

IRONWOOD PHARMACEUTICALS INC

Form 10-Q

August 07, 2012

[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 June 30, 2012

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
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of July 25, 2012, there were 75,732,437 shares of Class A common stock outstanding and 31,626,315 shares of Class B common stock outstanding.

Table of Contents

IRONWOOD PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2012

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>
	<u>Condensed Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011</u> 1
	<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Six</u>
	<u>Months Ended June 30, 2012 and 2011</u> 2
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30,</u>
	<u>2012 and 2011</u> 3
	<u>Notes to Condensed Consolidated Financial Statements</u> 4
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of</u>
	<u>Operations</u> 21
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 30
<u>Item 4.</u>	<u>Controls and Procedures</u> 30
<u>PART II OTHER INFORMATION</u>	
<u>Item 1A.</u>	<u>Risk Factors</u> 31
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities</u> 48
<u>Item 6.</u>	<u>Exhibits</u> 48
	<u>Signatures</u> 49

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)**

	June 30,		December 31,
	2012		2011
Assets			
Current assets:			
Cash and cash equivalents	\$ 87,083	\$	87,282
Available-for-sale securities	70,570		76,734
Accounts receivable	22		74
Related party accounts receivable, net	2,444		578
Prepaid expenses and other current assets	5,964		2,899
Total current assets	166,083		167,567
Restricted cash	7,647		7,647
Property and equipment, net	34,859		33,625
Other assets	74		138
Total assets	\$ 208,663	\$	208,977
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 6,921	\$	6,436
Related party accounts payable, net	3,705		
Accrued research and development costs	6,907		7,010
Accrued expenses	13,216		11,122
Current portion of capital lease obligations	277		233
Current portion of deferred rent	4,517		4,042
Current portion of deferred revenue	13,578		36,291
Total current liabilities	49,121		65,134
Capital lease obligations, net of current portion	364		422
Deferred rent, net of current portion	10,832		12,435
Deferred revenue, net of current portion	19,565		21,130
Commitments and contingencies (Note 7)			
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 at June 30, 2012 and December 31, 2011

Class A common stock, \$0.001 par value, 500,000,000 shares authorized and 75,644,436 and 61,801,770 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively

76

62

Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 31,696,007 and 38,914,080 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively

32

39

Additional paid-in capital

637,478

542,141

Accumulated deficit

(508,796)

(432,392)

Accumulated other comprehensive income (loss)

(9)

6

Total stockholders' equity

128,781

109,856

Total liabilities and stockholders' equity

\$

208,663

\$

208,977

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Collaborative arrangements revenue	\$ 14,604	\$ 11,262	\$ 26,852	\$ 21,499
Operating expenses:				
Research and development	32,238	19,409	61,748	38,964
General and administrative	23,200	10,805	41,574	20,029
Total operating expenses	55,438	30,214	103,322	58,993
Loss from operations	(40,834)	(18,952)	(76,470)	(37,494)
Other income (expense):				
Interest expense	(13)	(17)	(27)	(33)
Interest and investment income	44	125	93	279
Other income				3
Other income (expense), net	31	108	66	249
Net loss	\$ (40,803)	\$ (18,844)	\$ (76,404)	\$ (37,245)
Net loss per share basic and diluted	\$ (0.38)	\$ (0.19)	\$ (0.73)	\$ (0.37)
Weighted average number of common shares used in net loss per share basic and diluted	107,078,150	99,674,969	105,414,607	99,458,336
Comprehensive loss	\$ (40,815)	\$ (18,843)	\$ (76,419)	\$ (37,193)

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)**

	Six Months Ended	
	June 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (76,404)	\$ (37,245)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,490	5,037
Share-based compensation expense	7,777	5,649
Accretion of discount/premium on investment securities	579	1,342
Changes in assets and liabilities:		
Accounts receivable	(1,814)	268
Restricted cash		2,833
Prepaid expenses and other current assets	(3,065)	662
Other assets	64	60
Accounts payable and accrued expenses	6,713	1,571
Accrued research and development costs	(103)	(2,711)
Deferred revenue	(24,278)	(20,734)
Deferred rent	(1,128)	250
Other liabilities		897
Net cash used in operating activities	(86,169)	(42,121)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(44,655)	(57,082)
Sales and maturities of available-for-sale securities	50,225	106,586
Purchases of property and equipment	(7,037)	(5,467)
Net cash provided by (used in) investing activities	(1,467)	44,037
Cash flows from financing activities:		
Proceeds from issuance of common stock	85,228	
Proceeds from exercise of stock options and employee stock purchase plan	2,343	2,094
Payments on capital leases	(134)	(146)
Net cash provided by financing activities	87,437	1,948
Net increase (decrease) in cash and cash equivalents	(199)	3,864
Cash and cash equivalents, beginning of period	87,282	44,321
Cash and cash equivalents, end of period	\$ 87,083	\$ 48,185
Supplemental cash flow disclosures:		
Cash paid for interest	\$ 24	\$ 35
Purchases under capital leases	\$ 120	\$ 325

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 (Continued)

(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 agonist (GCCA) being developed for the treatment of patients with irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). In August 2011, the Company and its U.S. collaboration partner, Forest Laboratories, Inc. (Forest) submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for linaclotide for the treatment of IBS-C and CC. In April 2012, the FDA extended its standard ten-month review period by three months, so the FDA Prescription Drug User Fee Act (PDUFA) target action date is now in September 2012.

In September 2011, the Company's European partner, Ammirall, S.A. (Ammirall) submitted a Market Authorization Application (MAA) to the European Medicines Agency (EMA) for linaclotide for the treatment of patients with IBS-C, and Ammirall continues to work with the EMA in its review.

The Company's Japanese partner, Astellas Pharma Inc. (Astellas), continues to develop linaclotide for the treatment of patients with IBS-C in Japan and certain other Asian countries.

The Company continues to assess alternatives to bring linaclotide to IBS-C and CC sufferers in the parts of the world outside of its partnered territories, which include China. In May 2012, the Company submitted a Clinical Trial Application (CTA) to China's State Food and Drug Administration for a Phase 3 trial of linaclotide in patients with IBS-C. The CTA has been accepted for review.

The Company continues to assess lifecycle management opportunities for linaclotide to ensure that it is maximizing the drug's potential value. As part of its long-term strategy, the Company and Forest initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CC. In addition, the Company continues to explore the potential for linaclotide in the pediatric population as well as in other gastrointestinal indications.

The Company also has a pipeline focused on early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, central nervous system (CNS) disorders, respiratory disease and cardiovascular disease.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The Company was incorporated in Delaware on January 5, 1998. On April 7, 2008, the Company changed its name from Microbia, Inc. to Ironwood Pharmaceuticals, Inc. The Company currently operates in one reportable business segment human therapeutics.

The Company has generated an accumulated deficit as of June 30, 2012 of approximately \$508.8 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. Additionally, in February 2012, the Company sold 6,037,500 shares of its Class A common stock through a follow-on public offering and raised a total of approximately \$85.2 million in net proceeds (Note 8).

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying condensed consolidated financial statements and the related disclosures as of June 30, 2012 and for the three and six months ended June 30, 2012 and 2011 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 February 29, 2012. The December 31, 2011 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 June 30, 2012, results of its operations for the three and six months

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

ended June 30, 2012 and 2011 and its cash flows for the six months ended June 30, 2012 and 2011. The interim results for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Ironwood Pharmaceuticals, Inc. and its wholly owned subsidiaries, Ironwood Pharmaceuticals Securities Corporation and Ironwood Pharmaceuticals GmbH. All intercompany transactions and balances are eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company's management evaluates its estimates, including those related to revenue recognition, available-for-sale securities, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, 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 a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds. The carrying amount of cash equivalents approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately \$85.6 million and \$77.2 million at June 30, 2012 and December 31, 2011, respectively.

