

IRONWOOD PHARMACEUTICALS INC

Form 10-Q

November 09, 2011

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from            to

Commission file number: 001-34620

# IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**04-3404176**

(I.R.S. Employer  
Identification Number)

**301 Binney Street**

**Cambridge, Massachusetts**

(Address of Principal Executive Offices)

**02142**

(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  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of November 1, 2011, there were 59,875,478 shares of Class A common stock outstanding and 40,660,822 shares of Class B common stock outstanding.





Table of Contents**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, 2011	December 31, 2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 68,820	\$ 44,321
Available-for-sale securities	106,309	203,706
Accounts receivable	74	19
Related party accounts receivable, net	667	2,876
Prepaid expenses and other assets	2,896	5,320
Restricted cash		2,833
Total current assets	178,766	259,075
Restricted cash	7,647	7,647
Property and equipment, net	32,875	34,369
Other assets	192	274
Total assets	\$ 219,480	\$ 301,365
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,390	\$ 4,302
Accrued research and development costs	7,629	8,140
Accrued expenses	9,247	8,938
Current portion of capital lease obligations	228	197
Current portion of deferred rent	3,707	2,799
Current portion of deferred revenue	47,647	40,050
Total current liabilities	70,848	64,426
Capital lease obligations, net of current portion	481	393
Deferred rent, net of current portion	13,308	14,612
Deferred revenue, net of current portion	21,913	62,383
Commitments and contingencies (Note 8)		
Stockholders' equity:		

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Preferred stock, \$0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding

Class A common stock, \$0.001 par value, 500,000,000 shares authorized and 58,805,086 and 48,202,089 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	59	48
Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 41,684,472 and 50,970,247 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	42	51
Additional paid-in capital	538,241	526,991
Accumulated deficit	(425,418)	(367,540)
Accumulated other comprehensive income	6	1
Total stockholders' equity	112,930	159,551
Total liabilities and stockholders' equity	\$ 219,480	\$ 301,365

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

Table of Contents**Ironwood Pharmaceuticals, Inc.****Condensed Consolidated Statements of Operations****(in thousands, except share and per share amounts)****(unaudited)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Collaborative arrangements revenue	\$ 12,218	\$ 9,059	\$ 33,717	\$ 27,085
Operating expenses:				
Research and development	22,905	18,742	61,869	56,188
General and administrative	10,929	6,482	30,958	18,868
Total operating expenses	33,834	25,224	92,827	75,056
Loss from operations	(21,616)	(16,165)	(59,110)	(47,971)
Other income (expense):				
Interest expense	(16)	(81)	(49)	(178)
Interest and investment income	105	188	384	445
Other income	897		900	
Other income (expense), net	986	107	1,235	267
Net loss from continuing operations before income tax expense (benefit)	(20,630)	(16,058)	(57,875)	(47,704)
Income tax expense (benefit)	3	(2,944)	3	(2,944)
Net loss from continuing operations	(20,633)	(13,114)	(57,878)	(44,760)
Net income from discontinued operations		6,367		4,551
Net loss	(20,633)	(6,747)	(57,878)	(40,209)
Net income from discontinued operations attributable to noncontrolling interest		(1,523)		(1,121)
Net loss attributable to Ironwood Pharmaceuticals, Inc.	\$ (20,633)	\$ (8,270)	\$ (57,878)	\$ (41,330)
Net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted:				
Continuing operations	\$ (0.21)	\$ (0.13)	\$ (0.58)	\$ (0.52)
Discontinued operations		0.05		0.04
Net loss per share	\$ (0.21)	\$ (0.08)	\$ (0.58)	\$ (0.48)
Weighted average number of common shares used in net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	100,174,100	97,925,657	99,699,545	86,633,080

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





Table of Contents**Ironwood Pharmaceuticals, Inc.****Condensed Consolidated Statements of Cash Flows**

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (57,878)	\$ (40,209)
Income from discontinued operations		4,551
Loss from continuing operations	(57,878)	(44,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,323	4,245
Loss on disposal of property and equipment	8	249
Share-based compensation expense	8,511	5,136
Accretion of discount/premium on investment securities	1,851	895
Changes in assets and liabilities:		
Accounts receivable	2,154	170
Restricted cash	2,833	(2,348)
Prepaid expenses and other current assets	2,424	(1,896)
Other assets	82	(296)
Accounts payable and accrued expenses	(1,064)	3,011
Accrued research and development costs	(511)	(7,073)
Deferred revenue	(32,873)	(26,097)
Deferred rent	(396)	7,480
Net cash used in operating activities from continuing operations	(67,536)	(61,284)
Net cash used in operating activities from discontinued operations		(5,969)
Total net cash used in operating activities	(67,536)	(67,253)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(81,524)	(322,319)
Sales and maturities of available-for-sale securities	177,075	129,337
Proceeds from sale of subsidiary		9,500
Purchases of property and equipment	(6,033)	(15,090)
Proceeds from sale of property and equipment	4	
Net cash provided by (used in) investing activities from continuing operations	89,522	(198,572)
Net cash provided by investing activities from discontinued operations		1
Total net cash provided by (used in) investing activities	89,522	(198,571)
Cash flows from financing activities:		
Proceeds from initial public offering		203,167
Proceeds from exercise of stock options, stock purchase plan and issuance of restricted stock	2,719	1,215
Payments on borrowings	(206)	(1,891)

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Net cash provided by financing activities from continuing operations	2,513	202,491
Net cash used in financing activities from discontinued operations		(277)
Net cash provided by financing activities	2,513	202,214
Net increase (decrease) in cash and cash equivalents	24,499	(63,610)
Cash and cash equivalents, beginning of period	44,321	122,306
Cash and cash equivalents, end of period	\$ 68,820	\$ 58,696
Supplemental cash flow disclosures:		
Cash paid for interest (including discontinued operations)	\$ 47	\$ 308
Cash paid for income taxes	\$ 3	\$
Debt and interest paid by purchases of subsidiary	\$	\$ 1,075
Purchases under capital leases	\$ 325	\$ 529

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

Table of Contents

**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 differentiated medicines that improve patients' lives. The Company's lead product candidate is linaclotide, a guanylate cyclase type-C (GC-C) agonist being developed for the treatment of patients with irritable bowel syndrome with constipation (IBS-C) or chronic constipation (CC). The Company and its U.S. collaboration partner, Forest Laboratories, Inc. (Forest), announced in August 2011 that they submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for linaclotide. On September 29, 2011, the Company and its European partner, Almirall, S.A. (Almirall) each announced that Almirall submitted a Market Authorization Application (MAA) to the European Medicines Agency (EMA) for linaclotide for the treatment of IBS-C. The Company also has a pipeline focused on both research and development of early stage product candidates and preclinical research in multiple therapeutic areas, including gastrointestinal disease, pain and inflammation, respiratory disease and cardiovascular disease.

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) engaged in a specialty biochemicals business based on a proprietary strain-development platform. In September 2010, the Company sold its interest in Microbia to DSM Holding Company USA, Inc. (DSM) (Note 2).

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 has generated an accumulated deficit as of September 30, 2011 of approximately \$425.4 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).

**2. Summary of Significant Accounting Policies**

**Unaudited Interim Financial Statements**

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The accompanying condensed consolidated financial statements and the related disclosures as of September 30, 2011 and for the three and nine months ended September 30, 2011 and 2010 are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. ( 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, 2011. The December 31, 2010 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, 2011 and results of its operations for the three and nine months ended September 30, 2011 and 2010, and its cash flows for the nine months ended September 30, 2011 and 2010. The interim results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

**Principles of Consolidation**

The accompanying condensed consolidated financial statements of Ironwood Pharmaceuticals, Inc. include the revenue, expenses and cash flows of Microbia, over which the Company exercised control until September 21, 2010, when the Company sold its 85% 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**

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. As a result of the sale of its interest in Microbia, the Company ceased to have any financial interest in Microbia. The Company maintained no further investment in Microbia and recorded a gain on the sale of Microbia in its consolidated statements of operations of approximately \$12.2 million at the time of the sale.

Additionally, in accordance with the applicable accounting standards, the Company considered if the operations and cash flows of Microbia had been eliminated from the ongoing operations of the Company and if the Company would 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. The Company determined that Microbia met the requirements for presentation as discontinued operations and accordingly, the Company classified the assets, liabilities, operations and cash flows of Microbia as discontinued operations for all periods presented prior to the sale.

The agreement with DSM also included future contingent consideration in the form of a royalty on future sales of products incorporating Microbia's technology through the earlier of a) 2024, b) the invalidity of any Microbia patent, or c) the maximum agreed upon amount is reached. As of September 30, 2011, no amounts have been recorded for the contingent consideration in the Company's condensed consolidated financial statements.

**Use of Estimates**

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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, research and development expense, 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 consist of money market funds and certain 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 \$61.5 million and \$39.2 million at September 30, 2011 and December 31, 2010, 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

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

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 months ended September 30, 2011.

**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 primarily consist of U.S. government-sponsored securities and U.S. Treasury securities and 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 and license agreements with Almirall and Astellas Pharma Inc. (Astellas) (Note 5) for which the Company does not obtain collateral. Accounts receivable from Forest and Almirall are presented as related party accounts receivable on the condensed consolidated balance sheets as both entities own common stock of the Company.

