IRONWOOD PHARMACEUTICALS INC
Form 10-Q
November 06, 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 September 30, 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	**04-3404176**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
301 Binney Street **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	(Zip Code)

(617) 621-7722

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes 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 October 29, 2012, there were 76,594,242 shares of Class A common stock outstanding and 30,911,113 shares of Class B common stock outstanding.

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the timing, investment and associated activities involved in commercializing LINZESS in the U.S.;
- our ability to manufacture sufficient amounts of LINZESS for commercial launch;
- our partners ability to obtain foreign regulatory approval of linaclotide and the ability of all of our product candidates to meet existing or future regulatory standards;
- our expectations regarding U.S. and foreign regulatory requirements, including our post-approval, non-clinical and clinical post-marketing plan with the FDA to understand linaclotide s efficacy and safety in pediatric patients;
- the safety profile and related adverse events of linaclotide in adult patients;
- the ability of our partners to perform their obligations under our collaboration and license agreements with them;
- the therapeutic benefits and effectiveness of our product candidates;
- our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates, as well as the in-licensing or acquisition of externally discovered programs;
- our expectations as to future financial performance, expense levels, capital raising and liquidity sources;

- the ability to compete with other companies that are or may be developing or selling products that are competitive with our products and product candidates;

- the status of government regulation in the life sciences industry, particularly with respect to health care reform;

- anticipated trends and challenges in our potential markets; and

- our ability to attract and motivate key personnel.

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

You should not unduly rely on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Unless required by law, we undertake no obligation to publicly update or revise

Table of Contents

any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

NOTE REGARDING TRADEMARKS

LINZESS and CONSTELLA® are trademarks of Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this Form 10-Q are the property of their respective owners. All rights reserved.

Table of Contents

IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2012

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(unaudited)

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 125,867	$ 87,282
Available-for-sale securities	67,456	76,734
Accounts receivable	169	74
Related party accounts receivable, net	13	578
Inventory	965	
Prepaid expenses and other current assets	7,877	2,899
Total current assets	202,347	167,567
Restricted cash	7,647	7,647
Property and equipment, net	36,470	33,625
Other assets	54	138
Total assets	$ 246,518	$ 208,977
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,652	$ 6,436
Related party accounts payable, net	2,141	
Accrued research and development costs	6,154	7,010
Accrued expenses	16,689	11,122
Current portion of capital lease obligations	280	233
Current portion of deferred rent	4,531	4,042
Current portion of deferred revenue	3,130	36,291
Total current liabilities	35,577	65,134
Capital lease obligations, net of current portion	361	422
Deferred rent, net of current portion	9,690	12,435
Deferred revenue, net of current portion	18,782	21,130
Commitments and contingencies (Note 9)		

Stockholders equity:				
Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding at September 30, 2012 and December 31, 2011				
Class A common stock, $0.001 par value, 500,000,000 shares authorized and 76,567,991 and 61,801,770 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		77		62
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 30,911,113 and 38,914,080 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		31		39
Additional paid-in capital		643,154		542,141
Accumulated deficit		(461,161)		(432,392)
Accumulated other comprehensive income		7		6
Total stockholders equity		182,108		109,856
Total liabilities and stockholders equity	$	246,518	$	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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Collaborative arrangements revenue	$ 96,413	$ 12,218	$ 123,265	$ 33,717
Operating expenses:				
Research and development	23,453	22,905	85,201	61,869
General and administrative	25,352	10,929	66,926	30,958
Total operating expenses	48,805	33,834	152,127	92,827
Income (loss) from operations	47,608	(21,616)	(28,862)	(59,110)
Other income (expense):				
Interest expense	(14)	(16)	(41)	(49)
Interest and investment income	41	105	134	384
Other income		897		900
Other income (expense), net	27	986	93	1,235
Net income (loss) before income taxes	47,635	(20,630)	(28,769)	(57,875)
Income tax expense		3		3
Net income (loss)	$ 47,635	$ (20,633)	$ (28,769)	$ (57,878)
Basic net income (loss) per share	$ 0.44	$ (0.21)	$ (0.27)	$ (0.58)
Diluted net income (loss) per share	$ 0.42	$ (0.21)	$ (0.27)	$ (0.58)
Weighted average number of common shares used in:				
Basic net income (loss) per share	107,266,823	100,174,100	106,036,522	99,699,545
Diluted net income (loss) per share	114,337,327	100,174,100	106,036,522	99,699,545
Comprehensive income (loss)	$ 47,651	$ (20,680)	$ (28,768)	$ (57,873)