Available-for-Sale Securities

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

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and investment income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no other-than-temporary impairments for the three and six months ended June 30, 2012 and 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. Treasury securities and certain U.S. government sponsored 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.

Table of Contents**Ironwood Pharmaceuticals, Inc.**

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Accounts receivable, including related party accounts receivable, primarily consist of amounts due under the collaboration agreement with Forest and license agreements with Almirall and Astellas (Note 4) for which the Company does not obtain collateral. Accounts receivable or payable, to or from Forest and Almirall are presented as related party transactions on the condensed consolidated balance sheets as both entities own common stock of the Company.

The Company's significant customers are summarized in the table below. The percentages of revenue recognized during the three and six months ended June 30, 2012 and 2011 are shown, as well as the accounts receivable balance, net of any payables due, at June 30, 2012 and December 31, 2011.

Forest	%	86%	37%	48%	41%	51%
Astellas	1%	11%	6%	8%	6%	9%

For the three and six months ended June 30, 2012 and 2011, no additional customers accounted for more than 10% of the Company's revenue.

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, including participation on a joint development committee, and (iii) the manufacture of active pharmaceutical ingredient (API) and development materials for the collaborative partner which are reimbursed at a contractually determined rate. To date, the Company's collaborative research and development and licensing agreements have included only the license to develop and commercialize linaclotide, the Company's GCCA. Non-refundable payments to the Company under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of API and development materials, (iv) payments based upon the achievement of certain milestones, and (v) royalties on product sales.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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

At June 30, 2012, the Company had collaboration and license agreements with Forest, Ammirall and Astellas. Refer to Note 4, Collaboration and License Agreements, for additional discussion of these agreements.

Agreements Entered into Prior to January 1, 2011

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* (ASC 605-25), in accounting for these agreements. Under ASC 605-25, the Company is required to identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Collaborative research and development and licensing agreements that contain multiple deliverables are divided into separate units of accounting if certain criteria are met, as follows:

- Delivered element(s) has value to the collaborator on a standalone basis,
- There is objective and reliable evidence of the fair value of the undelivered obligation(s), and
- If the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially within the Company's control.

The Company allocates arrangement consideration among the separate units of accounting either on the basis of each unit's

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

respective fair value or using the residual method, and applies the applicable revenue recognition criteria to each of the separate units. If the separation criteria are not met, revenue of the combined unit of accounting is recorded based on the method appropriate for the last delivered item. 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.

Up-Front License Fees

The Company recognizes revenue from nonrefundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the period over which the research and development is expected to occur or manufacturing services are expected to be provided. Accordingly, the Company is required to make estimates regarding the drug development and commercialization timelines for drugs and drug candidates being developed pursuant to the applicable agreement. The determination of the length of the period over which to recognize the revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Quarterly, the Company reassesses its period of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. During the three and six months ended June 30, 2012, the Company's estimates regarding the period of performance under its collaborative research and development and licensing agreements did not change; however, they have changed in the past and may change in the future. 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 are deferred if the relevant facts and circumstances dictate that the license does not have standalone value to the partner. 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.

Milestones

At the inception of each arrangement 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. 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

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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.

Prior to January 1, 2011, in those circumstances where a substantive milestone was achieved, collection of the related receivable is reasonably assured and the Company had remaining obligations to perform under the collaboration arrangement, the Company 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 Accounting Standards Update (ASU) No. 2010-17, *Revenue Recognition Milestone Method* (ASU 2010-17) on a prospective basis. Under ASU 2010-17, in those circumstances where a substantive milestone is achieved and collection of the related receivable is reasonably assured, the Company recognizes revenue related to the milestone in its entirety in the period in which the milestone is achieved. Milestone payments received prior to the adoption of ASU 2010-17 have continued to be recognized over the remaining period of performance. Milestones that are not considered substantive are recognized on a straight-line basis over the remaining period of performance.

Substantive milestones are due to the Company upon NDA approval of linaclotide in the U.S., upon the initiation of a Phase 3 study for linaclotide in Japan, upon the filing and approval of the Japanese equivalent of an NDA with the relevant regulatory authority in Japan. Refer to Note 4 for details on the specific milestones in each of the Company's agreements.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Other

The Company produces development materials and API for its collaborators and is reimbursed at a contracted rate. 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 nature and contractual terms of the arrangement and the nature of the Company's business operations to determine whether research and development funding will result in collaborative revenues or an offset to research and development expenses. Additionally, the Company considers the factors or indicators within this arrangement to determine whether reporting transactions under the Company's collaboration agreements on a gross or net basis is appropriate. The Company records revenue transactions gross in the condensed consolidated statements of comprehensive income (loss) if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

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

Agreements Entered into or Materially Modified on or after January 1, 2011

Effective January 1, 2011, the Company adopted ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13), on a prospective basis. ASU 2009-13 amends ASC 605-25 to provide updated revenue recognition guidance on whether multiple deliverables in an arrangement exist, how multiple deliverables in an arrangement should be separated and how the arrangement consideration should be allocated. More specifically, the revised guidance eliminates the requirement to establish vendor-specific objective evidence of fair value or third-party evidence of fair value of undelivered elements in order to separate a deliverable. Additionally, ASU 2009-13 eliminates the use of the residual method by requiring revenues to be allocated using the relative selling price method. Under the relative selling price method, arrangement consideration is allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values (i) vendor-specific objective evidence of selling price, (ii) third-party evidence of selling price, and (iii) best estimate of the selling price (BESP). The BESP reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a standalone basis. Since January 1, 2011, the Company has not entered into any material agreements or material modifications to existing agreements that would be accounted for pursuant to this updated guidance. If the Company enters into or materially modifies an agreement with multiple deliverables, this updated guidance could have a material effect on the Company's consolidated financial statements in future periods.

Research and Development Costs

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

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary 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, including supply chain development; and other outside expenses.

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.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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 primarily relates to stock awards, restricted stock and stock options granted, modified, repurchased or cancelled on or after January 1, 2006. 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.

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 allocates undistributed earnings between the classes on a one-to-one basis when computing net loss per share. As a result, basic and diluted net loss per Class A and Class B shares are equivalent. 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.

Income Taxes

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 June 30, 2012 and December 31, 2011. Management reevaluates the positive and negative evidence on a quarterly basis.

The Company accounts for uncertain tax positions recognized in the condensed consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

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 June 30, 2012 or December 31, 2011.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company currently operates in one reportable business segment - human therapeutics.

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 May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends ASC 820, *Fair Value Measurement*, to ensure that fair value has the same meaning in GAAP and International Financial Reporting Standards (IFRS) and improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. ASU 2011-04 applies to all entities that measure assets, liabilities or instruments classified in shareholder's equity at fair value, or provide fair value disclosures for items not recorded at fair value. ASU 2011-04 results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRS. Consequently, ASU 2011-04 changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, ASU 2011-04 will not result in a change in the application of the requirements in ASC 820. Some of the requirements in ASU 2011-04 clarify the FASB's intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. ASU 2011-04 is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. Early application is not permitted. On January 1, 2012, the Company adopted ASU 2011-04 on a prospective basis. The adoption did not have a material impact on the Company's consolidated financial position or results of operations.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 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 public companies for fiscal years, and interim periods within those years, beginning after December 15, 2011 and should be applied retrospectively. In December 2011, the FASB issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12) which defers the effective date of the provisions of ASU 2011-05 pertaining to the presentation of reclassification adjustments out of accumulated other comprehensive income. All other requirements in ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-12 is effective for public companies for fiscal years, and interim periods within those years, beginning after December 15, 2011. On January 1, 2012, the Company adopted ASU 2011-05 and ASU 2011-12 on a retrospective basis. The Company has elected to present all nonowner changes in stockholders' equity in a single continuous statement of comprehensive income (loss). The adoption did not have a material impact on the Company's consolidated financial position or results of operations since these standards impact presentation only.