At September 30, 2011 and December 31, 2010, accounts receivable from Forest, net of any payables due Forest, accounted for approximately 89% of the Company's total accounts receivable. At September 30, 2011 and December 31, 2010, Almirall accounted for approximately less than 1% and 10%, respectively, of the Company's total accounts receivable. At September 30, 2011 and December 31, 2010, Astellas accounted for approximately 10% and less than 1%, respectively, of the Company's total accounts receivable.

The percentages of revenue from continuing operations recognized from significant customers of the Company in the three and nine months ended September 30, 2011 and 2010 are included in the following table:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
<b>Collaborative Partner:</b>				
Forest	45%	60%	49%	60%
Almirall	48%	29%	43%	31%
Astellas	7%	11%	8%	9%

For the three and nine months ended September 30, 2011 and 2010, no additional customers accounted for more than 10% of the Company's revenue from continuing operations. 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.

### Revenue Recognition

The Company's revenue is generated through collaborative research and development and licensing agreements. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) the manufacture of active pharmaceutical ingredient ( API ) and development materials for the collaborative partner. Payments to the Company under these agreements may include non-refundable license fees, payments for research and development activities, payments for the manufacture of API and development materials, payments based upon the achievement of certain milestones 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.



Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

For arrangements that include multiple deliverables, the Company follows the provisions of the Accounting Standards Codification ( ASC ) Topic 605-25, *Revenue Recognition - Multiple-Element Arrangements*, in accounting for these agreements. Effective January 1, 2011, the Company adopted Accounting Standards Update ( ASU ) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ( ASU 2009-13 ), which amends ASC Topic 605-25. Refer to Note 2, *Recently Adopted Accounting Standards*, for additional discussion of this standard and its impact on the Company's accounting for collaboration and license agreements. In order to account for these agreements, the Company must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on if certain criteria are met, including whether the delivered element has standalone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. 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 or determinable, and collection is reasonably assured.

At September 30, 2011, the Company had collaboration and license agreements with Forest, Almirall and Astellas. Refer to Note 5, *Collaboration and License Agreements*, for additional discussion of these agreements.

There are no performance, cancellation, termination or refund provisions in any of the Company's arrangements that contain material financial consequences to the Company.

*Collaboration and License Agreements*

The significant deliverables under the Company's collaboration and license agreements generally include the license to develop and commercialize linaclotide, the Company's GC-C agonist, and may also include deliverables related to research and development activities, and the manufacture of API and development materials for the collaborative partner.

Generally, collaboration and license agreements contain non-refundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) provide research and development activities, including participation on a joint development committee, (ii) manufacture API and development materials which are reimbursed at a contractually determined rate, (iii) earn payments upon the achievement of certain milestones, and (iv) earn royalty payments on sales of linaclotide. In determining the separate units of accounting, management evaluates whether the license has standalone value to the partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of peptide research expertise in the general marketplace. In addition, the Company considers whether the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, and whether the value of the license is dependent on the undelivered items and whether there are other vendors that can provide the undelivered item.

For all of the collaboration and license agreements discussed in Note 5, the licenses and research and development activities did not qualify as separate units of accounting since the licenses did not have standalone value without the research and development activities. Up-front payments on a license are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. The Company generally estimates this period as the estimated period of performance, which is typically the research and development term due to the Company's continuing involvement in the performance of research and development activities, primarily through its participation on a joint development committee. Typically the research and development term begins at the inception of the collaboration or license agreement and concludes when the Company's significant research and development obligations under the agreement have concluded. The Company believes this period of involvement is 60 months for the Forest collaboration, 41 months for the Almirall license agreement and 115 months for the Astellas license agreement. Quarterly, the Company reassesses its periods of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. In the event that a license were to be terminated, the Company would recognize as revenue any portion of the up-front fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

Up-front payments on a license may be recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered elements, which generally include research and development activities and manufacture of API and development materials.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

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. 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. Refer to Note 5 for details on the specific milestones in each of the Company's agreements.

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 has historically recognized as revenue on the date the milestone was achieved an amount equal to the applicable percentage of the performance period that had elapsed as of the date the milestone was achieved, with the balance being deferred and recognized on a straight-line basis over the remaining period of performance. Effective January 1, 2011, the Company adopted ASU No. 2010-17, *Revenue Recognition - Milestone Method* (ASU 2010-17). Refer to Note 2, *Recently Adopted Accounting Standards*, for additional discussion of the adoption of this standard and its prospective impact on the Company's accounting for collaboration and license agreements. Under ASU 2010-17, beginning January 1, 2011, in those circumstances where a substantive milestone is achieved and collection of the related receivable is reasonably assured, the Company will recognize revenue related to the milestone in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Milestone payments received in prior periods will continue to be recognized based upon the remaining period of performance.

The Company produces development materials and API for its collaborators and is reimbursed for its costs to produce the material. The Company recognizes revenue on development material and API when the material has passed all quality testing required for collaborator acceptance, delivery has occurred, title and risk of loss have transferred to the collaborator, the price is fixed or determinable, and collection is reasonably assured.

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.

**Services Revenue**

Prior to September 2010, 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 or 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 from discontinued operations.

### **Research and Development Costs**

The Company expenses research and development costs to operations as incurred. The Company defers and capitalizes non-refundable 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 are comprised of 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 from discontinued operations.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

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 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.

### **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 unvested restricted stock and 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 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 income (loss) per share attributable to both continuing and discontinued operations. The income attributable to the noncontrolling interest is included in the net income 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.

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, 2011 and December 31, 2010. Management reevaluates the positive and negative evidence on a quarterly basis.

Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(unaudited)**

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.

**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, 2011.

**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 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):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Net loss attributable to Ironwood Pharmaceuticals, Inc.	\$ (20,633)	\$ (8,270)	\$ (57,878)	\$ (41,330)
Change in unrealized gain (loss) on investments	(47)	4	5	48
Comprehensive loss attributable to Ironwood Pharmaceuticals, Inc.	\$ (20,680)	\$ (8,266)	\$ (57,873)	\$ (41,282)

**Segment Information**

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 from discontinued operations.

### **New Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ( 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 Adopted Accounting Standards*

In October 2009, the FASB issued ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC 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



Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

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. On January 1, 2011, the Company adopted ASU 2009-13 on a prospective basis. The adoption did not have a material impact on the Company's consolidated financial position or results of operations.

In April 2010, the FASB issued ASU 2010-17. ASU 2010-17 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, if the milestone meets all the criteria within the guidance to be considered substantive. This ASU is effective for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. On January 1, 2011, the Company adopted ASU 2010-17 to change its accounting policy to begin applying the milestone method on a prospective basis. As the Company elected prospective adoption, there was no material impact on its consolidated financial position or results of operations. However, the adoption of ASU 2010-17 is expected to impact the Company's accounting for any milestone payments received in future periods.

*Recently Issued Accounting Standards*

In December 2010, the FASB issued ASU No. 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers* (ASU 2010-27) which provides guidance on how to recognize and classify the fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (together, the Acts). The Acts impose an annual fee for each calendar year beginning on or after January 1, 2011 payable by branded prescription drug manufacturers and importers on branded prescription drugs. The liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation over the calendar year that it is payable. ASU 2010-27 is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective. As the Company does not currently have a commercial product, the effect of this guidance will be limited to future transactions.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards (IFRS) as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders' equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company expects to adopt this standard beginning in 2012. As ASU 2011-05 impacts presentation only, it will have no effect on the Company's consolidated financial position or 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 expenses.

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.

Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(unaudited)****4. Net Loss Per Share**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
<b>Numerator:</b>				
Net loss from continuing operations	\$ (20,633)	\$ (13,114)	\$ (57,878)	\$ (44,760)
Net income from discontinued operations		6,367		4,551
Less: net income from discontinued operations attributable to noncontrolling interest		(1,523)		(1,121)
Net income from discontinued operations attributable to Ironwood Pharmaceuticals, Inc.		4,844		3,430
Net loss attributable to Ironwood Pharmaceuticals, Inc.	\$ (20,633)	\$ (8,270)	\$ (57,878)	\$ (41,330)
<b>Denominator:</b>				
Weighted average number of common shares used in net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	100,174,100	97,925,657	99,699,545	86,633,080
Net loss per share associated with continuing operations	\$ (0.21)	\$ (0.13)	\$ (0.58)	\$ (0.52)
Net income per share associated with discontinued operations attributable to Ironwood Pharmaceuticals, Inc.	\$	\$ 0.05	\$	\$ 0.04
Net loss per share attributable to Ironwood Pharmaceuticals, Inc. basic and diluted	\$ (0.21)	\$ (0.08)	\$ (0.58)	\$ (0.48)

The net income attributable to noncontrolling interest is reflected in the net income 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, 2011 and 2010, as they would be anti-dilutive:

**At September 30,**

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

	2011	2010
Options to purchase common stock	15,861,198	14,580,846
Shares subject to repurchase	181,807	311,841
	16,043,005	14,892,687

### 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 IBS-C, CC and other 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 U.S. 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 the license to jointly develop and commercialize linaclotide did not have standalone value without the research and development activities provided by the Company, the Company is recognizing the up-front license fee as revenue on a straight-line basis over 60 months, which is the Company's estimate of the period over which linaclotide will be jointly developed under the collaboration. At September 30, 2011, approximately \$13.4 million of the up-front license fee remains deferred and is being recognized on a straight-line basis.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

over the remaining estimated development period. The collaboration agreement also includes contingent milestone payments, as well as a contingent equity investment based on the achievement of specific development and commercial milestones. These payments, including the up-front license fee, could total up to \$330.0 million if certain development and sales milestones are achieved for linaclotide. At September 30, 2011, \$100.0 million in license fees and milestone payments has already been received and Forest made the equity investment when it purchased \$25.0 million of the Company's capital stock. Of the remaining milestones, each of which the Company considers substantive, pre-commercial milestone payments could total up to \$20.0 million upon NDA acceptance by the FDA and up to \$85.0 million upon NDA approval. The Company can also achieve up to approximately \$100.0 million in a sales related milestone if certain conditions are met.

