	(8,287)	(47,971)	(39,449)
Other income (expense):				
Interest expense	(81)	(72)	(178)	(256)
Interest and investment income	188	28	445	212
Remeasurement of forward purchase contracts				(100)
Other income (expense), net	107	(44)	267	(144)
Net loss from continuing operations before income tax benefit	(16,058)	(8,331)	(47,704)	(39,593)
Income tax benefit		(153)		(153)
Net loss from continuing operations	(16,058)	(8,178)	(47,704)	(39,440)
Net income (loss) from discontinued operations	9,311	(3,243)	7,495	(9,298)
Net loss	(6,747)	(11,421)	(40,209)	(48,738)
Net (income) loss from discontinued operations attributable to noncontrolling interest	(1,523)	519	(1,121)	1,483
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,270)	$ (10,902)	$ (41,330)	$ (47,255)

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Three Months and Nine Months Ended September 30, 2010 Compared to Three Months and Nine Months Ended September 30, 2009

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2010	2009	$	%	2010	2009	$	%
	(dollars in thousands)				(dollars in thousands)			
Collaborative arrangements revenue	$ 9,059	$ 15,257	$ (6,198)	(40.6)%	$ 27,085	$ 25,917	$ 1,168	4.5%

Collaborative Arrangements Revenue. The decrease in revenue from collaborative arrangements for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was primarily due to the achievement of a $20.0 million milestone in the Forest collaboration in July 2009. In the three months ended September 30, 2009, we recognized approximately $7.5 million at the time of achievement of this milestone and amortized approximately $0.7 million of the remaining deferred revenue compared to the amortization of approximately $1.0 million of the remaining deferred revenue during the three months ended September 30, 2010. This is partially offset by the recognition of approximately $1.0 million more revenue in the three months ended September 30, 2010 from shipments of clinical trial materials to Astellas than in the corresponding period in 2009.

The increase in revenue from collaborative arrangements for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was primarily due to increases in revenue from the Almirall license agreement, which we entered into in April 2009, and the Astellas license agreement, which we entered into in November 2009, offset by decreases in revenue from the Forest collaboration. In the nine months ended September 30, 2010 we recognized approximately $7.9 million of revenue versus approximately $4.4 million of revenue in the comparable period of 2009 related to the $38.0 million up-front license payment received in May 2009 from Almirall and the amortization of the deferred revenue resulting from recording the initial $6.0 million valuation of the Almirall forward purchase contract. In the nine months ended September 30, 2010 we recognized approximately $1.8 million of revenue related to the $30.0 million up-front license payment received in November 2009 from Astellas versus none in the comparable period of 2009 as the development period and related amortization did not commence until March 2010. Additionally, in the nine months ended September 30, 2010 we recognized approximately $1.0 million from shipments of clinical trial materials to both Almirall and Astellas which did not occur in 2009. This is offset by a decrease in revenue recognized in relation to the Forest collaboration primarily due to the achievement of a $20.0 million milestone in July 2009. During the nine months ended September 30, 2010 we recognized $3.0 million related to this milestone compared to approximately $8.2 million during the same period in 2009, a decrease of approximately $5.2 million. The decrease is a result of recognition of approximately $7.5 million of revenue upon achievement of this milestone in July 2009.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2010	2009	$	%	2010	2009	$	%
	(dollars in thousands)				(dollars in thousands)			
Operating Expenses:								
Research and development	$ 18,742	$ 18,603	$ 139	0.8%	$ 56,188	$ 51,918	$ 4,270	8.2%
General and administrative	6,482	4,941	1,541	31.2%	18,868	13,448	5,420	40.3%
Total operating expenses	$ 25,224	$ 23,544	$ 1,680	7.1%	$ 75,056	$ 65,366	$ 9,690	14.8%

Research and Development Expense. The increase in research and development expense for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was primarily due to an increase of approximately $1.2 million in compensation, benefits, and employee related expenses primarily due to increased headcount, an increase of approximately $0.5 million due to the implementation in the first quarter of 2010 of our employee incentive plan, an approximately $0.5 million increase in stock compensation expense primarily related to our annual stock option grant made in February 2010, an approximately $1.2 million increase in allocated facilities costs primarily due to increased rent expense associated with the additional space we acquired at our 301 Binney Street facility in February 2010, offset by a decrease of approximately $3.3 million in support of the Phase 3 clinical trials for linaclotide, primarily resulting from lower clinical trial, manufacturing, and collaboration expenses as one IBS-C trial was completed and the second trial is nearing completion and registration batches of active pharmaceutical ingredient, or API, have been completed.

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The increase in research and development expense for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was primarily due to an increase of approximately $2.3 million in compensation, benefits, and employee related expenses primarily due to an increase in headcount, an increase of approximately $1.2 million due to the implementation in the first quarter of 2010 of our employee incentive plan, an approximately $1.0 million increase in stock compensation expense primarily related to our annual stock option grant made in February 2010, an approximately $0.6 million increase in internal research and development costs in support of our internal pipeline, an increase of approximately $1.4 million in allocated facilities and research and development support services, offset by a decrease of approximately $2.7 million expenses to support the Phase 3 clinical trials for linaclotide, primarily resulting from lower manufacturing costs and collaboration expenses.

General and Administrative Expense. The increase in general and administrative expense for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was due to an approximately $0.7 million increase in compensation and benefits related expenses due to increased headcount, an approximately $0.2 million increase in stock compensation expense primarily related to our annual stock option grant made in February 2010, an approximately $0.2 million increase due to the implementation in the first quarter of 2010 of our employee incentive plan, an approximately $0.3 million increase in allocated facilities costs primarily due to increased rent expense associated with the additional space we acquired at our 301 Binney Street facility in February 2010, and an increase in external consulting costs of approximately $0.4 million associated with preparing to commercialize linaclotide and costs related to public company compliance requirements, offset by an increase of approximately $0.5 million in the reimbursement from Forest on our collaborative commercial activities.

