IRONWOOD PHARMACEUTICALS INC Form 10-Q May 10, 2012 Table of Contents

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

For the transition period from

to

Commission file number: 001-34620

## IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(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 x No o

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

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

Large accelerated filer x

Accelerated filer o

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

Smaller reporting company o

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

As of May 1, 2012, there were 75,387,167 shares of Class A common stock outstanding and 31,828,007 shares of Class B common stock outstanding.

#### Table of Contents

#### IRONWOOD PHARMACEUTICALS, INC.

#### **QUARTERLY REPORT ON FORM 10-Q**

#### FOR THE QUARTER ENDED MARCH 31, 2012

#### TABLE OF CONTENTS

		Page
	PART I FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	
<del></del>	Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011	1
	Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three	
	Months Ended March 31, 2012 and 2011	2
	Condensed Consolidated Statements of Cash Flows for the Three Months Ended	
	March 31, 2012 and 2011	3
	Notes to Condensed Consolidated Financial Statements	4
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	s 21
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
<u>Item 4.</u>	Controls and Procedures	29
	PART II OTHER INFORMATION	
Item 1A.	Risk Factors	30
Item 2.	Unregistered Sales of Equity Securities	47
Item 6.	Exhibits	47
	Signatures	48

#### 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)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 131,612	\$ 87,282
Available-for-sale securities	70,496	76,734
Accounts receivable	109	74
Related party accounts receivable, net		578
Prepaid expenses and other current assets	4,048	2,899
Total current assets	206,265	167,567
Restricted cash	7,647	7,647
Property and equipment, net	35,140	33,625
Other assets	124	138
Total assets	\$ 249,176	\$ 208,977
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 1,996	\$ 6,436
Related party accounts payable, net	1,175	
Accrued research and development costs	7,958	7,010
Accrued expenses	11,598	11,122
Current portion of capital lease obligations	271	233
Current portion of deferred rent	4,350	4,042
Current portion of deferred revenue	24,935	36,291
Total current liabilities	52,283	65,134
Capital lease obligations, net of current portion	435	422
Deferred rent, net of current portion	11,964	12,435
Deferred revenue, net of current portion	20,348	21,130
Commitments and contingencies (Note 7)		
Stockholders equity:		

Preferred stock, \$0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding at March 31,2012 and December 31,2011

outstanding at March 51, 2012 and December 51, 2011		
Class A common stock, \$0.001 par value, 500,000,000 shares authorized and 75,316,558 and		
61,801,770 shares issued and outstanding at March 31, 2012 and December 31, 2011,		
respectively	75	62
Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 31,675,966 and		
38,914,080 shares issued and outstanding at March 31, 2012 and December 31, 2011,		
respectively	32	39
Additional paid-in capital	632,029	542,141
Accumulated deficit	(467,993)	(432,392)
Accumulated other comprehensive income	3	6
Total stockholders equity	164,146	109,856
Total liabilities and stockholders equity	\$ 249,176 \$	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 Income (Loss)**

#### (In thousands, except share and per share amounts)

#### (unaudited)

			onths End	ed
		2012		2011
Collaborative arrangements revenue	\$	12,248	\$	10,237
Operating expenses:				
Research and development		29,510		19,555
General and administrative		18,374		9,224
Total operating expenses		47,884		28,779
Loss from operations		(35,636)		(18,542)
Other income (expense):				
Interest expense		(14)		(16)
Interest and investment income		49		154
Other income				3
Other income (expense), net		35		141
Net loss		(35,601)		(18,401)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments		(3)		51
Other comprehensive income (loss)		(3)		51
Comprehensive loss	\$	(35,604)	\$	(18,350)
Net loss per share basic and diluted	\$	(0.34)	\$	(0.19)
Weighted average number of common shares used in net loss per share	basic and diluted	103,751,060		99,075,187