Table of Contents**Ironwood Pharmaceuticals, Inc.**

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

3. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss per share by the weighted average number of common shares outstanding during the period.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of June 30, 2012 and 2011, as they would be anti-dilutive:

	At June 30,	
	2012	2011
Options to purchase common stock	18,693,553	15,786,758
Shares subject to repurchase	121,146	203,201
	18,814,669	15,989,959

4. 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. 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 June 30, 2012, approximately \$2.9 million of the up-front license fee remains deferred. 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 June 30, 2012, \$120.0 million in license fees and milestone payments has already been received, as well as a \$25.0 million equity investment in the Company's capital stock. Of the remaining milestones, each of which the Company considers

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

substantive, pre-commercial milestone payments could total 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 June 30, 2012, approximately \$0.4 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 four of the development milestones under this agreement, all 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 June 30, 2012, approximately \$0.4 million and \$0.8 million of the milestone payments, respectively, remain deferred and are being recognized on a straight-line basis over the remaining estimated development period. In October 2011, the Company achieved the pre-commercial milestones of FDA acceptance of the linaclotide NDA for both IBS-C and CC and received milestone payments of \$20.0 million from Forest. In accordance with ASU 2010-17, adopted in January 2011, these milestones were recognized as revenue in their entirety upon achievement.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The Company recognized revenue from the Forest collaboration agreement totaling approximately \$5.5 million and \$10.9 million during the three and six months ended June 30, 2012, respectively and approximately \$5.5 million and \$10.9 million during the three and six months ended June 30, 2011, respectively.

Further, because the Company shares development costs equally with Forest, payments from Forest with respect to both research and development and general and administrative 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 recognized approximately \$1.3 million and \$38,000 in incremental research and development costs during the three and six months ended June 30, 2012, respectively, and approximately \$2.9 million and \$4.9 million in incremental general and administrative expense, respectively. During the three and six months ended June 30, 2011, as a result of the cost-sharing arrangements under the collaboration, the Company offset approximately \$2.0 million and \$6.2 million, respectively, against research and development expense and offset approximately \$0.5 million and \$0.7 million against general and administrative expense, respectively.

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 net of taxes withheld. 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 based on the Company's assessment of approval timelines adjusted its amortization of the remaining deferred revenue, accordingly. This resulted in the recognition of an additional approximately \$5.0 million of revenue in the year ended December 31, 2011. At June 30, 2012, approximately \$3.6 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 June 30, 2012, \$19.0 million, net of foreign withholding taxes, in milestone payments has already been received, as well as a \$15.0 million equity investment in the Company's capital stock. Remaining pre-commercial milestone payments, each of which the Company 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.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 the associated deferred revenue is being recorded over the revised period on a prospective basis. At June 30, 2012, approximately \$0.6 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-

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

line basis over the remaining development period. At June 30, 2012, approximately \$1.8 million of the milestone payment remains deferred.

The Company recognized approximately \$8.4 million and \$14.3 million in total revenue from the Almirall license agreement during the three and six months ended June 30, 2012, respectively, including approximately \$2.4 million in each period from the sale of API to Almirall. The Company recognized approximately \$4.9 million and \$8.7 million in total revenue from the Almirall license agreement during the three and six months ended June 30, 2011, respectively, including approximately \$0.4 million in each period 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, the 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. 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 June 30, 2012, approximately \$22.7 million of the up-front license fee remains deferred. During the three and six months ended June 30, 2012, the Company recognized approximately \$0.8 million and \$1.7 million, respectively, in revenue from the Astellas license agreement, including approximately \$22,000 and \$0.1 million, respectively, from the sale of API to Astellas. During the three and six months ended June 30, 2011, the Company recognized approximately \$0.9 million and \$1.9 million, respectively, in revenue from the Astellas license agreement, including approximately \$0.1 million and \$0.3 million, respectively from the sale of API to Astellas.

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

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 for each product pending the achievement of certain development and commercialization milestones. These contingent milestones could total up to approximately \$111.5 million per product if all milestones are achieved. The Company will expense these payments as incurred. During the three and six months ended June 30, 2012, the Company recorded approximately \$0.7 million and \$1.4 million, respectively, in research and development expense associated with the Protagonist agreement. During the three and six months ended June 30, 2011, the Company recorded approximately \$0.6 million and \$3.8 million, respectively, in research and development expense, including the up-front payment, associated with the Protagonist agreement.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Bionomics Limited

On January 4, 2012, the Company entered into a collaboration, research and license agreement with Bionomics Limited ("Bionomics") in which it licensed the rights to Bionomics' investigational anti-anxiety compound, BNC210. Under the terms of the agreement, the Company and Bionomics will collaborate on initial research and the Company will be responsible for worldwide development and commercialization of any resulting products, including funding of clinical trials. In connection with entering into the agreement, the Company made an up-front payment to Bionomics of \$3.0 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 Bionomics to perform certain drug discovery activities, will make certain milestone payments pending the achievement of certain development and regulatory milestones, and will make royalty payments if BNC210 is ever successfully commercialized. Pending achievement of certain development and regulatory milestones, Bionomics could receive up to \$345.0 million in up-front and milestone payments and research funding, as well as royalties on sales of products incorporating BNC210 and other related compounds. The Company will expense these payments as incurred. During the three and six months ended June 30, 2012, the Company recorded approximately \$0.4 million and \$3.7 million, respectively, in research and development expense, including the up-front payment, associated with the Bionomics agreement.

Other

The Company has other collaborations that are not individually significant to its business. Pursuant to the terms of those agreements, the Company may be required to pay additional amounts upon the achievement of various development, regulatory and commercial milestones which in the aggregate could be significant. The Company may also incur significant research and development costs if the related product candidate were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring. During the six months ended June 30, 2012, the Company incurred \$1.0 million in research and development expense associated with a research and development milestone under one of the Company's other collaboration agreements. During the three months ended June 30, 2012, and the three and six months ended June 30, 2011, there were no significant milestones achieved under the Company's other collaborations.

5. 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 June 30, 2012 and December 31, 2011 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability.

The Company's investment portfolio includes many fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company applies other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare valuations. 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.

Table of Contents**Ironwood Pharmaceuticals, Inc.**

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The following tables present the assets the Company has measured at fair value on a recurring basis (in thousands):

Description	June 30, 2012	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)	\$ 85,567	\$ 85,567	\$	\$
U.S. government-sponsored securities	70,570		70,570	
Total	\$ 156,137	\$ 85,567	\$ 70,570	\$

Description	December 31, 2011	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)	\$ 77,158	\$ 77,158	\$	\$
U.S. Treasury securities	21,821	21,821		
U.S. government-sponsored securities	54,913		54,913	
Total	\$ 153,892	\$ 98,979	\$ 54,913	\$

Cash equivalents, accounts receivable, including related party accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and the current portion of capital lease obligations at June 30, 2012 and December 31, 2011 are carried at amounts that approximate fair value due to their short-term maturities.