The increase in general and administrative expense for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was due to an approximately $1.7 million increase in compensation and benefits related expenses as a result of increased headcount, an approximately $1.1 million increase in stock compensation expense primarily related to our annual stock option grant made in February 2010, an approximately $0.5 million increase due to the implementation in the first quarter of 2010 of our employee incentive plan, an approximately $0.8 million increase in allocated facilities costs primarily due to increased rent and depreciation expense associated with the additional space we acquired at our 301 Binney Street facility in February 2010, an increase of approximately $0.2 million in audit and tax fees associated with being a newly public company, and an increase in consulting costs of approximately $1.3 million associated with preparing to commercialize linaclotide and other business development activities, as well as compliance with the Sarbanes-Oxley Act of 2002 and stock administration, offset by an increase of approximately $0.6 million in the reimbursement from Forest on our collaborative commercial activities.

Other Income (Expense), Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2010	2009	$	%	2010	2009	$	%
	(dollars in thousands)				(dollars in thousands)			
Other income (expense):								
Interest expense	$ (81)	$ (72)	$ (9)	(12.5)%	$ (178)	$ (256)	$ 78	30.5%
Interest and investment income	188	28	160	571.4%	445	212	233	109.9%
Remeasurement of forward purchase contracts				%		(100)	100	100.0%
Total other income (expense), net	$ 107	$ (44)	$ 151	343.2%	$ 267	$ (144)	$ 411	285.4%

Interest Expense. The increase in interest expense for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was primarily the result of the early payment fees incurred by the repayment of the long-term debt, along with the interest associated with capital leases obtained in December 2009 and June 2010.

The decrease in interest expense for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was the result of a reduction in long-term debt.

Interest and Investment Income. The increase in interest and investment income for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was due to higher average investment balances as a result of investing the proceeds of our IPO.

The increase in interest and investment income for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was due to higher average investment balances as a result of investing the proceeds of our IPO, partially offset by lower prevailing interest rates during the period.

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Remeasurement of Forward Purchase Contracts. The increase in the remeasurement of forward purchase contracts for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 resulted from the final settlement of the Forest forward purchase contract in July 2009 and the Almirall forward purchase contract in November 2009. The Forest forward purchase contract was remeasured in July 2009 when Forest made its equity investment and the Almirall forward purchase contract was remeasured at September 30, 2009, resulting in a total remeasurement loss of $0 and $0.1 million over the three and nine months ended September 30, 2009, respectively. As a result of the final settlements of both forward purchase contracts, there was not a corresponding remeasurement at September 30, 2010.

Net (Income) Loss From Discontinued Operations. The increase in net income from discontinued operations for the three and nine months ended September 30, 2010 compared to the three and nine months ended September 30, 2009 was primarily a result of the approximately $12.2 million gain recognized on the sale of Microbia (deconsolidation) in September 2010.

Net (Income) Loss From Discontinued Operations Attributable to Noncontrolling Interest. The approximately $2.0 million increase in net income from discontinued operations attributable to noncontrolling interest for the three months ended September 30, 2010 compared to the same period for the prior year was primarily due to lower expenses resulting from reduced headcount associated with the December 2009 restructuring activities and the noncontrolling interest s share of the forgiveness of all intercompany debt by Ironwood Pharmaceuticals, Inc.

The approximately $2.6 million increase in net income from discontinued operations attributable to noncontrolling interest for the nine months ended September 30, 2010 compared to the same period for the prior year was primarily due to lower expenses resulting from reduced headcount associated with the December 2009 restructuring activities, approximately $1.8 million in revenue recorded in June 2010 associated with the termination of the T&L agreement and the portion of forgiven intercompany debt and payables attributable to noncontrolling interest.

Liquidity and Capital Resources

The following table sets forth the major sources and uses of cash for each of the periods set forth below:

	Nine Months Ended September 30,	
	2010	2009
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (67,253)	$ (13,914)
Investing activities	(198,571)	965
Financing activities	202,214	26,831
Net (decrease) increase in cash and cash equivalents	$ (63,610)	$ 13,882

We have incurred losses since our inception on January 5, 1998 and, as of September 30, 2010, we had a cumulative deficit of approximately $355.9 million. We have financed our operations to date primarily through the sale of preferred stock and common stock, including approximately $203.2 million of net proceeds from our IPO, payments received under collaborative arrangements, including reimbursement of certain expenses, debt financings and interest earned on investments. At September 30, 2010, we had approximately $250.8 million of unrestricted cash, cash equivalents and available-for-sale securities. Our cash and cash equivalents include amounts held in money market funds, stated at cost plus accrued interest, which approximates fair market value, U.S. Treasury securities and U.S. government-sponsored entities. Our

available-for-sale securities include amounts held in U.S. government-sponsored entities and U.S. Treasury securities. We invest cash in excess of immediate requirements in accordance with our investment policy which limits the amounts we may invest in any one type of investment and requires all investments held by us to be A+ rated so as to primarily achieve liquidity and capital preservation.

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Cash Flows From Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all our activities other than investing and financing activities. Our operating cash flow is derived by adjusting our net loss for:

- Non-cash items such as depreciation, share-based compensation expense, remeasurement of forward purchase contracts and accretion of discount/premium on investment securities;

- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

Net cash used in operating activities totaled approximately $67.3 million for the nine months ended September 30, 2010. The primary uses of cash were our net loss from continuing operations of approximately $47.7 million, approximately $3.1 million used in operating activities from discontinued operations and a decrease of approximately $27.0 million in working capital resulting primarily from reductions in deferred revenue as revenue was recognized from our Forest collaboration agreement and our Almirall and Astellas license agreements. These uses of cash were partially offset by non-cash items of approximately $10.5 million.

Net cash used in operating activities totaled approximately $13.9 million for the nine months ended September 30, 2009. The primary uses of cash were our net loss from continuing operations of approximately $39.4 million and approximately $8.6 million included in net cash used in operating activities from discontinued operations, offset by approximately $7.2 million in non-cash items and approximately $26.9 million increase in working capital. The increase in working capital was due primarily to an increase in deferred revenue resulting from the up-front cash payment associated with the Almirall license agreement of $38.0 million and the $20.0 million milestone payment related to the Forest collaboration agreement, partially offset by reductions in deferred revenue as revenue was recognized from our Forest collaboration and our Almirall license agreement.