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

#### Table of Contents

#### Ironwood Pharmaceuticals, Inc.

#### **Condensed Consolidated Statements of Cash Flows**

#### (In thousands)

#### (unaudited)

	Three Months Ended March 31,		
	2012		2011
Cash flows from operating activities:			
Net loss	\$ (35,601)	\$	(18,401)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,680		2,133
Loss on disposal of property and equipment	1		
Share-based compensation expense	3,721		2,698
Accretion of discount/premium on investment securities	309		727
Changes in assets and liabilities:			
Accounts receivable	543		(1,289)
Restricted cash			2,833
Prepaid expenses and other current assets	(1,149)		1,021
Other assets	14		23
Accounts payable and accrued expenses	(2,227)		(2,962)
Accrued research and development costs	948		(88)
Deferred revenue	(12,138)		(10,013)
Deferred rent	(163)		(595)
Net cash used in operating activities	(43,062)		(23,913)
Cash flows from investing activities:			
Purchases of available-for-sale securities	(23,339)		(39,436)
Sales and maturities of available-for-sale securities	29,265		68,111
Purchases of property and equipment	(4,642)		(3,468)
Proceeds from sale of property and equipment	4		
Net cash provided by investing activities	1,288		25,207
Cash flows from financing activities:			
Proceeds from issuance of common stock	85,228		
Proceeds from exercise of stock options	945		675
Payments on borrowings	(69)		(76)
Net cash provided by financing activities	86,104		599
Net increase in cash and cash equivalents	44,330		1,893
Cash and cash equivalents, beginning of period	87,282		44,321
Cash and cash equivalents, end of period	\$ 131,612	\$	46,214
Supplemental cash flow disclosures:			
Cash paid for interest	\$ 12	\$	15
Purchases under capital leases	\$ 120	\$	325

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

<b>7D 1</b>	1			c.	$\sim$			
Tal	٦I	$\boldsymbol{e}$	$\cap$ 1	1		۱n	tei	ntc

Ironwood	Pharmace	euticals.	Inc.
----------	----------	-----------	------

#### **Notes to Condensed Consolidated Financial Statements**

#### (unaudited)

#### 1. Nature of Business

Ironwood Pharmaceuticals, Inc. (the Company ) is an entrepreneurial pharmaceutical company that discovers, develops and intends to commercialize differentiated medicines that improve patients lives. The Company s lead product candidate is linaclotide, a guanylate cyclase type-C 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 February 2012, the FDA informed the Company and Forest that it will not schedule an advisory committee meeting in connection with its review of the NDA. 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, Almirall, S.A. ( Almirall ) submitted a Market Authorization Application ( MAA ) to the European Medicines Agency ( EMA ) for linaclotide for the treatment of patients with IBS-C, and Almirall 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.

The Company also continues to assess lifecycle management opportunities for linaclotide in order to ensure that it is maximizing the drug s potential value. Based on its preliminary efforts to date, the Company anticipates that these activities will include the exploration of the potential for linaclotide in the pediatric population as well as in other gastrointestinal indications.

The Company also has 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 (CNS) disorders, respiratory disease and cardiovascular disease.

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 March 31, 2012 of approximately \$468.0 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 firm commitment, underwritten 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 March 31, 2012 and for the three months ended March 31, 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 March 31, 2012 and results of its operations and its cash flows for the three months ended March 31, 2012 and 2011. The interim results for the three months ended March 31, 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.

4

<b>7D 1</b>	1			c.	$\sim$			
Tal	٦I	$\boldsymbol{e}$	$\cap$ 1	1		۱n	tei	ntc

Ironwood	Pharma	ceuticals.	Inc.
----------	--------	------------	------

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

(unaudited)

#### **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 \$128.3 million and \$77.2 million at March 31, 2012 and December 31, 2011, respectively.

#### **Available-for-Sale Securities**

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

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and investment income. To determine whether an other-than-temporary impairment exists, the Company considers whether it

has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no other-than-temporary impairments for the three months ended March 31, 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 savailable-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.

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 from Forest and Almirall are presented as related party accounts receivable on the condensed consolidated balance sheets as both entities own common stock of the Company.

At March 31, 2012 and December 31, 2011, accounts receivable from Forest, net of any payables due Forest, accounted for approximately 0% and 86%, respectively, of the Company s total accounts receivable. At March 31, 2012 and December 31, 2011, Almirall accounted for approximately 0% and 2%, respectively, of the Company s total accounts receivable. At March 31, 2012 and December 31, 2011, Astellas accounted for approximately 100% and 11%, respectively, of the Company s total accounts receivable.