The collaboration agreement included a contingent equity investment, in the form of a forward purchase contract, which required Forest to purchase shares of the Company's convertible preferred stock, upon achievement of a specific clinical milestone. Based on the Company's evaluation, this financial instrument was considered an asset or liability, which was required to be carried at fair value. At the inception of the arrangement, the Company valued the contingent equity investment and recorded a \$9.0 million asset and incremental deferred revenue. 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 60 months from the inception of the arrangement. At September 30, 2011, approximately \$1.7 million of the incremental deferred revenue remains deferred. In July 2009, the Company achieved the clinical milestone triggering the equity investment and 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 Company has achieved two of the development milestones under this agreement, both of which the Company determined to be substantive. In September 2008, the Company achieved a clinical milestone which triggered a \$10.0 million milestone payment and in July 2009, the Company achieved a second clinical milestone which triggered a \$20.0 million milestone payment. At September 30, 2011, approximately \$1.9 million and \$3.8 million of the milestone payments, respectively, remain deferred and are being recognized on a straight-line basis over the remaining estimated development period.

The Company recognized revenue from the Forest collaboration agreement totaling approximately \$5.5 million during both the three months ended September 30, 2011 and 2010 and approximately \$16.4 million during both the nine months ended September 30, 2011 and 2010.

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 \$0.3 million and \$7.2 million during the three and nine months ended September 30, 2011, respectively, and approximately \$4.5 million and \$12.9 million during the three and nine months ended September 30, 2010, 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 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 the license to develop and commercialize linaclotide did not have standalone value without the research and development activities provided by the Company, the Company is recognizing the up-front license fee as revenue on a straight-line basis over the development period, the Company's estimate of the period over which linaclotide will be developed under the license agreement for the European territory. In June 2011, the Company revised its estimate of the development period from 50 months to 41 months and adjusted its amortization of the remaining deferred revenue accordingly. At September 30, 2011, approximately \$14.3 million of the up-front license fee remains deferred. The license agreement also includes contingent milestone payments, as well as a contingent equity investment, that could total up to \$55.0 million upon achievement of specific clinical and sales milestones. At September 30, 2011, \$19.0 million, net of foreign withholding taxes, in milestone payments has already been received and Almirall made the equity investment when it purchased \$15.0 million of the Company's capital stock. Remaining pre-commercial milestone payments, each of which the Company

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

considers substantive, consist of \$4.0 million due upon the first commercial launch in each of the five major E.U. countries set forth in the agreement.

The license agreement included a contingent equity investment, in the form of a forward purchase contract, which required Almirall to purchase shares of the Company's convertible preferred stock, upon achievement of a specific clinical milestone. Based on the Company's evaluation, this financial instrument was considered an asset or liability, which was required to be carried at fair value. The contingent equity investment was valued at inception at its fair value. At the inception of the arrangement, the Company valued the contingent equity investment and recorded a \$6.0 million asset and incremental deferred revenue. 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 was originally estimated to be 50 months and was revised in June 2011 to 41 months. The reduction in the development period was recorded as a change in estimate and deferred revenue will be recorded over the revised period on a prospective basis. At September 30, 2011, approximately \$2.3 million of the incremental deferred revenue remains deferred. In November 2009, the Company achieved the clinical milestone triggering the equity investment and 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.

In November 2010, the Company achieved a second development milestone under the Almirall license agreement, which the Company determined to be substantive, which resulted in a \$19.0 million payment, representing a \$20.0 million milestone, net of foreign withholding taxes. The Company recognized revenue of approximately \$7.2 million upon achievement of the milestone. This amount represented the portion of the milestone payment equal to the applicable percentage of the performance period that had elapsed as of the date the milestone was achieved. The remainder of the balance was deferred, and is being recognized on a straight-line basis over the remaining development period. At September 30, 2011, approximately \$7.1 million of the milestone payment remains deferred.

The Company recognized approximately \$5.9 million and \$14.6 million in total revenue from the Almirall license agreement during the three and nine months ended September 30, 2011, respectively, including approximately \$0 and \$0.5 million, respectively, from the sale of API to Almirall. During the three and nine months ended September 30, 2010, the Company recognized approximately \$2.6 million and \$8.3 million, respectively, in total revenue from the Almirall license agreement, including approximately \$0 and \$0.4 million, respectively, from the sale of API to Almirall.

**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 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, each of which the Company considers substantive, that could total up to \$45.0 million. These milestone payments consist of \$15.0 million upon initiation of a Phase 3 study for linaclotide in Japan, \$15.0 million upon filing of the Japanese equivalent of an NDA with the relevant regulatory authority in Japan, and \$15.0 million upon approval of such equivalent by the relevant regulatory authority. 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 the license to develop and commercialize linaclotide did not have standalone value without the research and development activities provided by the Company, 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, 2011, approximately \$25.0 million of the up-front license fee remains deferred. During the three and nine months ended September 30, 2011, the Company recognized approximately \$0.9 million and \$2.7 million, respectively, in revenue from the Astellas license agreement, including approximately \$0.1 million and \$0.4 million, respectively, from the sale of clinical materials to Astellas. 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.



Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

**Protagonist Therapeutics, Inc.**

The Company entered into a collaboration agreement with Protagonist Therapeutics, Inc. and Protagonist Pty Ltd. (collectively "Protagonist") in January 2011. Under this agreement, Protagonist will use its proprietary technology platform to discover peptides against certain targets and the Company has the rights to develop and commercialize these peptides. In connection with entering into the agreement, the Company made an up-front payment to Protagonist of approximately \$2.8 million. In accordance with the applicable accounting guidance, the Company expensed the up-front payment as research and development expense. The Company also funds full-time equivalents for Protagonist's drug discovery activities, and will make certain milestone and royalty payments pending the achievement of certain development and commercialization milestones. The Company will expense these payments as incurred. During the three and nine months ended September 30, 2011, the Company recorded approximately \$0.6 million and \$4.4 million, respectively, in research and development expense, including the up-front payment, associated with the Protagonist agreement.

**Depomed, Inc.**

On July 27, 2011, the Company entered into a collaboration and license agreement with Depomed, Inc. ("Depomed") in which it has licensed the rights to Depomed's Acuform gastric retentive drug delivery technology. In connection with entering into the agreement, the Company made an up-front payment to Depomed of approximately \$0.9 million. In accordance with the applicable accounting guidance, the Company expensed the up-front payment as research and development expense. The Company also funds full-time equivalents of certain of Depomed's development activities, and could make certain milestone and royalty payments pending the achievement of certain development and commercialization milestones. The Company will expense these payments as incurred. During the three and nine months ended September 30, 2011, the Company recorded approximately \$1.0 million in research and development expense, including the up-front payment, associated with the Depomed agreement.

**6. Fair Value of Financial Instruments**

The tables below present information about the Company's assets that are measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 and indicate 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.

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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):

Description	Fair Value Measurements at Reporting Date Using			
	September 30, 2011	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)	\$ 61,495	\$ 61,495		\$
U.S. government-sponsored securities	54,326		54,326	
U.S. Treasury securities	51,983	51,983		
Total	\$ 167,804	\$ 113,478	\$ 54,326	\$

Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

Description	December 31, 2010	Fair Value Measurements at Reporting Date Using		
		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)	\$ 36,228	\$ 36,228	\$	\$
U.S. government-sponsored securities (included in cash and cash equivalents)	2,998		2,998	
U.S. Treasury securities	116,219	116,219		
U.S. government-sponsored securities	87,487		87,487	
Total	\$ 242,932	\$ 152,447	\$ 90,485	\$

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and the current portion of capital lease obligations at September 30, 2011 and December 31, 2010 are carried at amounts that approximate fair value due to their short-term maturities.

Capital lease obligations at September 30, 2011 and December 31, 2010 approximate fair value as they bear interest at a rate approximating a market interest rate.