Cash Flows From Investing Activities

Cash used in investing activities for the nine months ended September 30, 2010 totaled approximately $198.6 million and resulted primarily from the purchase of approximately $322.3 million of securities related to the investment of the net proceeds of our IPO and the purchase of approximately $15.1 million of property and equipment associated with the expansion of our 301 Binney Street facility. These uses of cash were partially offset by the sale and maturity of approximately $129.3 million in investments and approximately $9.5 million in proceeds received from DSM for the sale of our interest in Microbia.

Cash provided by investing activities for the nine months ended September 30, 2009 totaled approximately $1.0 million and resulted primarily from the sales and maturities of securities of approximately $30.9 million, partially offset by the purchase of approximately $26.7 million of securities, the purchase of approximately $3.2 million of property and equipment of which approximately $0.5 million is included in net cash

provided by (used in) investing activities from discontinued operations.

Cash Flows From Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2010 totaled approximately $202.2 million and resulted primarily from the net proceeds of our IPO of approximately $203.2 million.

Cash provided by financing activities for the nine months ended September 30, 2009 totaled approximately $26.8 million primarily resulting from approximately $25.2 million in proceeds from the sale of preferred stock and approximately $1.5 million received from net borrowings under our debt facility of which approximately $1.4 million is included in net cash (used in) provided by financing activities from discontinued operations.

Funding Requirements

To date, we have not commercialized any products and have not achieved profitability. We anticipate that we will continue to incur substantial net losses for the next several years as we further develop and prepare for the potential commercial launch of linaclotide, continue to invest in our pipeline, develop the organization required to sell our product candidates and operate as a publicly traded company.

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We have generated revenue from services, up-front license fees and milestones, but have not generated any product revenue since our inception and do not expect to generate any product revenue from our collaborative arrangements or the sale of products unless we receive regulatory approval for commercial sale of linaclotide. We believe that our existing cash, cash equivalents and available-for-sale securities balances, interest income we earn on these balances, and amounts we expect to receive from our collaborators under existing contractual obligations will be sufficient to meet our anticipated cash requirements to complete development and commercialize linaclotide with our partner Forest for the U.S. market, and to fund our currently contemplated research and development efforts for at least the next five years, based on our current business plan. Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to obtain regulatory approval, and the costs to commercialize our product candidates are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the Risk Factors section of this Quarterly Report on Form 10-Q. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Due to the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate precisely the amounts of capital outlays and operating expenditures necessary to complete the development of, and to obtain regulatory approval for, linaclotide and our other product candidates for all of the indications for which we believe each product candidate is suited. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the time and costs involved in obtaining regulatory approvals for our product candidates;
- the rate of progress and cost of our commercialization activities;
- the success of our research and development efforts;
- the expenses we incur in marketing and selling our product candidates;
- the revenue generated by sales of our product candidates;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any additional collaborative, licensing or other arrangements that we may establish; and

- the acquisition of businesses, products and technologies.

Contractual Commitments and Obligations

The disclosure of our contractual obligations and commitments is set forth under the heading *Management s Discussion and Analysis of Financial Condition and Results of Operations - Contractual Commitments and Obligations* in our Annual Report on Form 10-K for the year ended December 31, 2009. As a result of the sale of our interest in Microbia to DSM, Microbia will not incur approximately $0.8 million of contingent restructuring costs related to its November 2009 restructuring.

In June 2010, we entered into a commercial supply agreement with PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB for the purchase of a portion of the linaclotide API that will be used to seek regulatory approval of linaclotide in the United States, Canada and/or Mexico, and, pending any such approval, that will be commercialized in such country. The commercial supply agreement contains minimum purchase requirements that commence with the commercial launch of linaclotide and that are dependent upon forecasted commercial requirements. Since, at this time, linaclotide has not yet been approved for commercialization and future commercial demand for linaclotide is unknown, we cannot estimate our future minimum purchase requirements under the commercial supply agreement.

In September 2010, we repaid all outstanding principal and interest under our loan and security agreement with a financing company which was used to finance the purchase of laboratory and other equipment. We incurred pre-payment fees of approximately $67,000 in conjunction with the repayment of debt of which approximately $31,000 is included in net income (loss) from discontinued operations and the remainder is included in interest expense in the statements of operations.

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Related Party Transactions

We have and currently obtain legal services from a law firm that is an investor of ours. We paid approximately $96,000 and $196,000 in legal fees to this investor during the three and nine months ended September 30, 2010, respectively and approximately $4,000 and $8,000 during the three and nine months ended September 30, 2009, respectively.

In September 2006, T&L became a related party when we sold to them 1,823,529 shares of common stock of Microbia at the aggregate purchase price of approximately $2,000, and sold 7,000,000 shares of convertible preferred stock of Microbia at the aggregate purchase price of $7.0 million. T&L accounted for approximately 0% and 98% of our revenue from discontinued operations for the three and nine months ended September 30, 2010, respectively, and 100% of our revenue from discontinued operations for the three and nine months ended September 30, 2009. On June 15, 2010, T&L and Microbia entered into an agreement to terminate their collaboration. The terms and conditions of the termination agreement include an exchange of intellectual property and a one-time payment to Microbia of approximately $1.8 million. All current and future obligations between Microbia and T&L are terminated as a result of this agreement. As a result of the sale of our interest in Microbia to DSM, T&L is no longer a related party.

In September 2009, Forest became a related party when we sold to them 2,083,333 shares of our convertible preferred stock at a price of $12.00 per share for cash proceeds of $25.0 million. Forest accounted for approximately 60% of our revenue from continuing operations for the three and nine months ended September 30, 2010 and approximately 83% of our revenue from continuing operations for the three and nine months ended September 30, 2009.

In November 2009, Almirall became a related party when we sold to them 681,819 shares of our convertible preferred stock at a price of $22.00 per share for cash proceeds of $15.0 million. Almirall accounted for approximately 29% and 31% of our revenue from continuing operations for the three and nine months ended September 30, 2010, respectively, and approximately 17% of our revenue from continuing operations for both the three and nine months ended September 30, 2009.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued

standards that are not yet effective will not have a material impact on our consolidated financial position or results of operations upon adoption.

Recently Issued Accounting Standards

In April 2010, the FASB issued Accounting Standards Update, or ASU, No. 2010-17, *Revenue Recognition Milestone Method,* or ASU 2010-017. ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This ASU is effective on a prospective basis for research and development milestones achieved in fiscal years, beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. As we plan to implement ASU No. 2010-17 prospectively, the effect of this guidance will be limited to future transactions.