#### **Table of Contents**

#### Ironwood Pharmaceuticals, Inc.

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

#### (unaudited)

The percentages of revenue recognized from significant customers of the Company in the three months ended March 31, 2012 and 2011 are included in the following table:

# Three Months Ended March 31, Collaborative Partner: 2012 2011 Forest 45% 53% Almirall 48% 37% Astellas 7% 10%

For the three months ended March 31, 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.

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 March 31, 2012, the Company had collaboration and license agreements with Forest, Almirall 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 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.

<b>7D 1</b>	1			c.	$\sim$			
Tal	٦I	$\boldsymbol{e}$	$\cap$ 1	1		۱n	tei	ntc

Ironwood	Pharma	ceuticals.	Inc.
----------	--------	------------	------

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

(unaudited)

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. The Company generally assesses the estimated period of performance to approximate the research and development term due to the Company s continuing involvement in the performance of research and development activities. Typically the research and development term begins at the inception of the collaboration or license agreement and concludes when the Company significant research and development obligations under the agreement have ended. 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 months ended March 31, 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 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.

<b>7D</b> 1	1	-	_	
1 21	$\mathbf{n}$	nt.	( '(	ntents

Ironwood	Pharma	ceuticals.	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 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	Pharmaceutical	s, 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 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**

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 March 31, 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 March 31, 2012 or December 31, 2011.

Tab]	le of	Contents

Ironwood	Pharma	ceuticals.	. 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 sequity 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, 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.

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. 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 calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended				
	Marc	h 31,			
	2012		2011		
Numerator:					
Net loss	\$ (35,601)	\$	(18,401)		
Denominator:					
Weighted average number of common shares used in net					
loss per share basic and diluted	103,751,060		99,075,187		
Net loss per share basic and diluted	\$ (0.34)	\$	(0.19)		

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of March 31, 2012 and 2011, as they would be anti-dilutive:

	At March 31,			
	2012			
Options to purchase common stock	18,631,592	16,038,788		
Shares subject to repurchase	140,000	252,094		
	18,771,592	16,290,882		

#### 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 sestimate of the period over which linaclotide will be jointly developed under the collaboration. At March 31, 2012, approximately \$6.4 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 March 31, 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 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 March 31, 2012, approximately \$0.8 million of the incremental deferred revenue remains deferred. In July 2009, the

#### **Table of Contents**

#### Ironwood Pharmaceuticals, Inc.

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

#### (unaudited)

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 March 31, 2012, approximately \$0.9 million and \$1.8 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.

The Company recognized revenue from the Forest collaboration agreement totaling approximately \$5.5 million and \$5.4 million during the three months ended March 31, 2012 and 2011, respectively.

Further, because the Company shares development costs equally with Forest, payments from Forest with respect to research and development costs incurred by the Company are recorded as a reduction to expense, and not as revenue. As a result of the cost-sharing arrangements under the collaboration, the Company offset approximately \$1.2 million and \$4.2 million during the three months ended March 31, 2012 and 2011, respectively, against research and development expense. During the three months ended March 31, 2011, the Company offset approximately \$0.2 million against general and administrative expense. The Company recognized approximately \$2.0 million in incremental general and administrative expense associated with the Forest collaboration during the three months ended March 31, 2012.

#### 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 2011. At March 31, 2012, approximately \$7.1 million of the up-front license fee remains deferred. The license agreement also includes contingent milestone payments, as well as a contingent equity investment, that could total up to \$55.0 million upon achievement of specific clinical and sales milestones. At March 31, 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.

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 March 31, 2012, approximately \$1.1 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.

<b>m</b>	. 1		c			
Tal	hl	e	ot	on	itei	nts

#### Ironwood Pharmaceuticals, Inc.

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

#### (unaudited)

In November 2010, the Company achieved a second development milestone under the Almirall license agreement, which the Company determined to be substantive, which resulted in a \$19.0 million payment, representing a \$20.0 million milestone, net of foreign withholding taxes. The Company recognized revenue of approximately \$7.2 million upon achievement of the milestone. This amount represented the portion of the milestone payment equal to the applicable percentage of the performance period that had elapsed as of the date the milestone was achieved. The remainder of the balance was deferred, and is being recognized on a straight-line basis over the remaining development period. At March 31, 2012, approximately \$3.6 million of the milestone payment remains deferred.

The Company recognized approximately \$5.9 million and \$3.8 million in total revenue from the Almirall license agreement during the three months ended March 31, 2012 and 2011, respectively, including approximately \$18,000 from the sale of API to Almirall during the three months ended March 31, 2011.