**7. Available-for-Sale Investments**

The following tables summarize the available-for-sale securities held at September 30, 2011 and December 31, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>September 30, 2011:</b>				
U.S. government-sponsored securities	\$ 54,344	\$ 4	\$ (22)	\$ 54,326
U.S. Treasury securities	51,959	24		51,983
Total	\$ 106,303	\$ 28	\$ (22)	\$ 106,309

Amortized Cost	Gross Unrealized	Gross Unrealized	Fair Value
----------------	---------------------	---------------------	------------

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

			Gains		Losses		
<b>December 31, 2010:</b>							
U.S. government-sponsored securities	\$	87,503	\$	3	\$	(19)	\$ 87,487
U.S. Treasury securities		116,200		24		(5)	116,219
Total	\$	203,703	\$	27	\$	(24)	\$ 203,706

The contractual maturity of all securities held at September 30, 2011 was one year or less. There were sixteen investments in an unrealized loss position at September 30, 2011, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities was approximately \$44.6 million. 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 Company did not hold any securities with an other-than-temporary impairment at September 30, 2011.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

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 its facility and various equipment under leases that expire at varying dates through 2018. Certain of these leases contain renewal options, and require the Company to pay operating costs, including property taxes, insurance and maintenance.

In January 2007, the Company entered into a lease agreement for 113,646 rentable square feet of office and lab space at 301 Binney Street, Cambridge, Massachusetts. The initial term of the lease is eight years expiring in January 2016, and the Company has the right to extend the initial term for two additional terms of five years each. The Company's occupancy of the space occurred in four distinct phases, and rent for each phase commenced at the earlier of a contractually set date or the occupancy date. Base rent for the space ranges from \$49.25 to \$60.50 per rentable square foot per year. Base rent escalates in January 2012 based upon a formula that is tied to the Consumer Price Index. The space was delivered to the Company in September 2007, and rent payments for the initial occupancy commenced in January 2008. The rent expense, inclusive of the escalating rent payments and free rent period is recognized on a straight-line basis over the term of the lease agreement. In accordance with the terms of the lease agreement, in the second quarter of 2010, the Company increased the letter of credit securing its obligations under the lease agreement by approximately \$2.3 million.

The Company amended the lease agreement in February 2010, July 2010 and February 2011 (together the Amendments) in order to lease additional space. Pursuant to the Amendments, the Company leases an additional 80,340 rentable square feet of the 301 Binney Street building, comprised of (a) an initial phase of 35,444 rentable square feet (the Initial Phase), (b) a second phase of 21,589 rentable square feet (the Second Phase) and (c) a third phase of 23,307 rentable square feet (the Third Phase). Rent for the Initial Phase commenced on July 1, 2010, rent for the Second Phase commenced on March 1, 2011 and rent for the Third Phase will commence no later than February 15, 2012. Initial base rent for the Initial Phase is \$42.00 per rentable square foot per year and the initial base rent for the Second Phase and Third Phase is \$42.50 per rentable square foot per year. Base rent for the Initial Phase, Second Phase and Third Phase will increase annually by \$0.50 per rentable square foot. The Amendments do not change the expiration date of the lease agreement.

The landlord has reimbursed the Company for its tenant improvements for the space occupied prior to the Amendments at a set rate per rentable square foot. Under the terms of the Amendments, the landlord has or will provide the Company with an allowance for the expansion space, which consists of \$55.00 per rentable square foot for tenant improvements in the Initial Phase and the Second Phase and an allowance of \$40.00 per rentable square foot for the Third Phase. As of September 30, 2011, approximately \$15.9 million has been paid to the Company as reimbursement for tenant improvements under the lease agreement, including the Amendments. The reimbursement amount is recorded as deferred rent on the condensed consolidated balance sheets and is being amortized as a reduction to rent expense over the term of the lease agreement.

The Company, and in some cases, along with its collaboration partner, Forest, has entered into multiple commercial supply agreements for the purchase of linaclotide API and drug product. Some of the agreements contain minimum purchase commitments, the earliest of which commences in 2012. As of September 30, 2011, the Company's minimum purchase requirement across all the agreements is approximately \$45.0 million through 2017.

#### **9. Restricted Stock**

In 2009, the Company granted 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 Amended and Restated 2005 Stock Incentive Plan ( "2005 Plan" ) and the Company's director compensation program. 115,549 shares of restricted common stock granted 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 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.

Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(unaudited)**

A summary of the unvested shares of restricted stock as of September 30, 2011 is presented below:

	Shares		Weighted Average Grant Date Fair Value
Unvested at December 31, 2010	270,000	\$	5.69
Granted		\$	
Vested	(62,500)	\$	5.71
Forfeited	(27,500)	\$	5.48
Unvested at September 30, 2011	180,000	\$	5.72

**10. Stock Option Plans**

The Company has several share-based compensation plans under which stock options, restricted stock, restricted stock units, and other share-based awards are available for grant to employees, directors and consultants of the Company. At September 30, 2011 and December 31, 2010, options for 3,013,488 and 5,574,857 shares, respectively, were available for future grant under the plans.

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, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Expected volatility	49.6%	57.5%	43.5%	57.7%
Expected term (in years)	6.5	6.5	6.5	6.5

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Risk-free interest rate	2.2%	2.3%	2.7%	3.0%
Expected dividend yield	%	%	%	%

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		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
<b>Ironwood:</b>				
Employee stock options	\$ 2,645	\$ 1,572	\$ 7,888	\$ 4,437
Restricted stock awards	108	121	323	348
Non-employee stock options	35	127	113	185
ESPP	67	55	165	55
Stock awards	7	8	22	111
	2,862	1,883	8,511	5,136
Microbia Stock Plan (included in discontinued operations)		14		59
	\$ 2,862	\$ 1,897	\$ 8,511	\$ 5,195



Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(unaudited)**

Share-based compensation is reflected in the condensed consolidated statements of operations as follows for the three and nine months ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Research and development	\$ 1,653	\$ 1,093	\$ 4,456	\$ 2,849
General and administrative	1,209	790	4,055	2,287
Net loss from discontinued operations		14		59

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

	Shares of Common Stock Attributable to Options	Weighted Average Exercise Price	Weighted Average Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2010	14,603,229	\$ 4.25	6.44	\$ 91,575
Granted	2,783,550	\$ 12.13		
Exercised	(1,308,892)	\$ 1.80		
Cancelled	(216,689)	\$ 8.32		
Outstanding at September 30, 2011	15,861,198	\$ 5.78	6.48	\$ 84,672
Vested or expected to vest at September 30, 2011	14,545,649	\$ 5.72	6.41	\$ 78,389
Exercisable at September 30, 2011(1)	6,880,386	\$ 3.24	4.96	\$ 52,446

(1) All stock options granted under the 1998 Amended and Restated Stock Option Plan, the Amended and Restated 2002 Stock Incentive Plan and the 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, 2011.

The weighted average grant date fair value per share of options granted to employees during the three and nine months ended September 30, 2011 was approximately \$7.86 and \$6.32, respectively, and approximately \$6.04 and \$6.58 during the three and nine months ended September 30, 2010, respectively. The grant date fair value of the options granted to employees during the three and nine months ended September 30, 2011 was approximately \$2.7 million and \$17.6 million, respectively, and approximately \$2.2 million and \$14.7 million during the three and nine months ended September 30, 2010, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2011 was approximately \$2.6 million and \$15.4 million, respectively, and approximately \$5.7 million and \$14.1

million during the three and nine months ended September 30, 2010, respectively.

As of September 30, 2011, there was approximately \$1.0 million and \$23.7 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 2.3 years and 3.1 years, respectively. 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 in the Company. The Company paid approximately \$29,000 and \$124,000 in legal fees to this investor during the three and nine months ended September 30, 2011, respectively, and approximately \$96,000 and \$196,000 during the three and nine months ended September 30, 2010, respectively.

Table of Contents**Ironwood Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(unaudited)**

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).

**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.

The following table reports revenue and loss from operations for the Company's reportable segments for the three and nine months ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Revenue:</b>				
Human therapeutics	\$ 12,218	\$ 9,059	\$ 33,717	\$ 27,085
Bio manufacturing (included in discontinued operations)				1,985
Total	\$ 12,218	\$ 9,059	\$ 33,717	\$ 29,070
<b>Loss from operations:</b>				
Human therapeutics	\$ (21,616)	\$ (16,165)	\$ (59,110)	\$ (47,971)
Bio manufacturing (included in discontinued operations)		(2,790)		(4,531)
Total	\$ (21,616)	\$ (18,955)	\$ (59,110)	\$ (52,502)
			<b>September 30,</b>	<b>December 31,</b>
			<b>2011</b>	<b>2010</b>
<b>Total assets:</b>				
Human therapeutics			\$ 219,480	\$ 301,365
Bio manufacturing (included in discontinued operations)				
Total			\$ 219,480	\$ 301,365

At September 30, 2011 and December 31, 2010, all of the Company's accounts receivable related to the human therapeutics segment.

**13. State Grant**

In May 2011, the Company recorded approximately \$0.9 million as a receivable associated with the Life Sciences Tax Incentive Program from the Massachusetts Life Sciences Center. The program was established in 2008 in order to incentivize life sciences companies to create new sustained jobs in Massachusetts. Jobs must be maintained for at least five years, during which time the grant proceeds can be recovered by the Massachusetts Department of Revenue ( DOR ) if the Company does not meet and maintain its job creation commitments. The Company received the funds in July 2011 and recognized the award as other income in its condensed consolidated statement of operations in September 2011, as the Company believes it has satisfied its job creation commitments. The Company's hiring plan for 2011-2015 is significantly in excess of the hiring requirement for the 5 year period, as such, the Company believes that the likelihood of recovery of the award by the DOR is remote.