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13. ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification, or ASC, Subtopic 605-25 (previously included within EITF 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21). The consensus to ASU 2009-13 provides accounting principles and application guidance on whether

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multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and allows for retrospective application. We are currently evaluating the potential impact of this standard on our financial position and results of operations.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk***

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We invest our cash in a variety of financial instruments, principally deposits, securities issued by the U.S. government and its agencies and money market instruments. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 1% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed and auction rate securities and the resulting effect on various securities markets. We do not currently have any auction rate securities. We do not believe our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

Our capital lease obligations bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates.

Foreign Currency Risk

We have no operations outside the U.S. and do not have any foreign currency or other derivative financial instruments.

Effects of Inflation

We do not believe that inflation and changing prices have had a material effect on our business over the three and nine months ended September 30, 2010 and 2009.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management,

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including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. ***Risk Factors***

Our future operating results could differ materially from the results described in this report due to the risks and uncertainties related to our business, including those discussed below. Furthermore, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements. We refer you to our Special Note Regarding Forward-Looking Statements which identifies the forward-looking statements in this report.

Risks Related to Our Business and Industry

We are largely dependent on the success of linaclotide, which may never receive regulatory approval or be successfully commercialized.

We currently have one product candidate, linaclotide, in Phase 3 clinical development. Our other drug candidates are in earlier stages of development. Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from sales, and we may never be able to develop marketable drugs. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products is subject to extensive regulation by the FDA and foreign regulatory authorities, and regulations differ from jurisdiction to jurisdiction. We are not permitted to market any of our product candidates in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign jurisdictions until we receive the requisite approvals from such jurisdictions. We have neither submitted an NDA nor received marketing approval for linaclotide in any jurisdiction. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Potential risks include those that the regulatory authorities:

- may not deem linaclotide or another product candidate safe and effective;
- may not find the data from preclinical studies and clinical trials sufficient to support approval;
- may not approve of manufacturing processes and facilities; or
- may change their approval policies or adopt new regulations.

Linaclotide is a first-in-class compound that is currently in Phase 3 clinical development for the treatment of IBS-C and CC. We recently announced the positive top-line results from each of the two Phase 3 clinical trials assessing the safety and efficacy of linaclotide in patients with IBS-C, and in November 2009, we announced that we achieved positive results in each of our Phase 3 CC trials. Even though linaclotide met the endpoints of the CC trials and the top-line results indicate that it met the endpoints of the IBS-C trials, it may not be approved for either or both indications or for any other indication for which we seek approval from the FDA.

Further, the FDA and any foreign regulatory authority may disagree with our trial design or our interpretation of data from clinical trials, or they may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. The FDA and any foreign regulatory authority might also approve linaclotide for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA and any foreign regulatory authority may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of linaclotide. Any failure to obtain regulatory approval of linaclotide would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue.

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Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of linaclotide, which could prevent or significantly delay regulatory approval.

Our product candidates are prone to the risks of failure inherent in drug development most pharmaceutical product candidates fail. Before obtaining regulatory approvals for the commercial sale of linaclotide or any other product candidate for a specific indication, we must demonstrate with substantial evidence gathered in well-controlled clinical trials and to the satisfaction of the FDA, with respect to approval in the U.S., and to the satisfaction of similar regulatory authorities in other jurisdictions, with respect to approval in those jurisdictions, that the product candidate is safe and effective for use for the target indication. Although we recently announced the positive top-line results from each of the two Phase 3 IBS-C clinical trials, we are still analyzing the data from each of the trials. In addition, our long-term safety study that was undertaken to assess the safety and tolerability profile of linaclotide in patients dosed with linaclotide over a 78-week period, still is underway.

The results from the preclinical and clinical trials that we have completed for linaclotide may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and similar regulatory authorities in other jurisdictions in order to obtain the requisite regulatory approvals for linaclotide. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If linaclotide is not shown to be safe and effective, our clinical development programs could be delayed or terminated. Our failure to adequately demonstrate the efficacy and safety of linaclotide or any other product candidates that we may develop, in-license or acquire would prevent receipt of regulatory approval and, ultimately, the commercialization of that product candidate.

Linaclotide may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval or limit its commercial potential.

Undesirable side effects caused by linaclotide could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential products liability claims. Earlier this year, we completed our evaluation of the data from our CC studies, but we are currently evaluating the data from our IBS-C trials and we still are conducting a long-term safety study in patients dosed with linaclotide over a 78-week period. Any serious adverse events deemed to be caused by linaclotide could have a material adverse effect upon the linaclotide program and our business as a whole. The most common adverse event to date in the clinical studies evaluating the safety and efficacy of linaclotide has been diarrhea. For the most part, the diarrhea has been considered mild or moderate by the patients, but in a small percentage of patients, it has been severe enough for patients to discontinue participation in a study. There have been no serious adverse events in patients treated with linaclotide that were deemed by a study investigator to be definitively related or probably related to linaclotide treatment. There have been a small number of serious adverse events in patients treated with linaclotide that were deemed by an independent study investigator to be possibly related to linaclotide treatment, involving cases of abdominal pain, acute gastroenteritis, aplastic anemia, atrial fibrillation, bowel obstruction, bronchitis, gall stones, ileus, pericarditis, stroke and thrombosed hemorrhoids. At the end of the linaclotide development program, the incidence of these events in linaclotide recipients will be compared to the population at-large to assess whether linaclotide increases the risks of such events. Finally, there have been no deaths in our trials that were considered by a study investigator to be related to linaclotide treatment.

If linaclotide receives marketing approval, and we or others later identify undesirable side effects caused by the product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of linaclotide;

- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of linaclotide and could substantially increase commercialization costs.

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Delays in the completion of clinical testing of any of our product candidates could result in increased costs and delay or limit our ability to generate revenues.

Delays in the completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial;

- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- manufacturing sufficient quantities of a product candidate for use in clinical trials;

- obtaining institutional review board approval to conduct a clinical trial at a prospective site;

- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar conditions; and

- signing-up patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, an institutional review board overseeing the clinical trial at a clinical trial site (with respect to that site), the FDA, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the study protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- unforeseen safety issues; and

- lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Each protocol amendment requires institutional review board review and approval, which may adversely impact the costs, timing or successful completion of the associated clinical trials. If we experience delays in completion or if we terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

Because we work with Forest Laboratories, Inc. to develop, promote and manufacture linaclotide in North America, we are dependent upon a third party in our efforts to obtain regulatory approval for, and to commercialize, linaclotide within our expected timeframes.