#### 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 is 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 is estimate of the period over which linaclotide will be developed under the license agreement for the Asian market. At March 31, 2012, approximately \$23.5 million of the up-front license fee remains deferred. During the three months ended March 31, 2012 and 2011, the Company recognized approximately \$0.9 million and \$1.0 million, respectively, in revenue from the Astellas license agreement, including approximately \$0.1 million and \$0.2 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 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 months ended March 31, 2012 and 2011, the Company recorded approximately \$0.7 million and \$3.2 million, respectively, in research and development expense, including the up-front payment, associated with the Protagonist agreement.

<b>m</b>	. 1		c			
Tal	hl	e	ot	on	itei	nts

Ironwood	Pharma	ceuticals.	. 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 months ended March 31, 2012, the Company recorded approximately \$3.3 million 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 three months ended March 31, 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.

#### 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 March 31, 2012 and December 31, 2011 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or

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

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):

		Fair Value Measurements at Reporting Date Using					
	March 31,		Quoted Prices in Active Markets for Identical Assets	Si	gnificant Other Observable Inputs	Significar Unobserva Inputs	
Description	2012		(Level 1)		(Level 2)	(Level 3)	)
Money market funds (included in cash and cash							
equivalents)	\$ 128,336	\$	128,336	\$		\$	
U.S. Treasury securities	1,004		1,004				
U.S. government-sponsored securities	69,492				69,492		
Total	\$ 198,832	\$	129,340	\$	69,492	\$	

			Fair Value Measurements at Reporting Date Using				
	ъ		Quoted Prices in Active Markets for		Significant Other Observable		Significant Unobservable
Description	ע	ecember 31, 2011		Identical Assets (Level 1)		Inputs (Level 2)	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 March 31, 2012 and December 31, 2011 are carried at amounts that approximate fair value due to their short-term maturities.

Capital lease obligations at March 31, 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

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

	Amo	ortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	ì	Fair Value
March 31, 2012:							
U.S. government-sponsored securities	\$	69,489	\$	7	\$	(4) \$	69,492
U.S. Treasury securities		1,004					1,004
Total	\$	70,493	\$	7	\$	(4) \$	70,496

	Amortizeo	d 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
		15					

#### **Table of Contents**

#### Ironwood Pharmaceuticals, Inc.

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

#### (unaudited)

The contractual maturities of all securities held at March 31, 2012 are one year or less. There were eleven investments classified as available-for-sale securities in an unrealized loss position at March 31, 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 \$19.8 million. There were twelve 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 an other-than-temporary impairment at March 31, 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.

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 will commence no later than 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 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 March 31, 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.

16

#### **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 March 31, 2012, the Company s minimum purchase requirement across all the agreements is approximately \$58.7 million through 2017. The Company s minimum purchase requirement by year is as follows: approximately \$16.5 million, \$7.2 million, \$9.7 million, \$9.7 million, \$9.7 million, \$9.7 million and \$5.9 million for the years ending December 31, 2012 (9 months), 2013, 2014, 2015, 2016 and 2017, respectively.

#### 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.

As of March 31, 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 consolidated financial statements.

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. The Company intends to use these proceeds for general corporate purposes, including to further strengthen its balance sheet in advance of the potential market launch of linaclotide (if approved).

17

#### **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 March 31, 2012 is presented below:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2011	160,000	5.72
Granted	\$	6
Vested	(20,000) \$	5.72
Forfeited	\$	6
Unvested at March 31, 2012	140,000	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 March 31, 2012 and December 31, 2011, there were 3,776,715 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.

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 months ended March 31, 2012 and 2011:

18

	Three Months March 3	
	2012	2011
Expected volatility	50.3%	49.9%
Expected term (in years)	6.5	6.5
Risk-free interest rate	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				
	March 31,				
	2012		2011		
Employee stock options	\$ 3,439	\$	2,484		
Restricted stock awards	107		118		
Non-employee stock options	30		37		
Employee stock purchase plan	138		51		
Stock awards	7		8		
	\$ 3,721	\$	2,698		

Share-based compensation is reflected in the condensed consolidated statements of comprehensive income (loss) as follows for the three months ended March 31, 2012 and 2011 (in thousands):

		Three Months Ended						
		March 31,						
	20	012		2011				
Research and development	\$	1,951	\$		1,338			
General and administrative		1,770			1,360			

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	2,584,850	\$ 14.40		
Exercised	(238,613)	\$ 3.93		
Cancelled	(139,145)	\$ 10.94		

Outstanding at March 31, 2012	18,631,592 \$	7.24	6.68 \$	117,455
Vested or expected to vest at March 31, 2012	17,247,890 \$	7.10	6.58 \$	110,994
Exercisable at March 31, 2012(1)	8,288,298 \$	3.84	4.87 \$	78,656

<sup>(1)</sup> 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 March 31, 2012.