Capital lease obligations at June 30, 2012 and December 31, 2011 approximate fair value as they bear interest at a rate approximating a market interest rate.

6. Available-for-Sale Investments

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The following tables summarize the available-for-sale securities held at June 30, 2012 and December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2012:				
U.S. government-sponsored securities	\$ 70,579	\$ 3	\$ (12)	\$ 70,570
Total	\$ 70,579	\$ 3	\$ (12)	\$ 70,570

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2011:				
U.S. government-sponsored securities	\$ 54,911	\$ 12	\$ (10)	\$ 54,913
U.S. Treasury securities	21,817	4		21,821
Total	\$ 76,728	\$ 16	\$ (10)	\$ 76,734

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The contractual maturities of all securities held at June 30, 2012 are one year or less. There were 22 investments classified as available-for-sale securities in an unrealized loss position at June 30, 2012, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities was approximately \$42.6 million. There were 12 investments classified as available-for-sale securities in an unrealized loss position at December 31, 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 \$35.5 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 does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity. The Company did not hold any securities with other-than-temporary impairment at June 30, 2012.

Gross realized gains and losses on the sales of investments have not been material to the Company's consolidated results of operations.

7. Commitments and Contingencies

The Company leases its facility, offsite data storage location 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 escalated in January 2012 by 6.8% based upon a formula 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, the Company maintains a letter of credit securing its obligations under the lease agreement of approximately \$7.6 million.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The Company amended the lease agreement in February 2010, July 2010, February 2011 and October 2011 (together the Amendments) in order to lease additional space. Pursuant to the Amendments, the Company leases an additional 96,613 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), (c) a third phase of 17,863 rentable square feet (the Third Phase) and (d) a fourth phase of 21,717 rentable square feet (the Fourth Phase). Rent for the Initial Phase commenced on July 1, 2010, rent for the Second Phase commenced on March 1, 2011, rent for the Third Phase commenced on January 1, 2012, and rent for the Fourth Phase commenced on June 1, 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, Third Phase and Fourth Phase is \$42.50 per rentable square foot per year. Base rent for the Initial Phase, Second Phase, Third Phase and Fourth Phase will increase annually by \$0.50 per rentable square foot. Consistent with the Company's treatment of the lease expense associated with the initial lease agreement, lease expense associated with the Amendments, inclusive of the escalating rent payments, is recognized on a straight-line basis over the term of the lease agreement. 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 additional 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 and the Fourth Phase. As of June 30, 2012, approximately \$16.6 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 or the Amendments, as applicable.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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. Certain of the agreements contain minimum purchase commitments, the earliest of which commenced in 2012. As of June 30, 2012, the Company's minimum purchase requirements are as follows: approximately \$16.6 million, \$7.3 million, \$9.7 million, \$9.7 million, \$9.7 million and \$5.9 million for the years ending December 31, 2012 (6 months), 2013, 2014, 2015, 2016 and 2017, respectively.

During the six months ended June 30, 2012, the Company executed a non-cancelable purchase order for drug-product manufacturing equipment in the amount of approximately \$2.7 million, of which, the Company has paid approximately \$0.8 million to date. The balance will be paid in increments upon the delivery of the equipment and upon the installation of the equipment, both anticipated to occur in the fourth quarter of 2012.

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under a non-cancelable operating lease. The Company has a standard indemnification arrangement under the lease that requires it to indemnify its landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's lease. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

As of June 30, 2012 and December 31, 2011, the Company had not experienced any material losses related to these indemnification obligations and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible. As a result, the Company has not established any related reserves.

Litigation

From time to time, the Company is involved in various legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. While the outcome of these other claims cannot be predicted with certainty, management does not believe that the outcome of any of these other legal matters, individually and in aggregate, will have a material adverse effect on the Company's financial position.

8. Stockholders' Equity

Common Stock

In February 2012, the Company sold 6,037,500 shares of its Class A common stock through a firm commitment, underwritten public offering at a price to the public of \$15.09 per share. As a result of the offering, the Company received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately \$85.2 million.

Table of Contents**Ironwood Pharmaceuticals, Inc.**

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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.

A summary of the unvested shares of restricted stock as of June 30, 2012 is presented below:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2011	160,000	\$ 5.72
Granted		\$
Vested	(40,000)	\$ 5.72
Forfeited		\$
Unvested at June 30, 2012	120,000	\$ 5.72

9. 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 June 30, 2012 and December 31, 2011, there were 3,438,331 shares and 6,222,981 shares, respectively, available for future grant under all of 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.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 six months ended June 30, 2012 and 2011:

	Three Months Ended June 30,		Six Months Ended June 30,		
	2012	2011	2012	2011	
Expected volatility	49.6%	48.3%	50.2%	49.6%	
Expected term (in years)	6.5	6.5	6.5	6.5	
Risk-free interest rate	1.3%	2.6%	1.3%	2.8%	
Expected dividend yield	%	%	%	%	

Table of Contents**Ironwood Pharmaceuticals, Inc.**

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Employee stock options	\$ 3,792	\$ 2,759	\$ 7,231	\$ 5,243
Restricted stock awards	106	97	213	215
Non-employee stock options	15	41	45	78
ESPP	135	47	273	98
Stock awards	8	7	15	15
	\$ 4,056	\$ 2,951	\$ 7,777	\$ 5,649

Share-based compensation is reflected in the condensed consolidated statements of comprehensive income (loss) as follows for the three and six months ended June 30, 2012 and 2011 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research and development	\$ 2,077	\$ 1,465	\$ 4,028	\$ 2,803
General and administrative	1,979	1,486	3,749	2,846

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, 2011	16,424,500	\$ 6.09	6.40	\$ 98,999
Granted	3,050,850	\$ 14.16		
Exercised	(514,493)	\$ 3.18		
Cancelled	(267,304)	\$ 12.12		

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Outstanding at June 30, 2012	18,693,553	\$	7.41	6.56	\$	121,956
Vested or expected to vest at June 30, 2012	17,382,144	\$	7.30	6.48	\$	115,204
Exercisable at June 30, 2012(1)	8,619,611	\$	4.28	4.92	\$	82,176

(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 June 30, 2012.

The weighted-average grant date fair value per share of options granted to employees during the three and six months ended June 30, 2012 was approximately \$6.35 and \$7.09, respectively, and approximately \$7.67 and \$6.10 during the three and six months ended June 30, 2011, respectively. The aggregate grant-date fair value of the options granted to employees during the three and six months ended June 30, 2012 was approximately \$3.0 million and \$21.6 million, respectively, and approximately \$3.0 million and \$14.9 million during the three and six months ended June 30, 2011, respectively. The total intrinsic value of options exercised during the three and six months ended June 30, 2012 was approximately \$2.9 million and \$5.4 million, respectively, and approximately \$6.6 million and \$12.8 million during the three and six months ended June 30, 2011, respectively.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

As of June 30, 2012, there was approximately \$0.6 million and \$37.0 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 1.5 years and 3.4 years, respectively. The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures.

10. 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 \$6,000 and \$159,000 in legal fees to this investor during the three and six months ended June 30, 2012, respectively, and approximately \$57,000 and \$95,000 during the three and six months ended June 30, 2011, respectively. At June 30, 2012, the Company had approximately \$6,800 of accounts payable due to this related party. At December 31, 2011, the Company had approximately \$26,000 of accounts payable due to this related party.