We co-develop and plan to co-promote linaclotide in the U.S. with Forest. Forest plays a significant role in the conduct of the clinical trials for linaclotide and the subsequent collection and analysis of data. In addition, Forest is responsible for completing the manufacturing process of linaclotide upon production of the API, which consists of finishing and packaging linaclotide into capsules. Employees of Forest are not our employees, and we have limited ability to control the amount or timing of resources that they devote to linaclotide. If Forest fails to devote sufficient time and resources to linaclotide, or if its performance is substandard, it will delay the potential approval of regulatory applications for linaclotide as well as the commercialization and manufacturing of linaclotide. A material breach by Forest of our collaboration agreement could also delay regulatory approval and commercialization of linaclotide. In addition, the execution of our clinical development program for linaclotide, and the compilation and analysis of the data produced from the clinical trials, requires coordination among various parties. These functions may not be carried out effectively and efficiently if these parties fail to communicate and coordinate with one another. Moreover, although we have non-compete restrictions in place

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with Forest, Forest may have relationships with other commercial entities, some of which may compete with us. If Forest assists our competitors, it could harm our competitive position.

We may face competition in the IBS-C and CC marketplace for linaclotide, and new products may emerge that provide different or better alternatives for treatment of gastrointestinal conditions.

If approved and commercialized, linaclotide will compete globally with certain prescription therapies and over the counter products for the treatment of IBS-C and CC, or certain associated symptoms. The availability of prescription competitors and over the counter products for gastrointestinal conditions could limit the demand, and the price we are able to charge, for linaclotide unless we are able to differentiate linaclotide on the basis of its clinical benefits in our clinical trials. New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render linaclotide obsolete or noncompetitive.

We believe other companies are developing products which could compete with linaclotide, should they be approved by the FDA. Currently, there are a few compounds in late stage development for the treatment of patients with either IBS-C or CC. To our knowledge, other potential competitors also are in earlier stages of development. If our potential competitors are successful in completing drug development for their drug candidates and obtain approval from the FDA, they could limit the demand for linaclotide.

Certain of our competitors have substantially greater financial, technical and human resources than us. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields.

We have limited sales and marketing experience and resources, and we may not be able to effectively market and sell linaclotide.

With linaclotide, we are developing a product candidate for large markets traditionally served by general practitioners and internists, as well as gastrointestinal specialists. Traditional pharmaceutical companies employ groups of sales representatives to call on these large generalist physician populations. In order to adequately address these physician groups, we must optimize our co-development and co-promotion relationship in the U.S., Canada and Mexico with Forest, our license and commercialization relationship in Europe with Almirall, and our license and commercialization relationship in certain Asian countries with Astellas. Likewise, we must either establish sales and marketing collaborations or co-promotion arrangements or expend significant resources to develop our own sales and marketing presence outside of North America, Europe, and those Asian countries. We currently possess limited resources and may not be successful in establishing additional collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators, co-promoters and sales force personnel. By entering into strategic collaborations or similar arrangements, we rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to develop or effectively commercialize linaclotide because they cannot obtain the necessary regulatory approvals, lack adequate financial or other resources or decide to focus on other initiatives.

Even if linaclotide receives regulatory approval, it may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Linaclotide and our other product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

- impose civil or criminal penalties;

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- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

Even if linaclotide receives regulatory approval in the U.S., we or our collaborators may never receive approval to commercialize linaclotide outside of the U.S.

In April 2009, we entered into an out-license agreement with Almirall for European rights to develop and commercialize linaclotide. In November 2009, we entered into an out-license agreement with Astellas for rights to develop and commercialize linaclotide in certain Asian countries. In the future, we may seek to commercialize linaclotide in foreign countries outside of Europe and those Asian countries with other parties or by ourselves. In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the U.S. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that linaclotide may not be approved for all indications requested, which could limit the uses of linaclotide and have an adverse effect on its commercial potential or require costly post-marketing studies.

If we or our collaboration partners and other third parties upon whom we rely to produce linaclotide are unable to satisfy FDA quality standards and related regulatory requirements, experience manufacturing difficulties, or are unable to manufacture sufficient quantities of our product candidates, our development and commercialization efforts may be materially harmed.

We do not currently possess internal manufacturing capacity. We currently utilize the services of contract manufacturers to manufacture our clinical supplies. With respect to the manufacturing of linaclotide, we (along with our U.S. collaboration partner, Forest) entered into a commercial supply agreement with PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB for the manufacture of the linaclotide API that will be used to obtain regulatory approval of linaclotide in the United States, Canada and/or Mexico, and, pending any such approval, that will be incorporated into finished product for commercialization in such country. In addition, we continue to pursue long-term

commercial supply agreements with other manufacturers for the linaclotide API. We may not be able to enter into long-term agreements with such other manufacturers on commercially reasonable terms, or at all. If we enter into a long-term commercial supply agreement with another manufacturer but then change or add manufacturers, the FDA and comparable foreign regulators must approve these manufacturers facilities and processes prior to use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidates. While we believe we will have long term arrangements to produce a sufficient amount of API, if we lose a manufacturer, it would take us a substantial amount of time to identify and develop a relationship with an alternative manufacturer.