The weighted-average grant date fair value per share of options granted to employees during the three months ended March 31, 2012 and 2011 was approximately \$7.20 and \$5.80, respectively. The aggregate grant-date fair value of the options granted to employees during the three months ended March 31, 2012 and 2011 was approximately \$18.6 million and \$11.9 million, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2012 and 2011 was approximately \$2.4 million and \$6.2 million, respectively.

Tab]	le of	Contents

#### Ironwood Pharmaceuticals, Inc.

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

#### (unaudited)

As of March 31, 2012, there was approximately \$0.8 million and \$38.7 million of unrecognized share-based compensation, net of estimated forfeitures, related to restricted stock awards and unvested stock option grants with time-based vesting, respectively, which are expected to be recognized over a weighted-average period of 1.75 years and 2.96 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 \$152,000 and \$39,000 in legal fees to this investor during the three months ended March 31, 2012 and 2011, respectively. At March 31, 2012, the Company did not have any 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.

#### 11. Subsequent Events

In April 2012, the Company and Forest announced that the FDA has extended its standard ten-month review period of the linaclotide NDA by three months, so the FDA PDUFA target action date is now expected to occur in September 2012.

#### 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 February 2012, the FDA informed us and Forest that it will not schedule an advisory committee meeting in connection with its review of the NDA. 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. 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.

We also continue to assess lifecycle management opportunities for linaclotide in order to ensure that it is maximizing the drug s potential value. Based on our preliminary efforts to date, we anticipate that these activities will include the exploration of 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 \$35.6 million and \$18.4 million in the three months ended March 31, 2012 and 2011, respectively. As of March 31, 2012, we had an accumulated deficit of approximately \$468.0 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. We intend to use these proceeds for general corporate purposes, including to further strengthen our balance sheet in advance of the potential market launch of linaclotide (if approved).

#### **Financial Overview**

*Revenue*. Revenue is generated primarily through our collaboration agreement with Forest, and our license agreements with Almirall, and Astellas Pharma Inc., or Astellas. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) the manufacture of active pharmaceutical ingredient, or API, and

#### **Table of Contents**

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 now expected to occur in September 2012.

Additionally, an MAA for linaclotide for IBS-C was submitted to the EMA by Almirall in September 2011 and Almirall continues to work with the EMA in its review.

Our Japanese partner, 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.

We also continue to assess lifecycle management opportunities for linaclotide in order to ensure that it is maximizing the drug s potential value. Based on our preliminary efforts to date, we anticipate that these activities will include the exploration of 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.

The following table sets forth our research and development expenses related to our product pipeline for the three months ended March 31, 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.

## Three Months Ended March 31.

		murch or,		
	20	)12		2011
		(in thou	isands)	
Demonstrated clinical proof of concept	\$	10,145	\$	3,523
Early development candidates		6,093		2,784
Discovery research		3,570		4,894

We began tracking program expenses for linaclotide in 2004, and research and development program expenses from inception to March 31, 2012 were approximately \$158.2 million. The expenses for linaclotide include both reimbursements to us by Forest as well as our portion of costs incurred by Forest for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreement.

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

#### Table of Contents

As a

clinical tria	are successful in early stage clinical trials, we would expect external costs to increase as the programs progress through later stage als. The remainder of our research and development expense is not tracked by project as it consists primarily of our internal costs, and multiple projects that are in earlier stages of development and which typically share resources.
The succes	ssful 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 tical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly onsuming procedures.
	Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit regulatory approval.
• and are dif	The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a product candidate ficult to predict.
•	The costs, timing and outcome of regulatory review of a product candidate may not be favorable.
•	The emergence of competing technologies and products and other adverse market developments may negatively impact us.