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 4). These shares of preferred stock converted to the Company's common stock on a 1:1 basis upon the completion of the Company's initial public offering in February 2010. Amounts due to and due from Forest and Almirall are reflected as related party accounts payable and related party accounts receivable, respectively. These balances are reported net of any balances due to or from the related party. At June 30, 2012, the Company had approximately \$2.4 million in related party accounts receivable associated with Almirall and approximately \$3.7 million in related party accounts payable, net of related party accounts receivable associated with Forest. At December 31, 2011, the Company had approximately \$15,000 in related party accounts receivable associated with Almirall and approximately \$0.6 million in related party accounts receivable, net of related party accounts payable associated with Forest.

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, 2011 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 our mission, we are building a team, a culture and processes centered on creating and marketing internal drugs. We believe that linaclotide, our guanylate cyclase type-C agonist, or GCCA, being developed for the treatment of patients with irritable bowel syndrome with constipation, or IBS-C, and 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. In August 2011, we and our U.S. collaboration partner, Forest Laboratories, Inc., or Forest, submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for linaclotide for the treatment of IBS-C and CC. In April 2012, the FDA extended its standard ten-month review period by three months, so the FDA Prescription Drug User Fee Act, or PDUFA, target action date is now in September 2012.

In September 2011, our European partner, Almirall, S.A, or Almirall, submitted a Market Authorization Application, or MAA, to the European Medicines Agency, or EMA, for linaclotide for the treatment of patients with IBS-C, and Almirall continues to work with the EMA in its review.

Our Japanese partner, Astellas Pharma Inc., or Astellas, continues to develop linaclotide for the treatment of patients with IBS-C in Japan and certain other Asian countries.

We continue to assess alternatives to bring linaclotide to IBS-C and CC sufferers in the parts of the world outside of its partnered territories, which include China. In May 2012, we submitted a Clinical Trial Application, or CTA, to China's State Food and Drug Administration for a Phase 3 trial of linaclotide in patients with IBS-C. The CTA has been accepted for review.

We continue to assess lifecycle management opportunities for linaclotide to ensure that we are maximizing the drug's potential value. As part of our long-term strategy, we and Forest initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CC. In addition, we continue to explore the potential for linaclotide in the pediatric population as well as in other gastrointestinal indications.

We also have a pipeline focused on both research and development of early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, central nervous system, or CNS, disorders, respiratory disease and 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. on January 5, 1998. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc.

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.

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 of approximately \$40.8 million and \$76.4 million in the three and six months ended June 30, 2012,

Table of Contents

respectively, and approximately \$18.8 million and \$37.2 million in the three and six months ended June 30, 2011, respectively. As of June 30, 2012, we had an accumulated deficit of approximately \$508.8 million, and we expect to incur losses for the foreseeable future.

In February 2012, we sold 6,037,500 shares of our Class A common stock through a firm commitment, underwritten public offering at a price to the public of \$15.09 per share. As a result of the offering, we received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately \$85.2 million.

Financial Overview

Revenue. Revenue is generated primarily through our collaboration agreement with Forest, and our license agreements with Almirall and Astellas. 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, or API, and development materials for the collaborative partner. Payments to us may include one or more of the following: nonrefundable 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. Additionally, if linaclotide is approved by the FDA, we will receive payments from Forest for half of the net profit from linaclotide sales in the U.S. We expect our revenue to fluctuate in the short term based on clinical and commercial milestones and, if it is approved based on the potential variability of demand for linaclotide.

Research and development expense. Research and development expense consists of expenses incurred in connection with the discovery, development, manufacture and distribution 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. 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. An NDA for linaclotide with respect to both IBS-C and CC was submitted to the FDA and the PDUFA target action date is expected to occur in September 2012.

We continue to assess lifecycle management opportunities for linaclotide to ensure that we are maximizing the drug's potential value. As part of our long-term strategy, we and Forest initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CC. In addition, we continue to explore the potential for linaclotide in the pediatric population as well as in other gastrointestinal indications.

We also have a pipeline focused on both research and development of early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, CNS disorders, respiratory disease and cardiovascular disease.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

The following table sets forth our research and development expenses related to our product pipeline for the three and six months ended June 30, 2012 and 2011. These expenses relate primarily to external costs associated with manufacturing, including supply chain development, 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.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

Table of Contents

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	(in thousands)	2011	2012	(in thousands)	2011
Demonstrated clinical proof of concept	\$	10,907	\$ 5,428	\$	17,301	\$ 8,951
Early stage, pre-proof of concept		5,952	2,628		12,045	5,412
Early stage, preclinical		1,849	2,313		5,419	7,207

Since 2004, the date we began tracking costs by program, we have incurred approximately \$162.2 million of research and development expenses related to linaclotide. The expenses for linaclotide include both reimbursements to us by Forest as well as our portion of research and development costs incurred by Forest for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreement.

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.

The majority of our external costs are spent on linaclotide, as costs associated with later stage clinical trials are, in most cases, more significant than those incurred in earlier stages of our pipeline. Although we have completed the anticipated development program to support the linaclotide NDA and MAA, we expect to continue to incur costs to support linaclotide development in currently unpartnered territories and in other gastrointestinal indications. Additionally, 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. We do not allocate research and development overhead expense to specific programs as 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.

Table of Contents

- 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 data of each product candidate, the competitive landscape and ongoing assessments of such product candidate's commercial potential.

We expect our research and development costs will be substantial for the foreseeable future. We will continue to invest in linaclotide including the areas of its supply chain and the exploration of its utility in other gastrointestinal and pain indications and other patient populations. We will also invest in our other product candidates as we advance them through preclinical studies and clinical trials, in addition to funding full-time equivalents for research and development activities under our external collaboration and license agreements.

General and administrative expense. General and administrative expense consists primarily of compensation, benefits and other employee related expenses for personnel in our administrative, finance, legal, information technology, business development, commercial and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs and professional fees for accounting and legal services. We anticipate substantial increases in expenses related to developing the organization necessary to commercialize linaclotide.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the 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, research and development expenses 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. 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 six months ended June 30, 2012, we adopted Accounting Standards Update, or ASU, No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04, ASU No. 2011-05, *Presentation of Comprehensive Income*, or ASU 2011-05, and ASU 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, or ASU 2011-12, 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. There have been no significant changes to our critical accounting policies and 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 February 29, 2012 for additional information about these critical accounting policies, as well as a description of our other significant accounting policies.

Results of Operations

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

Table of Contents

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(in thousands)		(in thousands)	
Collaborative arrangements revenue	\$ 14,604	\$ 11,262	\$ 26,852	\$ 21,499
Operating expenses:				
Research and development	32,238	19,409	61,748	38,964
General and administrative	23,200	10,805	41,574	20,029
Total operating expenses	55,438	30,214	103,322	58,993
Loss from operations	(40,834)	(18,952)	(76,470)	(37,494)
Other income (expense):				
Interest expense	(13)	(17)	(27)	(33)
Interest and investment income	44	125	93	279
Other income				3
Other income (expense), net	31	108	66	249
Net loss	\$ (40,803)	\$ (18,844)	\$ (76,404)	\$ (37,245)

*Three and Six Months Ended June 30, 2012 Compared to Three and Six Months Ended June 30, 2011**Revenue*

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2012	2011	\$	%	2012	2011	\$	%
	(dollars in thousands)				(dollars in thousands)			
Collaborative arrangements revenue	\$ 14,604	\$ 11,262	\$ 3,342	29.7%	\$ 26,852	\$ 21,499	\$ 5,353	24.9%

Collaborative Arrangements Revenue. The increase in revenue from collaborative arrangements of approximately \$3.3 million for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 was primarily related to the Almirall license agreement. In June 2011, we revised our estimate of the development period associated with the Almirall license agreement which resulted in approximately \$1.4 million in additional revenue recognized during the three months ended June 2012. Additionally, during the three months ended June 30, 2012 we recognized approximately \$2.0 million more in shipments of linaclotide API to Almirall in anticipation of a potential commercial launch in Europe.