Peptide manufacturing is a highly specialized manufacturing business. These third party manufacturers acquire the raw materials for the API from a limited number of sources. Any curtailment in the availability of these raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

Upon production of our API, each of our collaboration partners, Forest, Almirall and Astellas, is responsible for completing the manufacturing process of linaclotide in its respective territory, which consists of finishing and packaging linaclotide into capsules. In addition, we are pursuing arrangements with other manufacturers to complete the manufacturing process of linaclotide in the parts of the world outside of our partnered territories. We will be dependent upon the success of our partners and these other manufacturers in producing drug product for commercial sale. No party has experience producing finished drug product for linaclotide at

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commercial scale, and such efforts may fail. Traditionally, peptide manufacturing is costly and time consuming, resulting in low yields and poor stability. We cannot give any assurances that we will overcome these issues when scaling up manufacturing for linaclotide.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, compliance with federal, state and foreign regulations, and the challenges associated with complex supply chain management. We, together with our partners Forest and Almirall, are currently evaluating the stability of different batch sizes of linaclotide at various points in time. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market linaclotide would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Each of the linaclotide manufacturers would need to comply with GMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of linaclotide may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements. We have little control over our manufacturers or collaboration partners compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the quality of linaclotide is compromised due to a manufacturers or collaboration partners failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize linaclotide, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of linaclotide or our other product candidates, entail higher costs or result in our being unable to effectively commercialize linaclotide or our other product candidates. Furthermore, if our manufacturers or collaboration partners fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

We are subject to uncertainty relating to reimbursement policies which, if not favorable for linaclotide, could hinder or prevent linaclotide s commercial success.

Our ability to commercialize linaclotide successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness

of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for linaclotide or we may be required to sell linaclotide at a discount.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of linaclotide in determining whether to approve reimbursement for linaclotide and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of linaclotide from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which linaclotide will be reimbursed to a smaller set than we believe it is effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or

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pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including linaclotide, to other available therapies. Further, several European countries have implemented government measures to either freeze or reduce pricing of pharmaceutical products, and it is expected that other countries will do so, as well. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect to experience pricing pressures in connection with the sale of linaclotide and our future products due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liabilities.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any approved product;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs of related litigation;
- distraction of management s attention from our primary business;
- substantial monetary awards to patients or other claimants;

- loss of revenues; and

- the inability to commercialize our product candidates.

We have obtained product liability insurance coverage for our clinical trials. Our insurance coverage is limited to $5 million per occurrence, and $10 million in the aggregate, and covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

In pursuing our growth strategy, we will incur a variety of costs and may devote resources to potential opportunities that are never completed or for which we never receive the benefit. Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

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The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Healthcare reform measures could hinder or prevent our product candidates commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the recent passing of the Patient Protection and Affordable Healthcare Act and the Health Care and Education Reconciliation Act. This healthcare reform law will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D as established under the Medicare Prescription Drug Improvement Act of 2003; each of these reforms could potentially increase our future revenue from linaclotide or any other product candidates that are approved for sale. The newly-enacted law, however, also implements cost containment measures that could adversely affect our future revenue. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care. The legislation also extends 340B discounted pricing on outpatient drugs to children s hospitals, critical access hospitals, and rural health centers; this expansion reduces the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform law, which become effective in 2011, may negatively affect our future revenue and prospects for profitability. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we would be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform law s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will also be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

In the aftermath of the healthcare reform law, private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services. These cost-control initiatives could decrease the price we might establish for linaclotide, which would result in lower product revenue or royalties payable to us.

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In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The recent U.S. legislation and these proposed reforms could result in reduced reimbursement rates for linaclotide and our other potential products, which would adversely affect our business strategy, operations and financial results.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

If our strategic alliances are unsuccessful, our operating results will be negatively impacted.

Our three primary strategic alliances are with Forest, Almirall and Astellas. The success of these arrangements is largely dependent on the resources, efforts and skills of these partners. Disputes and difficulties in such relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of these alliances are reduced or eliminated when strategic partners:

- terminate the agreements covering the strategic alliance;

- fail to devote financial or other resources to the alliances and thereby hinder or delay development, manufacturing or commercialization activities; or

- fail to maintain the financial resources necessary to continue financing their portion of the development, manufacturing or commercialization costs, or become insolvent or declare bankruptcy.

We continue to increase the size of our organization, and we may experience difficulties in managing growth.

We continue to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our product candidates. Our personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials, and the analysis of the data generated from those trials, effectively;

- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;

- improve our operational, financial and management controls, reporting systems and procedures; and

- attract and motivate sufficient numbers of talented employees.

We may not be able to manage our business effectively if we lose any of our current management team or if we are unable to attract and motivate key personnel.

We may not be able to attract or motivate qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the greater-Boston area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our objectives.

We are highly dependent on the development, regulatory, commercial and financial expertise of our management, particularly Peter M. Hecht, Ph.D., our Chief Executive Officer; Mark G. Currie, Ph.D., our Senior Vice President of Research and Development and our Chief Scientific Officer; Michael J. Higgins, our Senior Vice President, Chief Operating Officer and Chief Financial Officer; and Thomas A. McCourt, our Senior Vice President, Marketing and Sales and Chief Commercial Officer. Although no member of our management team has informed us to date that he or she intends to resign or retire, if we lose any members of our

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management team in the future, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, the Boston area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment efforts.

We also have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, such as linaclotide, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations include:

- federal healthcare program anti-kickback laws, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for

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violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our business involves the use of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures we use for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. The loss of clinical trial data from clinical trials for linaclotide could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

Risks Related to Intellectual Property

Limitations on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend on our ability to obtain and maintain patent protection for our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others.

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the U.S. and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

In addition, the laws of certain foreign countries do not protect proprietary rights to the same extent or in the same manner as the U.S., and therefore, we may encounter problems in protecting and defending our intellectual property in certain foreign jurisdictions.

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If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that our potential products may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware, that may be infringed by our product candidates. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that our product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties alleging that our product candidates infringe their intellectual property rights. If one of our product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable product candidate unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;

- a court prohibiting us from selling our product unless the third party licenses its rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and

- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not issuing.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for linaclotide in our potential markets, and failure to secure those registrations could adversely affect our business.