Table of Contents

**Ironwood Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(unaudited)**

**14. Subsequent Events**

In October 2011, the Company entered into a Fifth Amendment to its lease for 301 Binney Street. Under the amended lease, the Company leases an additional 21,717 square feet of the 301 Binney Street building. Rent for the additional space commences no later than June 1, 2012 and base rent will be \$42.50 per rentable square foot per year, and will increase annually by \$0.50 per rentable square foot. The landlord will provide the Company with a finish work allowance of \$40.00 per rentable square foot of additional space rented pursuant to this amendment. The Amendment does not change the January 2016 expiration date of the original lease.

On October 24, 2011, the Company and Forest announced that the FDA accepted the NDA for IBS-C and CC for review. As a result, the Company achieved two pre-commercial milestones under which it will receive total milestone payments of \$20.0 million (Note 5).

Table of Contents

**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, 2010 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 differentiated medicines that improve patients' lives. To achieve this, we are building a team, a culture and processes centered on creating and marketing important new drugs. We believe that linaclotide, our guanylate cyclase type-C, or GC-C, agonist being developed for the treatment of patients with irritable bowel syndrome with constipation, or IBS-C, or chronic constipation, or CC, could present patients and healthcare practitioners with a unique therapy for a major medical need not yet met by existing therapies. Linaclotide is our only product candidate that has demonstrated clinical proof of concept. On August 9, 2011, we and our U.S. collaboration partner, Forest Laboratories, Inc., or Forest, announced that we submitted a New Drug Application, or NDA, for the treatment of IBS-C and CC with the U.S. Food and Drug Administration, or FDA. On October 24, 2011, we and Forest announced that the FDA accepted the NDA for review. On September 29, 2011, we and our European partner, Almirall, S.A., or Almirall, each announced that Almirall submitted a Market Authorization Application, or MAA, to the European Medicines Agency, or EMA for linaclotide for the treatment of IBS-C. In addition to linaclotide, we have a pipeline of early stage, pre-proof of concept development candidates in multiple therapeutic areas, including gastrointestinal disease, pain and inflammation, and respiratory disease. We are also conducting early stage, preclinical research in these therapeutic areas, as well as in the area of cardiovascular disease. We have pursued a partnering strategy for commercializing linaclotide that has enabled us to retain significant control over linaclotide's development and commercialization, share the costs with high-quality collaborators whose capabilities complement ours, and retain approximately half of linaclotide's future long-term value 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, engaged 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

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

biomanufacturing segment. Our biomanufacturing segment, which comprised a much smaller part of our business, consisted of our majority ownership interest in Microbia. For the three and nine months ended September 30, 2010, results of operations of our biomanufacturing segment are included in net income 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 \$20.6 million and \$57.9 million in the three and nine months ended September 30, 2011, respectively, and approximately \$8.3 million and \$41.3 million in the three and nine months ended September 30, 2010, respectively. As of September 30, 2011, we had an accumulated deficit of approximately \$425.4 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, and our license agreements with Almirall, and Astellas Pharma Inc., or Astellas. The terms of these agreements include

Table of Contents

payment to us of one or more of the following: non-refundable, up-front license fees; milestone payments; payments for providing active pharmaceutical ingredient, or API; and royalties on product sales. Revenue from our human therapeutics segment is shown in our condensed consolidated statements of operations as collaborative arrangements revenue. As a result of the sale of our interest in Microbia, as discussed above, revenue from our biomanufacturing segment is included in net income from discontinued operations. We expect our revenue to fluctuate for the foreseeable future as our collaborative arrangements revenue is principally based on the achievement of pre-commercial and commercial milestones. During the fourth quarter of 2011, we expect an increase in our collaborative arrangements revenue as we achieved the pre-commercial milestones related to the FDA's acceptance of our NDA in October 2011, resulting in milestone payments of \$20.0 million due from Forest.

*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, research and development related 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 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 being developed for the treatment of IBS-C and CC and is our only product candidate that has demonstrated clinical proof of concept. Linaclotide achieved positive results in each of our two Phase 3 IBS-C trials and in each of our two Phase 3 CC trials. An NDA for linaclotide with respect to both IBS-C and CC was submitted to the FDA and accepted for review in October 2011, and an MAA for linaclotide for IBS-C was submitted to the EMA in September 2011. We have a pipeline of early stage, pre-proof of concept development candidates in multiple therapeutic areas, including gastrointestinal disease, pain and inflammation, and respiratory disease. We are also conducting early stage, preclinical research in these therapeutic areas, as well as in the area of cardiovascular disease.

The following table sets forth our research and development expenses related to our product pipeline for the three and nine months ended September 30, 2011 and 2010. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs. Costs related to facilities, depreciation, share-based compensation and research and development support services are not directly charged to programs.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
	(in thousands)		(in thousands)	
Demonstrated clinical proof of concept	\$ 6,290	\$ 5,507	\$ 15,241	\$ 20,716
Early stage, pre-proof of concept	3,916	3,727	9,328	9,005
Early stage, preclinical	3,606	1,466	10,813	4,637

We began tracking program expenses for linaclotide in 2004, and research and development program expenses from inception to September 30, 2011 were approximately \$138.6 million. 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.



## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The lengthy process of securing 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 our other product candidates 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, or any of our other product candidates will generate revenues and cash flows.

We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data. In addition, we are actively engaged in evaluating externally-discovered drug candidates at all stages of development. In evaluating potential assets, we apply the same criteria as those used for investments in internally-discovered assets.

Table of Contents

Historically, the majority of our external costs are related to linaclotide, as costs associated with later stage clinical trials are, in most cases, more significant than those incurred in earlier stages. We expect external costs related to the linaclotide program to continue to decrease provided that no other clinical trials are necessary to obtain regulatory approval in the U.S. If our other product candidates are successful in early stage clinical trials, we would expect external costs to increase as the programs progress through later stage clinical trials. Additionally, we expect our external costs to increase as we invest in externally-discovered drug candidates through arrangements such as our collaboration with Protagonist Therapeutics, Inc. and Protagonist Pty Ltd. (collectively Protagonist) and Depomed, Inc., or Depomed. During the three and nine months ended September 30, 2011, we recorded approximately \$1.6 million and \$5.4 million, respectively, in early stage, preclinical research and development expense associated with the Protagonist and Depomed agreements, including combined up-front payments of approximately \$3.7 million. The remainder of our 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 preclinical and 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, including externally-discovered product candidates, 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, corporate development, commercial and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs and professional fees for accounting and legal services. As a result of our initial public offering, or IPO, in February 2010, we experienced increases in general and administrative expense relating to operating as a public company. These increases included 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 fees for investor relations services. We anticipate general and administrative expenses to continue to increase as we develop our infrastructure and organization necessary to commercialize and support linaclotide.

Table of Contents

**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 U.S., 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 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, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13, and ASU No. 2010-17, *Revenue Recognition - Milestone Method*, or ASU 2010-17, as discussed in Note 2, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Other than the adoption of these two standards, there have been no significant changes to our critical accounting policies. In June 2011, we revised our estimate of the development period associated with our Almirall license agreement from 50 months to 41 months and adjusted the amortization of the remaining deferred revenue accordingly. Other than this change in estimate, there were no other significant changes in our critical accounting estimates, including as a result of the adoption of these standards. 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, 2011 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.

Table of Contents**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,	
	2011	2010	2011	2010
	(in thousands)		(in thousands)	
Collaborative arrangements revenue	\$ 12,218	\$ 9,059	\$ 33,717	\$ 27,085
Operating expenses:				
Research and development	22,905	18,742	61,869	56,188
General and administrative	10,929	6,482	30,958	18,868
Total operating expenses	33,834	25,224	92,827	75,056
Loss from operations	(21,616)	(16,165)	(59,110)	(47,971)
Other income (expense):				
Interest expense	(16)	(81)	(49)	(178)
Interest and investment income	105	188	384	445
Other income	897		900	
Other income (expense), net	986	107	1,235	267
Net loss from continuing operations before income tax expense (benefit)	(20,630)	(16,058)	(57,875)	(47,704)
Income tax expense (benefit)	3	(2,944)	3	(2,944)
Net loss from continuing operations	(20,633)	(13,114)	(57,878)	(44,760)
Net income from discontinued operations		6,367		4,551
Net loss	(20,633)	(6,747)	(57,878)	(40,209)
Net income from discontinued operations attributable to noncontrolling interest		(1,523)		(1,121)
Net loss attributable to Ironwood Pharmaceuticals, Inc.	\$ (20,633)	\$ (8,270)	\$ (57,878)	\$ (41,330)

**Three and Nine Months Ended September 30, 2011 Compared to Three and Nine Months Ended September 30, 2010***Revenue*

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$	%	2011	2010	\$	%
	(dollars in thousands)				(dollars in thousands)			
Collaborative arrangements revenue	\$ 12,218	\$ 9,059	\$ 3,159	34.9%	\$ 33,717	\$ 27,085	\$ 6,632	24.5%

*Collaborative Arrangements Revenue.* The increase in revenue of approximately \$3.2 million from collaborative arrangements for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was primarily related to the Almirall license agreement. The receipt of the \$19.0 million milestone payment, net of foreign withholding taxes, in November 2010 resulted in the recognition

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

of approximately \$1.8 million in revenue during the three months ended September 30, 2011 compared with none during the three months ended September 30, 2010. Additionally, in June 2011, we revised our estimate of the development period associated with the Almirall license agreement which resulted in approximately \$1.5 million in additional revenue recognized during the three months ended September 30, 2011 related to the up-front payment and the amortization of the deferred revenue associated with the forward purchase contract. These increases were partially offset as we recognized approximately \$0.1 million less in revenue in the three months ended September 30, 2011 from shipments of clinical trial materials to Almirall and Astellas than in the corresponding period in 2010.