The increase in revenue from collaborative arrangements of approximately \$5.4 million for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was primarily related to the Almirall license agreement. In June 2011, we revised our estimate of the development period associated with the Almirall license agreement which resulted in approximately \$3.5 million in additional revenue recognized during the six months ended June 2012. Additionally during the six months ended June 30, 2012 we recognized approximately \$2.0 million more in shipments of linaclotide API to Almirall in anticipation of a potential commercial launch in Europe.

Table of Contents*Operating Expenses*

	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2012	2011	\$	%	2012	2011	\$	%
	(dollars in thousands)				(dollars in thousands)			
Operating Expenses:								
Research and development	\$ 32,238	\$ 19,409	\$ 12,829	66.1%	\$ 61,748	\$ 38,964	\$ 22,784	58.5%
General and administrative	23,200	10,805	12,395	114.7%	41,574	20,029	21,545	107.6%
Total operating expenses	\$ 55,438	\$ 30,214	\$ 25,224	83.5%	\$ 103,322	\$ 58,993	\$ 44,329	75.1%

Research and Development Expense. The increase in research and development expense of approximately \$12.9 million for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 was primarily related to an increase of approximately \$2.8 million in compensation, benefits, and employee related expenses associated mainly with increased headcount; an increase of approximately \$0.6 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012; an increase of approximately \$5.4 million due to linaclotide development, consisting of increased contract manufacturing costs associated with validation of batches of linaclotide API in anticipation of a potential commercial launch, higher collaboration expenses from Forest and decreased reimbursements from Forest, partially offset by a decrease in contract research associated with lower clinical trial expenses; and an increase of approximately \$3.0 million in research costs related to our other pipeline candidates; and an increase of approximately \$1.2 million in research and development related facilities costs, including rent and amortization of leasehold improvements, associated with additional space we leased in our 301 Binney Street facility.

The increase in research and development expense of approximately \$22.8 million for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was primarily related to an increase of approximately \$7.6 million associated with linaclotide development, consisting of increased contract manufacturing costs associated with validation of batches of linaclotide API in anticipation of a potential commercial launch, higher collaboration expenses from Forest and decreased reimbursements from Forest, partially offset by a decrease in contract research associated with lower clinical trial expenses; an increase of approximately \$6.1 million in compensation, benefits, and employee related expenses associated mainly with increased headcount; an increase of approximately \$5.7 million in research costs related to our other pipeline candidates, including research and development fees, and upfront and milestone payments associated with our licensing agreements; an increase of approximately \$2.1 million in research and development related facilities costs, including rent and amortization of leasehold improvements, associated with additional space we leased in our 301 Binney Street facility; and an increase of approximately \$1.2 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012.

General and Administrative Expense. General and administrative expenses increased approximately \$12.4 million for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 primarily as a result of increases in our workforce expenses and infrastructure as we prepare for our anticipated commercial launch of linaclotide. These increases include approximately \$4.1 million in compensation, benefits and other employee related expenses associated with increased headcount; approximately \$3.5 million in net commercial expenses incurred by Forest in preparation for the commercial launch of linaclotide; external consulting costs of approximately \$3.5 million primarily associated with developing the infrastructure to commercialize and support linaclotide; approximately \$0.6 million in corporate legal expenses; and approximately \$0.5 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

General and administrative expenses increased approximately \$21.6 million for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 primarily as a result of increases in our workforce expenses and infrastructure as we prepare for our anticipated commercial launch of linaclotide. These increases include approximately \$6.9 million in compensation, benefits and other employee related expenses associated with increased headcount; external consulting costs of approximately \$6.2 million primarily associated with developing the infrastructure to commercialize and support linaclotide; approximately \$5.7 million in net commercial expenses incurred by Forest in preparation for the commercial launch of linaclotide; approximately \$0.9 million in general and administrative related facilities and IT infrastructure costs associated with operating our 301 Binney Street facility, including rent and amortization of leasehold improvements; approximately \$0.9 million in corporate legal and other professional service fees, and approximately \$0.9 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012.

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

Other income (expense):														
Interest expense	\$	(13)	\$	(17)	\$	4	23.5%	\$	(27)	\$	(33)	\$	6	18.2%
Interest and investment income		44		125		(81)	(64.8)%		93		279		(186)	(66.7)%
Other income							%				3		(3)	(100.0)%
Total other income (expense), net	\$	31	\$	108	\$	(77)	(71.3)%	\$	66	\$	249	\$	(183)	(73.5)%

Interest and Investment Income. The decrease in interest and investment income for both the three months ended June 30, 2012 compared to the three months ended June 30, 2011 and the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was primarily related to lower average cash balances and interest rates during the three and six months ended June 30, 2012.

Liquidity and Capital Resources

At June 30, 2012, we had approximately \$157.7 million of unrestricted cash, cash equivalents and available-for-sale securities. Our cash equivalents include amounts primarily 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. 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.

During the six months ended June 30, 2012, our cash balances decreased approximately \$0.2 million. This decrease is primarily due to the cash used to operate our business, as we made payments related to, among other things, research and development and general and administrative expenses as we continue to increase headcount and build infrastructure for our anticipated commercial launch of linaclotide and as we invest in our research pipeline. We also invested approximately \$7.0 million in capital expenditures and made payments of approximately \$0.1 million on our capital leases. These uses were partially offset by the approximately \$85.2 million in net proceeds from our public stock offering in February 2012 and approximately \$2.3 million in proceeds from the exercise of stock options and the issuance of shares pursuant to our employee stock purchase plan.

Sources of Liquidity

We have incurred losses since our inception on January 5, 1998 and, as of June 30, 2012; we had an accumulated deficit of approximately \$508.8 million. We have financed our operations to date primarily through both the private sale of our preferred stock and the public sale of our common stock, including approximately \$203.2 million of net proceeds from our IPO in February 2010 and approximately \$85.2 million of net proceeds from our public offering in February 2012; payments received under our strategic collaborative arrangements, including milestone payments and reimbursement of certain expenses; debt financings; strategic sale of assets or businesses and interest earned on investments. We

expect to receive \$85.0 million in milestone payments from Forest upon the FDA approval of linaclotide.

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 anticipated commercial launch of linaclotide, execute on that commercial launch, if approved, 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 unless we receive regulatory approval for commercial sale of linaclotide. As a result, we expect to incur future losses on a quarterly and annual basis at least until we obtain marketing approval and successfully commercialize a product.

Table of Contents

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 provides significant optionality and will be sufficient to meet our projected operating needs through the anticipated commercialization of linaclotide.

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 our 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 success of our third-party manufacturing activities;
- the rate of progress and cost of our commercialization activities;
- the expenses we incur in marketing and selling our product candidates;
- the revenue generated by sales of our product candidates;
- the success of our research and development efforts;
- 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.

Financing Strategy

We may require or access additional funding in the form of public or private equity offerings or debt financings or a credit facility, or we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts. We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

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, 2011. There have been no material changes to our Contractual Obligations and Commercial Commitments table presented for the year ended December 31, 2011 other than the commitments described below.

We, and in some cases, along with our collaboration partner, Forest, have entered into multiple commercial supply agreements with contract manufacturing organizations for the purchase of a portion of the linaclotide API and drug product that will be used to seek regulatory approval of linaclotide in North America and the E.U., and, depending on such approval, that would be used for commercial sales in such countries. Some of the agreements contain minimum purchase commitments. As of June 30, 2012, our minimum purchase requirement across all the agreements is approximately \$58.9 million and will be incurred through 2017.