We do not yet have registered trademarks for linaclotide in any jurisdiction. Although we have filed intent-to-use (ITU) trademark applications for linaclotide in the U.S., and we have received notices of allowance for some of these ITU applications, we may not receive notices of allowance on other of our ITU applications. In addition, our allowed ITU applications may not be allowed for registration in the U.S. or other jurisdictions, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and as such, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

In recent years, we have focused primarily on developing linaclotide, with the goal of supporting regulatory approval for this product candidate. We have financed our operations primarily through private placements of capital stock prior to our IPO, our IPO, and our collaboration and license arrangements, and we have incurred losses in each year since our inception in 1998. We incurred net losses attributable to Ironwood Pharmaceuticals, Inc. of approximately $8.3 million and $41.3 million in the three and nine months ended September 30, 2010, respectively, and approximately $10.9 million and $47.3 million in the three and nine months ended September 30, 2009, respectively. As of September 30, 2010, we had an accumulated deficit of approximately $355.9 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. We expect our expenses to increase in connection with our efforts to commercialize linaclotide and our research and development of our other product candidates. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

We have not generated any product revenue from our product candidates and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue from sales. To date, we have not generated any product revenue, and we do not know when, or if, we will generate any such revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

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- successfully complete our ongoing and planned clinical trials for linaclotide;

- obtain regulatory approvals for linaclotide;

- if regulatory approvals are received, manufacture commercial quantities of linaclotide at acceptable cost levels;

- optimize our relationship to co-develop and co-promote linaclotide in the U.S. with Forest, to commercialize linaclotide in Europe with Almirall and to commercialize linaclotide in certain Asian countries with Astellas; and

- potentially identify and enter into one or more strategic collaborations to market and sell linaclotide outside of North America, Europe and those Asian countries.

Even if linaclotide is approved for commercial sale, we anticipate incurring significant costs associated with commercialization. We may not achieve profitability after generating product sales. If we are unable to generate product revenues, we will not become profitable.

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing product candidates, conducting clinical trials, establishing manufacturing relationships and marketing drugs are expensive and uncertain. We believe that our cash on hand as of the date of this Quarterly Report on Form 10-Q and additional cash milestone payments we may receive from our collaborators will enable us to launch and commercialize linaclotide in the U.S. with our partner, Forest, and to fund our currently contemplated research and development efforts for at least the next five years based on our existing business plan. However, unforeseen circumstances may arise, or our strategic imperatives could change, requiring us to seek to raise additional funds. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for linaclotide and our other product candidates;

- the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;

- the timing of any regulatory approvals of our product candidates;

- the costs of establishing sales, marketing and distribution capabilities; and

- the status, terms and timing of any collaboration, licensing, co-promotion or other arrangements.

Additional funding may not be available on acceptable terms or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Our quarterly and annual operating results may fluctuate significantly.

We expect our operating results to be subject to frequent fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;

- addition or termination of clinical trials;

- any intellectual property infringement lawsuit in which we may become involved;

- regulatory developments affecting our product candidates;

- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;

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- the achievement and timing of milestone payments under our existing collaboration and license agreements;

- the costs associated with launching and commercializing linaclotide and any of our other product candidates, if we receive regulatory approval of such candidate; and

- if linaclotide receives regulatory approval, the level of underlying demand for that product and wholesalers buying patterns.

If our operating results fall below the expectations of investors or securities analysts, the price of our Class A common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through borrowing or licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

If we need to raise additional funds by issuing equity securities as a result of unforeseen circumstances or new strategic imperatives, our existing stockholders ownership will be diluted. If we seek to raise capital through debt financing, such transactions typically require covenants that restrict operating activities. Any borrowings under debt financing will need to be repaid, which creates additional financial risk, particularly if our business or prevailing financial market conditions are not conducive to paying-off or refinancing our outstanding debt obligations at maturity.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to achieve profitability or to respond to competitive pressures would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

We have limited experience complying with public company obligations.

We face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the federal securities laws, as well as other rules of the SEC and NASDAQ, has resulted in significant initial cost to us as well as ongoing increases in our legal, audit and financial compliance costs. As a newly public company, we will soon become subject to Section 404 of the Sarbanes-Oxley Act relating to internal controls over financial reporting. Although we have not identified any material weaknesses in our internal controls over financial reporting to date, we cannot assure that our internal controls over financial reporting will prove to be effective.

The recently enacted Dodd-Frank Wall Street Reform and Protection Act includes several corporate governance and executive compensation-related provisions that will necessitate new rules and regulations by the SEC related to say on pay and proxy access, among others. Our efforts to comply with the new requirements have resulted in, and will continue to result in, an increase in our costs related to compliance and a diversion of our legal, audit and finance team s attention from other business activities.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Class A common stock.

Risks Relating to Securities Markets and Investment in Our Stock

The concentration of our capital stock ownership with our pre-IPO investors (and their affiliates), founders, directors, executives and employees will limit your ability to influence certain corporate matters.

Each share of Class A common stock and each share of Class B common stock has one vote per share on all matters except for the following matters (for which each share of our Class B common stock has ten votes per share and each share of our Class A common stock has one vote per share):

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- adoption of a merger or consolidation agreement involving Ironwood;

- a sale of all or substantially all of Ironwood s assets;

- a dissolution or liquidation of Ironwood; and,

- every matter, if and when any individual, entity or group (as such term is used in Regulation 13D of the Exchange Act has, or has publicly disclosed (through a press release or a filing with the SEC) an intent to have, beneficial ownership of 30% or more of the number of outstanding shares of Class A common stock and Class B common stock, combined.

Because of our dual class common stock structure, the holders of our Class B common stock, who consist of our pre-IPO investors (and their affiliates), founders, directors, executives and employees, will continue to be able to control the corporate matters listed above if any such matter is submitted to our stockholders for approval even if they come to own less than 50% of the outstanding shares of our common stock. As of November 1, 2010, the holders of our Class A common stock own 47.1% and the holders of our Class B common stock own 52.9% of the outstanding shares of Class A common stock and Class B common stock, combined. However, because of our dual class common stock structure these holders of our Class A common stock have 8.2% and holders of our Class B common stock have 91.8% of the total votes in each of the matters identified in the list above. This concentrated control with our Class B common stock holders limits the ability of the Class A common stockholders to influence those corporate matters and, as a result, we may take actions that many of our stockholders do not view as beneficial, which could adversely affect the market price of our Class A common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could negatively impact the market price of our Class A common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control. These provisions include the following:

- Our certificate of incorporation provides for a dual class common stock structure. As a result of this structure, our pre-IPO investors (and each of their affiliates), founders, directors, executives and employees, each of whom hold shares of our Class B common stock, will have significant influence over certain matters requiring stockholder approval, including significant corporate transactions, such as a merger. This concentrated control could discourage others from initiating a change of control transaction that other stockholders may view as beneficial.

- Our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time. This staggered board structure prevents stockholders from replacing the entire board at a single stockholders meeting.

- Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors.