The increase in revenue of approximately \$6.6 million from collaborative arrangements for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was primarily due to the receipt of the \$19.0 million milestone payment, net of foreign withholding taxes, in November 2010 related to the Almirall license agreement. In the nine months ended September 30, 2011, we recognized approximately \$4.3 million related to this milestone payment compared with none during the nine months ended September 30, 2010. In June 2011, we revised our estimate of the development period associated with the Almirall

Table of Contents

license agreement which resulted in approximately \$2.0 million in additional revenue recognized during the nine months ended September 30, 2011 related to the up-front payment and the amortization of the deferred revenue associated with the forward purchase contract. Additionally, we recognized approximately \$0.5 million more in revenue from the up-front license payment related to the Astellas agreement during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010, as the development period and related amortization did not commence until March 2010. These increases were partially offset as we recognized approximately \$0.1 million less in revenue in the nine months ended September 30, 2011 from shipments of clinical trial materials to Almirall and Astellas than in the corresponding period in 2010.

*Operating Expenses*

	Three Months Ended				Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2011	2010	\$	%	2011	2010	\$	%
	(dollars in thousands)				(dollars in thousands)			
<b>Operating Expenses:</b>								
Research and development	\$ 22,905	\$ 18,742	\$ 4,163	22.2%	\$ 61,869	\$ 56,188	\$ 5,681	10.1%
General and administrative	10,929	6,482	4,447	68.6%	30,958	18,868	12,090	64.1%
Total operating expenses	\$ 33,834	\$ 25,224	\$ 8,610	34.1%	\$ 92,827	\$ 75,056	\$ 17,771	23.7%

*Research and Development Expense.* The increase in research and development expense of approximately \$4.2 million for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was primarily due to an increase of approximately \$2.5 million in compensation, benefits, share-based compensation, and other employee related expenses primarily due to increased headcount, an increase of approximately \$1.6 million in external research costs related to the research and development fees paid to Protagonist and Depomed, and an increase of approximately \$0.3 million in support of linaclotide. The increased contract manufacturing expense of \$1.3 million was partially offset by a decrease of approximately \$1.0 million due to lower clinical trial and net collaboration reimbursements as our CC and IBS-C trials were completed at the end of 2010.

The increase in research and development expense of approximately \$5.7 million for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was primarily due to an increase of approximately \$7.3 million in compensation, benefits, share-based compensation, and other employee related expenses primarily due to increased headcount, an increase of approximately \$5.4 million in external research costs related to the license and research and development fees paid to Protagonist and Depomed, and an increase of approximately \$1.0 million in external consulting costs primarily related to the preparation of the linaclotide NDA and developing the infrastructure to support post-approval compliance of linaclotide and an increase of approximately \$0.9 million in research and development related facilities and support costs associated with the additional space we leased in our 301 Binney Street facility, partially offset by a decrease of approximately \$8.8 million in support of the development of linaclotide, primarily resulting from lower clinical trial, manufacturing and net collaboration reimbursements as our CC and IBS-C trials were completed at the end of 2010.

*General and Administrative Expense.* The increase in general and administrative expense of approximately \$4.4 million for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to an increase of approximately \$2.2 million in compensation and benefits related expenses due to increased headcount, including share-based compensation expense primarily related to our new hire and annual stock option grants, an increase of approximately \$0.6 million in general and administrative related facilities costs associated with the additional space we leased in our 301 Binney Street facility, and an increase in external consulting costs, net of Forest reimbursement, of approximately \$1.4 million associated with developing the infrastructure to commercialize and support linaclotide.

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The increase in general and administrative expense of approximately \$12.1 million for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was primarily due to an increase of approximately \$5.6 million in compensation, benefits, and other employee related expenses primarily due to increased headcount, an increase of approximately \$1.7 million in share-based compensation expense primarily related to our new hire and annual stock option grants, an increase of approximately \$2.2 million in general and administrative related facilities costs associated with the additional space we leased in our 301 Binney Street facility, and an increase in external consulting costs, net of Forest reimbursement, of approximately \$2.2 million associated with developing the infrastructure to commercialize and support linaclotide.



Table of Contents*Other Income (Expense), Net*

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	Change		2011	2010	Change	
	(dollars in thousands)				(dollars in thousands)			
			\$	%			\$	%
Other income (expense):								
Interest expense	\$ (16)	\$ (81)	\$ 65	80.2%	\$ (49)	\$ (178)	\$ 129	72.5%
Interest and investment income	105	188	(83)	(44.1)%	384	445	(61)	(13.7)%
Other income	897		897	100.0%	900		900	100.0%
Total other income (expense), net	\$ 986	\$ 107	\$ 879	821.5%	\$ 1,235	\$ 267	\$ 968	362.5%

*Interest Expense.* The decrease in interest expense for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was primarily the result of the repayment of the long-term debt in September 2010, partially offset by increased interest expense resulting from the capital leases we entered into in 2010 and 2011.

*Interest and Investment Income.* The decrease in interest and investment income for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to lower average cash balances and interest rates during the three months ended September 30, 2011.

The decrease in interest and investment income for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was due to lower average cash balances during the nine months ended September 30, 2011 compared to the nine months ending September 30, 2010 resulting from the receipt of our IPO proceeds in February 2010.

*Other Income.* The increase in other income for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was primarily the result of the recognition of the Life Sciences Tax Incentive Program award of approximately \$0.9 million in September 2011.

*Income Tax Expense (Benefit).* The approximately \$2.9 million decrease in income tax benefit for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was related to intra-period income tax allocation requirements for which we recorded a benefit for income taxes from continuing operations of approximately \$2.9 million, offset by an identical income tax provision from discontinued operations for the three and nine months ended September 30, 2010. The intra-period income tax allocation considers discontinued operations for purposes of determining the amount of tax benefit that results from our loss from continuing operations.

*Net Income From Discontinued Operations.* The decrease in net income from discontinued operations for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was the result of the sale of Microbia, our former subsidiary, in September 2010.

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

*Net Income From Discontinued Operations Attributable to Noncontrolling Interest.* The decrease in net income from discontinued operations attributable to noncontrolling interest for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was the result of the sale of Microbia, our former subsidiary, in September 2010.

### 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,	
	2011	2010
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (67,536)	\$ (67,253)
Investing activities	89,522	(198,571)
Financing activities	2,513	202,214
Net increase (decrease) in cash and cash equivalents	\$ 24,499	\$ (63,610)

Table of Contents

We have incurred losses since our inception on January 5, 1998 and, as of September 30, 2011, we had a cumulative deficit of approximately \$425.4 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, 2011, we had approximately \$175.1 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. Our available-for-sale securities include amounts held in U.S. government-sponsored securities 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.

**Cash Flows From Operating Activities**

Net cash used in operating activities totaled approximately \$67.5 million for the nine months ended September 30, 2011. The primary uses of cash were our net loss from continuing operations of approximately \$57.9 million and a decrease of approximately \$27.3 million in working capital resulting primarily from reductions in deferred revenue as revenue was recognized from our collaboration and our license agreements. These uses of cash were partially offset by non-cash items of approximately \$17.7 million.

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 \$44.8 million, approximately \$6.0 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.

**Cash Flows From Investing Activities**

Cash provided by investing activities for the nine months ended September 30, 2011 totaled approximately \$89.5 million and resulted primarily from the sales and maturities of securities of approximately \$177.1 million, partially offset by the purchase of approximately \$81.5 million of securities and the purchase of approximately \$6.0 million of property and equipment associated with the expansion of our 301 Binney Street facility and our information technology infrastructure.

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 \$9.5 million in proceeds received from DSM for the sale of our interest in Microbia.

**Cash Flows From Financing Activities**

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Cash provided by financing activities for the nine months ended September 30, 2011 totaled approximately \$2.5 million primarily resulting from approximately \$2.7 million of proceeds from the exercise of stock options and the purchase of shares under the employee stock purchase plan, partially offset by payments on our capital leases.

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.

### ***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.

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

Table of Contents

unless we receive regulatory approval for commercial sale of linaclotide. 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 current or future collaborators provide significant optionality and would be sufficient to meet our projected operating needs through the anticipated commercialization of linaclotide. If our forecasted operating needs change, we may require additional funding in the form of public or private equity offerings or debt financings or we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts. In addition, if favorable financing opportunities arise, we may seek additional funding at such time. Our forecast of the period of time through which our financial resources will be adequate to support our operations, including the underlying estimates regarding the costs to obtain regulatory approval and the costs to commercialize linaclotide, is a forward-looking statement that involves 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, 2010.