Table of Contents

During the six months ended June 30, 2012, we executed a non-cancelable purchase order for drug-product manufacturing equipment in the amount of approximately \$2.7 million, of which, we have paid approximately \$0.8 million to date and the balance will be paid in increments upon the delivery of the equipment and upon the installation of the equipment, anticipated to occur in the fourth quarter of 2012.

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 May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends ASC 820, *Fair Value Measurement*, to ensure that fair value has the same meaning in GAAP and International Financial Reporting Standards (IFRS) and improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. ASU 2011-04 applies to all entities that measure assets, liabilities or instruments classified in shareholder s equity at fair value, or provide fair value disclosures for items not recorded at fair value. ASU 2011-04 results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. Consequently, ASU 2011-04 changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, ASU 2011-04 will not result in a change in the application of the requirements in ASC 820. Some of the requirements in ASU 2011-04 clarify the FASB s intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. ASU 2011-04 is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. Early application is not permitted. On January 1, 2012, we adopted ASU 2011-04 on a prospective basis. The adoption did not have a material impact on our consolidated financial position or results of operations.

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 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 public companies for fiscal years, and interim periods within those years, beginning after

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

December 15, 2011 and should be applied retrospectively. In December 2011, the FASB issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12) which defers the effective date of the provisions of ASU 2011-05 pertaining to the presentation of reclassification adjustments out of accumulated other comprehensive income. All other requirements in ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-12 is effective for public companies for fiscal years, and interim periods within those years, beginning after December 15, 2011. On January 1, 2012, we adopted ASU 2011-05 and ASU 2011-12 on a retrospective basis. We have elected to present all nonowner changes in stockholders' equity in a single continuous statement of comprehensive income. The adoption did not have a material impact on our consolidated financial position or results of operations since these standards impact presentation only.

Table of Contents

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

Interest Rate Risk

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

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

We do not believe our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents and available-for-sale securities at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

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

Foreign Currency Risk

We have no significant operations outside the U.S. We are not impacted significantly by foreign currency fluctuations and we have no other derivative financial instruments.

Effects of Inflation

We do not believe that inflation and changing prices over the three and six months ended June 30, 2012 and 2011 had a significant impact on our results of operations.

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.

In August 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. In October 2011, we and Forest announced that the FDA accepted the NDA for review. In April 2012, we and Forest announced that the FDA has extended its standard ten-month review period by three months, so the PDUFA target action date is now expected to occur in September 2012. We and Forest are not permitted to market linaclotide in the U.S. until we receive approval of the NDA from the FDA.

In September 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, and Almirall continues to work with the EMA in its review. 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. 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;

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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 GCCA that achieved positive results in each of our two Phase 3 IBS-C trials and each of our two Phase 3 CC trials. As part of linaclotide's lifecycle management, we and Forest anticipate exploring its potential in the pediatric population as well as in other gastrointestinal indications. Even though linaclotide met all primary and secondary endpoints in each of its IBS-C and CC 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

Linacotide 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 linacotide 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 product liability claims. Any serious adverse events deemed to be caused by linacotide could have a material adverse effect upon the linacotide program and our business as a whole. The most frequently reported adverse event to date in the clinical studies evaluating the safety and efficacy of linacotide has been diarrhea. In the four Phase 3 clinical trials, our results indicate that diarrhea was seen in 14% to 20% of linacotide-treated patients, and was the most common adverse event that led to study discontinuation in 3% to 6% of linacotide-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 linacotide treatment that were deemed by a study investigator or us to be definitely related or probably related to linacotide treatment, nor have there been any deaths in any patients receiving linacotide treatment that were deemed by a study investigator or us to be related to linacotide treatment.

If 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 linacotide;
- 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 linacotide and could substantially increase commercialization costs.

If we or our collaboration partners and other third parties upon whom we rely to produce linacotide 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 possess internal manufacturing capacity we use contract manufacturers to manufacture our clinical and commercial supplies. With respect to the manufacturing of linaclotide API, we have entered into commercial supply agreements with PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB and with Corden Pharma Colorado, Inc., 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 both our partnered and our unpartnered 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, Ammirall and Astellas, is responsible for completing the manufacturing process of linaclotide in its respective territory, which consists of finishing linaclotide into capsules and into final packaging. In addition, we have entered into an agreement with Almac Pharma Services Limited, or Almac, to complete the drug product 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 product for commercial sale. No party has experience producing 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 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, as well as 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-commercialize 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 submission or approval of regulatory applications for linaclotide, as well as the manufacturing and commercialization of linaclotide in the particular country. 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 in 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 aspects of 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, marketing, sales, field operations and medical science. The success of our collaborations is highly dependent on the resources, efforts and skills of our partners and their key employees. As we prepare for the transition of linaclotide from development to commercialization, the drug's success becomes more dependent on us maintaining highly collaborative and well aligned partnerships. 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. Given the inherent uncertainty and disruption that arises in a change of control, we cannot be sure that we would be able to successfully execute these courses of action. Finally, any change of control or in management may result in a reprioritization of linaclotide within such partner's profile, or such partner may fail to maintain the

Table of Contents

financial or other resources necessary to continue supporting its portion of the development, manufacturing or commercialization of linaclotide.

If one of our partners undergoes a change of control and the acquirer either is unable to perform such partner's obligations under its collaboration or license agreement with us or has a product that competes with linaclotide that such acquirer does not divest, 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, manufacture and commercialize linaclotide in that partnered territory on our own or we will need to establish a relationship with a new partner. In anticipation of commercialization of linaclotide in the U.S., we have assembled a team of manufacturing, quality, sales, marketing, payor and pricing and field operations specialists, in addition to specialized medical scientists, who represent the functional areas necessary for a successful commercial launch of a high potential, gastrointestinal therapy in North America. If Forest was subject to a change of control that allowed us to continue linaclotide's commercialization in North America on our own, and we chose to do so, we would need to enhance each of these functional aspects to replace the capabilities that Forest was previously providing to the collaboration. Although many members of our global operations, commercial and medical affairs teams have strategic oversight of, and a certain level of involvement in, their functional areas globally, we do not have corresponding operational capabilities in these areas outside of North America. If Almirall or Astellas was subject to a change of control that allowed us to continue linaclotide's development or commercialization in its territory on our own, and we chose to do so rather than establishing a relationship with a new partner, we would need to build operational capabilities in the relevant territory because we currently only have strategic leadership responsibility in each of these territories.

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.

In August 2011, we and Forest announced that we submitted an NDA with the FDA for linaclotide for the treatment of IBS-C and CC, and in October 2011, we and Forest announced that the FDA accepted the NDA for review. In April 2012, we and Forest announced that the FDA has extended its standard ten-month review period by three months, so the PDUFA target action date is now expected to occur in September 2012. However, even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on linaclotide's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Linaclotide or any other product candidate that is approved by the FDA for marketing 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 or withdraw 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.

Further, we and Forest anticipate exploring linaclotide's potential in the pediatric population as well as in other gastrointestinal indications. If, during the performance of any additional clinical studies on linaclotide, the drug fails to achieve any of its trial endpoints designed to measure its efficacy in such population or such indication, or any adverse events of unanticipated severity or

Table of Contents

frequency arise, linaclotide's commercial potential, even in any indication for which it is already approved at that time, may be materially harmed.