- Our board of directors may issue, without stockholder approval, shares of preferred stock. The ability to authorize preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

- Stockholders must provide advance notice to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders meeting. Furthermore, stockholders may only remove a member of our board of directors for cause. These provisions may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect such acquirer s own slate of directors or otherwise attempting to obtain control of our company.

- Our stockholders may not act by written consent. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions outside of a stockholders meeting.

- Special meetings of stockholders may be called only by the chairman of our board of directors, our chief executive officer or a majority of our board of directors. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to call a special meeting.

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- A majority of the outstanding shares of Class B common stock are required to amend our certificate of incorporation and a super-majority (80%) of the outstanding shares of Class B common stock are required to amend our by-laws, which make it more difficult to change the provisions described above.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation and our bylaws and in the Delaware General Corporation Law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors.

When holders of shares of our Class B common stock convert their shares into shares of Class A common stock, a significant number of shares of our Class A common stock could be sold into the market, which could reduce the trading price of our Class A common stock and impede our ability to raise future capital.

Any holder of our Class B common stock may convert his or her shares at any time into shares of Class A common stock on a share-for-share basis. Many of our pre-IPO stockholders are now eligible to sell unlimited amounts of their shares (as converted into Class A common stock) pursuant to Rule 144 under the Securities Act of 1933, as amended. When our pre-IPO stockholders sell substantial amounts of Class A common stock into the market, the market price of our Class A common stock could decrease significantly. In addition, the perception in the market that such stockholders might sell shares could also depress the market price of our Class A common stock. We also have registered all shares of Class A common stock that we may issue under our equity compensation plans, so these shares can be freely sold in the public market upon issuance.

To the extent outstanding stock options are exercised, there will be further dilution to investors in our Class A common stock.

As of September 30, 2010, we had options to purchase 2,234,306 shares of Class A common stock and 12,346,540 shares of Class B common stock outstanding, with exercise prices ranging from $0.31 to $13.95 per share and a weighted average exercise price of $3.94 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in further dilution to investors in our Class A common stock.

We expect that the price of our Class A common stock will fluctuate substantially.

The market price of our Class A common stock may be highly volatile due to many factors, including:

- the results from our clinical trials, including our Phase 3 clinical trials for linaclotide;

- FDA or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- the commercial performance of any of our product candidates that receive marketing approval;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- sales of additional shares of our common stock;
- additions or departures of key personnel;
- any third-party coverage and reimbursement policies for linaclotide;

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- developments concerning current or future strategic collaborations; and

- discussion of us or our stock price in the financial or scientific press or in online investor communities.

The realization of any of the risks described in these Risk Factors could have a dramatic and material adverse impact on the market price of our Class A common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our Class A common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the sections titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements. Forward-looking statements convey our expectations or forecasts of future events. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, anticipate and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, among other things, statements about:

- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;

- the timing, conduct and success of our clinical studies for our product candidates;

- our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;

- our expectations regarding federal, state and foreign regulatory requirements;

- the therapeutic benefits and effectiveness of our product candidates;

- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;

- our ability to manufacture or contract to manufacture sufficient amounts of our product candidates for clinical studies and products for commercialization activities;

- our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;

- our expectations as to future financial performance, expense levels and liquidity sources;
- the timing of commercializing our product candidates;
- our plan to develop a high-quality commercial organization;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- anticipated trends and challenges in our potential markets;
- the potential changes in the trading price of our Class A common stock;
- our ability to attract and motivate key personnel; and
- other factors discussed elsewhere in this Quarterly Report on Form 10-Q.

Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. These forward-looking statements may be affected by inaccurate assumptions or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions identified under the heading Risk Factors in this Quarterly Report on Form 10-Q. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur as contemplated, and actual results could differ materially from those anticipated in or implied by the forward-looking statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

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Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

Unregistered Sales of Equity Securities

We did not repurchase any of our equity securities during the quarter ended September 30, 2010.

Use of Proceeds

In February 2010, we completed our IPO of our Class A common stock pursuant to a Registration Statement on Form S-1, as amended (File No. 333-163275) that was declared effective on February 2, 2010. Under the registration statement, we registered the offering and sale of an aggregate of 19,166,667 shares of our Class A common stock. All of the 19,166,667 shares of Class A common stock registered under the registration statement, which included 2,500,000 shares of our Class A common stock sold pursuant to an over-allotment option granted to the underwriters, were sold at a price to the public of $11.25 per share. J.P. Morgan Securities Inc., Morgan Stanley & Co. Incorporated and Credit Suisse Securities (USA) LLC acted as joint book running managers of the offering and as representatives of the underwriters. The offering commenced on February 3, 2010 and closed on February 8, 2010. The sale of shares pursuant to the over-allotment option occurred on February 12, 2010. As a result of our IPO, we raised a total of $215.6 million in gross proceeds, and approximately $203.2 million in net proceeds after deducting underwriting discounts and commissions of $10.5 million and offering expenses of $1.9 million. We did not pay, directly or indirectly, any offering expenses to any of our directors or officers or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in our planned use of proceeds from the IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on February 4, 2010. As of September 30, 2010, approximately $139.7 million of the net proceeds remained available and were invested in highly liquid, short-term, interest-bearing funds, pending their use to fund our operations. Since our IPO, we estimate that we have used the proceeds in the following way:

- approximately $23.5 million to fund the development and commercialization of linaclotide;
- approximately $4.8 million to fund the research and development of IW-6118; and
- approximately $35.1 million for general corporate purposes.

Item 6. ***Exhibits***

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q.

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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.

Ironwood Pharmaceuticals, Inc.

Date: November 12, 2010	By:	/s/ PETER M. HECHT Peter M. Hecht, Ph.D. Chief Executive Officer and Director *(Principal Executive Officer)*
Date: November 12, 2010	By:	/s/ MICHAEL J. HIGGINS Michael J. Higgins Senior Vice President, Chief Operating Officer and Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*

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EXHIBIT INDEX

Exhibit No:	Description
3.1	Eleventh Amended and Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 of Ironwood Pharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 30, 2010.
3.2	Fifth Amended and Restated Bylaws. Incorporated by reference to Exhibit 3.2 of Ironwood Pharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 30, 2010.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

* Filed herewith.

Furnished herewith.