We, and in some cases, along with our collaboration partner, Forest, have entered into multiple commercial supply agreements for the purchase of linaclotide API and drug product. Some of the agreements contain minimum purchase commitments, the earliest of which commences in 2012. As of September 30, 2011, our minimum purchase requirement across all the agreements is approximately \$45.0 million through 2017.

### **Related Party Transactions**

We have and currently obtain legal services from a law firm that is an investor of ours. We paid approximately \$29,000 and \$124,000 in legal fees to this investor during the three and nine months ended September 30, 2011, respectively, and approximately \$96,000 and \$196,000 during the three and nine months ended September 30, 2010, respectively.

In September 2006, Tate & Lyle Investments, Ltd., or 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. In June 2010, T&L and

Table of Contents

Microbia entered into an agreement to terminate their collaboration. All current and future obligations between Microbia and T&L were 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 45% and 49% of our revenue from continuing operations for the three and nine months ended September 30, 2011, respectively, and approximately 60% for both the three and nine months ended September 30, 2010.

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 48% and 43% of our revenue from continuing operations for the three and nine months ended September 30, 2011, respectively, and approximately 29% and 31% for the three and nine months ended September 30, 2010, respectively.

**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 Adopted Accounting Standards***

In October 2009, the FASB issued 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*, or 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,

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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. On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The adoption did not have a material impact on our consolidated financial position or results of operations.

In April 2010, the FASB issued ASU 2010-17. ASU 2010-17 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 for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. On January 1, 2011, we adopted ASU 2010-17 to change our accounting policy to begin applying the milestone method on a prospective basis. As we elected prospective adoption, there was no material impact on our consolidated financial position or results of operations. However, the adoption of ASU 2010-17 is expected to impact the accounting for any milestone payments we receive in future periods.



Table of Contents

***Recently Issued Accounting Standards***

In December 2010, the FASB issued ASU No. 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers*, or ASU 2010-27, which provides guidance on how to recognize and classify the fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (together, the Acts). The Acts impose an annual fee for each calendar year beginning on or after January 1, 2011 payable by branded prescription drug manufacturers and importers on branded prescription drugs. The liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation over the calendar year that it is payable. ASU 2010-27 is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective. As we do not currently have a commercial product, the effect of this guidance will be limited to future transactions.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*, or ASU 2011-05, which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards, or IFRS, as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders' equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. We expect to adopt this standard beginning in 2012. As ASU 2011-05 impacts presentation only, it will have no effect on our consolidated financial position or 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 cash is deposited in and invested through highly rated financial institutions in North America.

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 100 basis point 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.

We do not believe our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity at this time, as they are invested in securities issued by the U.S. government. While we believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, we cannot provide assurance that in the future our investments will not be subject to adverse changes in market value.

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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, 2011 and 2010.

Table of Contents

**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, 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.

Table of Contents

**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

*In addition to the other information in this Quarterly Report on Form 10-Q, any of the factors described below could significantly and negatively affect our business, financial condition, results of operations or prospects. The trading price of our Class A common stock may decline due to these risks.*

**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.*

On August 9, 2011, we and our U.S. collaboration partner, Forest, announced that we submitted an NDA with the FDA for our lead product candidate, linaclotide, for the treatment of IBS-C and CC. On October 24, 2011, we and Forest announced that the FDA accepted the NDA for review, and the FDA Prescription Drug User Fee Act ( PDUFA ) target action date is expected to occur in June 2012. We and Forest are not permitted to market linaclotide in the U.S. until we receive approval of the NDA from the FDA.

On September 29, 2011, we and our European partner, Almirall, each announced that Almirall submitted an MAA, with the EMA for linaclotide for the treatment of IBS-C. Our other partners, including Almirall in Europe, are not permitted to market linaclotide in any foreign jurisdictions until they receive the requisite marketing approvals from the regulatory authorities in such jurisdictions.

Obtaining regulatory approval is a lengthy, expensive and uncertain process. Now that the FDA has accepted the NDA for linaclotide for filing, the FDA's review has just commenced. Similarly, the EMA's review of the MAA for linaclotide is just beginning. The FDA and foreign regulatory authorities have 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 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;

- may not approve linaclotide for both IBS-C and CC indications in the U.S.;
- may require significant warnings or restrictions on use to the product label for linaclotide; or
- may change their approval policies or adopt new regulations.

Linaclotide is our GC-C agonist that achieved positive results in each of our two Phase 3 IBS-C trials and each of our two Phase 3 CC trials. Even though linaclotide met all primary and secondary endpoints in each of these trials, it may not be approved for either or both indications or for any other indication for which we seek approval from the FDA or a foreign regulatory authority. 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.

Table of Contents

***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. 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. In the four Phase 3 clinical trials, our results indicate that diarrhea was seen in 14% to 20% of linaclotide-treated patients, and was the most common adverse event that led to study discontinuation in 3% to 6% of linaclotide-treated patients. 90% of patients who had diarrhea had mild to moderate episodes. In our clinical development program, there have been no serious adverse events in any patients receiving linaclotide treatment that were deemed by a study investigator or us to be definitely related or probably related to linaclotide treatment, nor have there been any deaths in any patients receiving linaclotide treatment that were deemed by a study investigator or us to be related to linaclotide treatment.

If linaclotide receives marketing approval, and undesirable side effects are caused or appear to be 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.

***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 use contract manufacturers to manufacture our clinical and commercial supplies. With respect to the manufacturing of linaclotide, we have entered into commercial supply agreements with PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB and with Corden Pharma Colorado, Inc. (formerly known as Roche Colorado Corporation), each for the manufacture of the linaclotide API that is being used to seek regulatory approval of linaclotide, and, pending any such approval, that will be incorporated into the finished product for commercialization in our partnered territories. However, if we change or add manufacturers, the regulatory authorities in each territory must approve these manufacturers facilities and processes prior to use, which may require compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of linaclotide. While we believe we will have 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.

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, changes in raw material suppliers may also 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 have entered into an agreement with Almac Pharma Services Limited, or Almac, to complete the manufacturing process of linaclotide in the parts of the world outside of our partnered territories and to introduce redundancy into our supply chain within our partnered territories. We will be dependent upon the success of our partners and Almac in producing drug product for commercial sale. No party has experience producing finished drug product for linaclotide at full commercial scale, and there can be no assurance that commercial scale manufacturing capacity will be achieved.

Table of Contents

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 commercial 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, as well as compliance with federal, state and foreign regulations, and the challenges associated with complex supply chain management. If our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA or EMA approval, and market and maintain an adequate commercial supply of linaclotide would be jeopardized.

Each of the linaclotide manufacturers needs to comply with good manufacturing practices, or GMP, requirements enforced by the FDA and foreign regulatory authorities through their facilities inspection programs. 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 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 GMP requirements, 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 in 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.

***Because we work with partners to develop, manufacture and promote linaclotide, we are dependent upon third parties, and our relationships with those third parties, in our efforts to obtain regulatory approval for, and to commercialize, linaclotide.***

We co-develop and plan to co-promote linaclotide in the U.S. with Forest. Forest played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data. In addition, since we will co-commercialize linaclotide in the U.S. with Forest, we are working closely with them to develop and implement a commercialization plan for linaclotide if and when it is approved by the FDA. Each of Almirall, our European partner, and Astellas, our partner in certain Asian countries, is responsible for completing the clinical programs and obtaining regulatory approval of linaclotide in its respective territory. Further, we and our other partners are responsible for reporting adverse event information to us and to Forest. In addition, each of our partners is responsible for completing the manufacturing process of linaclotide upon production of the API, which consists of finishing and packaging linaclotide into capsules. These functions may not be carried out effectively and efficiently if we fail to communicate and coordinate with our partners, and vice versa. Employees of our partners are not our employees, and we have limited ability to control the amount or timing of resources that they devote to linaclotide. If any of our partners 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 manufacturing and commercialization of linaclotide. A material breach by any of our partners of our collaboration agreement with such partner, or a significant disagreement between us and a partner, could also delay the regulatory approval and commercialization of linaclotide, potentially lead to costly litigation, and could have a material adverse impact on our financial condition. Moreover, although we have non-compete restrictions in place with each of our partners, they may have relationships with other commercial entities, some of which may compete with us. If any of our partners assists our competitors, it could harm our competitive position.