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 or our partners must 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 E.U., differs 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:

- 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 and Forest's sales and marketing organizations and our partners' distribution networks;
- 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 efficacy and safety profile of linaclotide, particularly if unanticipated adverse events related to linaclotide treatment arise and create safety concerns among potential patients or prescribers.

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 in the U.S. 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 an unsatisfactory price.

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

Table of Contents

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.

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.

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 and to effectively co-commercialize linaclotide with Forest, if it is approved, we must rapidly and efficiently build a high quality specialized and compliant national sales force, and we must properly train our sales team on the IBS-C and CC disease states as well as how to effectively promote linaclotide in a compliant manner in conjunction with Forest. Although we actively are preparing to hire and deploy this sales force if linaclotide is approved, we may not build it as quickly or

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

effectively as we anticipate, which may impede or delay our ability to maximize linaclotide's full commercial potential.

Once we have our sales team established, we must provide them with the highest quality support, guidance and oversight in order to enable them to effectively promote linaclotide to gastroenterologists and primary care physicians. Further, we must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around IBS-C, CC and the potential for linaclotide as an appropriate therapy. If we fail to perform these commercial functions in the highest quality manner, linaclotide will not achieve its maximum commercial potential.

In addition, we must optimize our co-commercialization 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-commercialization 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

Table of Contents

additional collaborations or co-commercialization arrangements on acceptable terms, if at all. We also face competition in our search for collaborators, co-commercialization and sales force personnel.

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 will 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;
- 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 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, fraud and reporting laws may prove costly.

Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent, our product candidates' commercial success.

The U.S. government and individual states are aggressively pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Healthcare Act, as modified by the Health Care and Education Reconciliation Act of 2010. These healthcare reform laws contain several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid

Table of Contents

managed care plans, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain health care providers. Additional provisions of the health care reform laws that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on pharmaceuticals sold to certain Medicare Part D beneficiaries.

In addition to governmental efforts in the United States, foreign jurisdictions as well as private health insurers and managed care plans are likely to continue challenging manufacturers' ability to obtain reimbursement, as well as the level of reimbursement, for pharmaceuticals and other healthcare related products and services. These cost-control initiatives could significantly decrease the available coverage and the price we might establish for linaclotide and our other potential products, which would have an adverse effect on our financial results.

The Food and Drug Administration Amendments Act of 2007 also provides 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 the benefit. Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. 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.

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;

Table of Contents

- 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

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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

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

- failure to conduct the clinical trial in accordance with regulatory requirements or the study protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- 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, operations and commercial personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses,

Table of Contents

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, clinical strategies and our global supply chain plans, 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;
- 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.

Table of Contents

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could 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. Synergy Pharmaceuticals, Inc., or Synergy, has recently filed a request for inter partes reexamination with the United States Patent and Trademark Office, or the USPTO, for our U.S. Patent 7,704,947, which covers a group of peptides that includes linaclotide and related molecules. The USPTO has not yet decided whether to order reexamination of this patent. If the USPTO does order reexamination of this patent, we cannot be certain that the validity of this patent will be

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

upheld. This patent is one of several issued patents and pending applications related to linaclotide, including a linaclotide composition of matter and methods of use patent (U.S. Patent 7,304,036) as well as additional patents and applications covering processes for making linaclotide, formulations, and dosing regimens. Although none of our other issued patents currently is subject to a patent reexamination or an inter partes request for reexamination, we cannot guarantee that they will not be subject to reexamination by the USPTO in the future. If any or all of our linaclotide-related patents were invalidated, we would still have five years of marketing exclusivity under the Hatch-Waxman Act once linaclotide was approved. We believe that each of the patents in our linaclotide patent portfolio was rightfully issued and the portfolio gives us sufficient freedom to operate, however, if any of our present or future patents is invalidated, this could have an adverse effect on our business and financial results, particularly for the period beyond five years following marketing approval.

Furthermore, the America Invents Act, which was recently signed into law, will make several major changes in the U.S. patent statutes over the course of the next few years. These changes will permit third parties to challenge our patents more easily and will create uncertainty with respect to the interpretation and practice of U.S. patent law for the foreseeable future.

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

Table of Contents

inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

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

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

Our commercial success will depend upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our products 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, 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 intellectual property rights. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the counter-party 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;

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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 or invalidity proceeding, a court or patent administrative body 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

Table of Contents

interpreted narrowly and could put our patent applications at risk of not issuing. In January 2012, we were issued a U.S. patent that covers the use of plecanatide, another GCCA being developed by Synergy for the treatment of IBS-C and constipation. In April 2012, we also received a notice of allowance from the European Patent Office for a European patent covering the use of plecanatide for the treatment of these disorders.

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

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 of approximately \$40.8 million and \$18.8 million in the three months ended June 30, 2012 and 2011, respectively. As of June 30, 2012, we had an accumulated deficit of approximately \$508.8 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 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 could force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing product candidates, conducting clinical trials, purchasing commercial quantities of pharmaceutical products 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:

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- the timing of any regulatory approvals of our product candidates;
- 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 rate of progress and cost of our clinical trials and other product development programs;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;
- the costs of establishing sales, marketing and distribution capabilities; and
- the status, terms and timing of any collaboration, licensing, co-commercialization 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.

Table of Contents

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:

- 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 candidates;
- 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.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and it is possible that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. We have completed several financings since our inception which may have resulted in a change in control as defined by Section 382, or could result in a change in control in the future.

Risks Relating to Securities Markets and Investment in Our Stock

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

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

- Our certificate of incorporation provides for a dual class common stock structure. As a result of this structure, holders of our Class B common stock have significant influence over certain matters requiring stockholder approval, including a merger involving Ironwood, a sale of substantially all Ironwood assets and a dissolution or liquidation of Ironwood. This concentrated control could discourage others from initiating a change of control transaction that other stockholders may view as beneficial.

Table of Contents

- 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.
- 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 bylaws, 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.

The concentration of voting control on certain corporate matters with our pre-IPO stockholders will limit your ability to influence such matters.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 certain corporate matters listed below 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 June 30, 2012, the holders of our Class A common stock own approximately 70% and the holders of our Class B common stock own approximately 30% 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 19% and holders of our Class B common stock have approximately 81% of the total votes on each of the matters identified in the list below. This concentrated control of our Class B common stockholders 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.

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

Table of Contents

- 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.

If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our Class A common stock could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The NASDAQ Stock Market or other regulatory authorities.

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;
- any third-party coverage and reimbursement policies for linaclotide;

- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results, 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;
- 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.

Table of Contents

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.

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:

- our ability to obtain U.S. and foreign regulatory approval of linaclotide and the ability of all of our product candidates to meet existing or future regulatory standards;
- our expectations regarding federal, state and foreign regulatory requirements;
- the safety profile and related adverse events of our product candidates;
- our ability to manufacture sufficient amounts of linaclotide for commercialization activities;
- the timing of commercializing our product candidates;
- the therapeutic benefits and effectiveness 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 plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates, as well as the in-licensing or acquisition of externally discovered programs;
- the success of our clinical studies for our product candidates;
- our expectations and desires 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;
- the status of government regulation in the life sciences industry, particularly with respect to health care reform;
- 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.

Table of Contents

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.

Item 2. *Unregistered Sales of Equity Securities*

We did not repurchase any of our equity securities during the quarter ended June 30, 2012.

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: August 7, 2012

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

Date: August 7, 2012

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

Exhibit No:	Description
3.1	Eleventh Amended and Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 of Ironwood Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 30, 2010.
3.2	Fifth Amended and Restated Bylaws. Incorporated by reference to Exhibit 3.2 of Ironwood Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 30, 2010.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Database.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

Furnished herewith.