***If any of our partners undergoes a change in control or management, this may adversely affect our collaborative relationship or the timeline and likelihood of achieving regulatory approval and, ultimately, the commercialization of linaclotide.***



## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

We work jointly and collaboratively with Forest, Ammirall and Astellas on many decisions related to the development, manufacturing and commercialization of linaclotide. In doing so, we have established relationships with several key members of our partners' management teams in functional areas such as development, quality, regulatory, operations and commercial. The success of our collaborations is highly dependent on the resources, efforts and skills of our partners and their key employees. If a partner undergoes a change of control or a change of management, we will need to reestablish many of these relationships and we will need to regain alignment of our development and commercialization strategy for linaclotide. Further, any change of control or management may result in a reprioritization of linaclotide within such partner's profile, or such partner may fail to maintain the financial resources necessary to continue financing its portion of the development, manufacturing or commercialization costs. In certain circumstances, if one of our partners undergoes a change of control, we have the right to terminate the collaboration or license agreement and reacquire that partner's rights with respect to linaclotide. If we elect to exercise these rights in such circumstances, we will need to either establish the capability to develop and commercialize linaclotide in that partnered territory on our own or we will need to establish a

Table of Contents

relationship with a new partner. In any of these situations, the timeline and likelihood of achieving regulatory approval and, ultimately, the commercialization of linaclotide would be at risk or impaired.

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

On August 9, 2011, we and Forest announced that we submitted an NDA with the FDA for linaclotide for the treatment of IBS-C and CC, and on October 24, 2011, we and Forest announced that the FDA accepted the NDA for review. However, 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 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 a 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;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted 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.*

We have out-licensed the European rights to develop and commercialize linaclotide to Almirall, and we have out-licensed the same rights in certain Asian countries to Astellas. 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. Almirall submitted an MAA with the EMA in September 2011. The time required to obtain approval in other jurisdictions, including the European Union, or E.U., 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.

*Linaclotide may not be widely adopted by patients, payors or healthcare providers, which would adversely impact our potential profitability and future business prospects.*

The commercial success of linaclotide depends upon its level of market adoption by patients, payors and healthcare providers. If linaclotide does not achieve an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be severely adversely impacted. The degree of market acceptance of linaclotide depends on a number of factors, including:

Table of Contents

- our ability to demonstrate to the medical community, particularly general practitioners, internists and gastrointestinal specialists who may purchase or prescribe linaclotide, the clinical efficacy and safety of linaclotide as the prescription product of choice for patients who suffer from IBS-C or CC;
- the effectiveness of our sales and marketing organizations and our distribution network;
- the ability of patients or providers to be adequately reimbursed for linaclotide in a timely manner from government and private payors; and
- the actual and perceived safety profile of linaclotide, particularly if unanticipated adverse events related to linaclotide treatment arise and create safety concerns among potential patients or prescribers.

*We may face competition in the IBS-C and CC marketplace, 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 and other potential competitors are in earlier stages of development for the treatment of patients with either IBS-C or CC. 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.*

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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-promotion relationship in the U.S. and license relationship in 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.

*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

Table of Contents

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 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. 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 healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations, the ongoing federal government debate on reducing the federal deficit and additional legislative proposals.

***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 prohibit, 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;

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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;
- 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;
- the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and
- the federal Physician Payments Sunshine Act, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professional and health care organizations.

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

Table of Contents

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 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.

***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 passing of the Patient Protection and Affordable Healthcare Act and the Health Care and Education Reconciliation Act. This healthcare reform law increases the number of individuals who receive health insurance coverage and closes 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 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 have taken effect or will become effective later this year, 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.

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. 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.

The Food and Drug Administration Amendments Act of 2007 gives 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.



*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 any 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. Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from sales of any product, and we may never be able to develop marketable drugs.

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.

Table of Contents

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.

*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.

Table of Contents

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.

***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, clinical and commercial 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. If we lose any members of our 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, as well as sales and marketing advisors who have assisted us in our commercialization strategy and brand plan for linaclotide. 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 and commercialization of products that may compete with ours.

*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;

Table of Contents

- 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 currently have product liability insurance coverage for our clinical trials that is 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.

***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.

**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.

Table of Contents

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.

*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 or may assert our patents are invalid. To counter ongoing or potential infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Litigation with generic manufacturers has become increasingly common in the biopharmaceutical industry. 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

Table of Contents

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.

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.

**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 the issuance of equity 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 \$20.6 million and \$57.9 million in the three and nine months ended September 30, 2011, respectively, and approximately \$8.3 million and \$41.3 million in the three and nine months ended September 30, 2010, respectively. As of September 30, 2011, we had an accumulated deficit of approximately \$425.4 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 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. Circumstances, our strategic imperatives, or opportunities to create or acquire new development programs could require us to, or we may choose 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;

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- the costs associated with launching and commercializing linaclotide, should it be approved by FDA;
- if linaclotide receives regulatory approval, the level of underlying demand for that product;
- 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:

Table of Contents

- the achievement and timing of milestone payments under our existing collaboration and license agreements;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the costs associated with launching and commercializing linaclotide and any of our product candidates, if we receive regulatory approval of such candidate;
- if linaclotide receives regulatory approval, the level of underlying demand for that product and wholesalers' buying patterns;
- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- regulatory developments affecting our product candidates; and
- any intellectual property infringement lawsuit in which we may become involved.

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.

**Risks Relating to Securities Markets and Investment in Our Stock**

*The concentration of our capital stock ownership with our pre-IPO stockholders 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:

- 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 that term is used in Regulation 13D of the Securities Exchange Act of 1934, as amended, or 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 certain of our 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, 2011, the holders of our Class A common stock own approximately 60% and the holders of our Class B common stock own approximately 40% 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 approximately 13% and holders of our Class B common stock have approximately 87% 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.

Table of Contents

*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, holders of our Class B common stock 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 are 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 are not 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 are not able to call a special meeting.

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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 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.

*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:

- 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;

Table of Contents

- announcements concerning product development results, including clinical trial 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 and annual 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;
- 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.



Table of Contents

**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. 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, expect, seek, 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;
- 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 safety profile and related adverse events of our product candidates;
- our ability to manufacture sufficient amounts of linaclotide for commercialization activities with target characteristics;
- the success of our clinical studies for our product candidates;
- our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;
- the ability of our partners to perform their obligations under our collaboration and license agreements with them;

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- our expectations as to future financial performance, expense levels, capital raising and liquidity sources;
- 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;
- 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 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.

Table of Contents

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

We did not repurchase any of our equity securities during the quarter ended September 30, 2011.

**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.

There were no material changes in our 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, 2011, we estimate that we used the proceeds in the following way:

- approximately \$45.3 million to fund the development and commercialization of linaclotide;
- approximately \$30.9 million to fund both research and development of early stage product candidates and preclinical research in multiple therapeutic areas, including gastrointestinal disease, pain and inflammation, respiratory disease, and cardiovascular disease; and
- approximately \$127.0 million for general corporate purposes.

**Item 6. *Exhibits***

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

Table of Contents

**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 9, 2011

By: /s/ PETER M. HECHT  
Peter M. Hecht, Ph.D.  
Chief Executive Officer and Director  
*(Principal Executive Officer)*

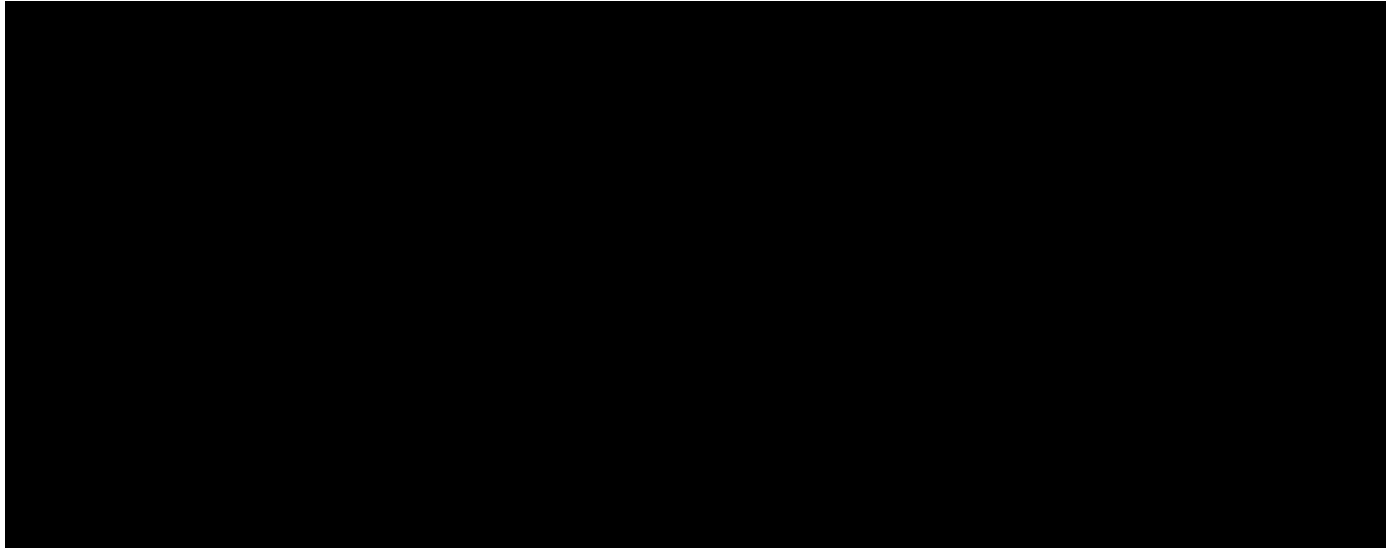
Date: November 9, 2011

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)*

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit No:</b>	<b>Description</b>
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.



---

\* Filed herewith.

Furnished herewith.