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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (28,769)	$ (57,878)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,522	7,323
Loss on disposal of property and equipment	20	8
Share-based compensation expense	12,912	8,511
Accretion of discount/premium on investment securities	840	1,851
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	470	2,154
Restricted cash		2,833
Prepaid expenses and other current assets	(4,978)	2,424
Inventory	(965)	
Other assets	84	82
Accounts payable and accrued expenses	3,311	(1,064)
Accrued research and development costs	(856)	(511)
Deferred revenue	(35,509)	(32,873)
Deferred rent	(2,256)	(396)
Net cash used in operating activities	(47,174)	(67,536)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(60,896)	(81,524)
Sales and maturities of available-for-sale securities	69,335	177,075
Purchases of property and equipment	(10,595)	(6,033)
Proceeds from sale of property and equipment	9	4
Net cash provided by (used in) investing activities	(2,147)	89,522
Cash flows from financing activities:		
Proceeds from issuance of common stock	85,228	
Proceeds from exercise of stock options and employee stock purchase plan	2,881	2,719
Payments on capital leases	(203)	(206)
Net cash provided by financing activities	87,906	2,513
Net increase in cash and cash equivalents	38,585	24,499
Cash and cash equivalents, beginning of period	87,282	44,321
Cash and cash equivalents, end of period	$ 125,867	$ 68,820
Supplemental cash flow disclosures:		
Cash paid for interest	$ 16	$ 47

Cash paid for income taxes	$	$ 3
Purchases under capital leases	$ 247	$ 325

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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Ironwood Pharmaceuticals, Inc. (the Company) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. The Company s lead product, linaclotide, will be marketed in the United States (U.S.) under the trademarked name of LINZESS. On August 30, 2012, the United States Food and Drug Administration (FDA) approved LINZESS as a once-daily treatment for adult men and women suffering from irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). LINZESS is the first FDA-approved guanylate cyclase type-C (GC-C) agonist and it was shown in clinical trials to help relieve abdominal pain and constipation associated with IBS-C and improve constipation symptoms associated with CIC. LINZESS is being commercialized in the U.S. by the Company and its collaboration partner, Forest Laboratories, Inc. (Forest) and will become commercially available for the first time in December 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. On September 21, 2012, the EMA s European Committee for Medicinal Products for Human Use, which provides non-binding recommendations for consideration by the EMA, issued a positive opinion recommending the marketing approval for linaclotide for the treatment of moderate to severe IBS-C in adults.

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

The Company continues to assess alternatives to bring linaclotide to IBS-C and CIC sufferers in the parts of the world outside of its partnered territories. In May 2012, the Company submitted a Clinical Trial Application (CTA) to China s State Food and Drug Administration for a Phase 3 trial of linaclotide in patients with IBS-C. The CTA has been accepted for review. In October 2012, the Company also entered into a collaboration agreement with AstraZeneca AB (AstraZeneca) to co-develop and co-commercialize linaclotide in China (Note 13).

The Company continues to assess opportunities to expand the utility of linaclotide as well as the patient population who could benefit from linaclotide to ensure that it is maximizing the drug s potential value. As part of its long-term strategy, the Company and Forest initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CIC. In addition, the Company continues to explore the potential for linaclotide in other patient populations as well as in other gastrointestinal indications.

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

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 September 30, 2012 of approximately $461.2 million since inception. In February 2010, the Company completed its initial public offering of Class A common stock and raised a total of approximately $203.2 million in net proceeds. Additionally, in February 2012, the Company sold 6,037,500 shares of its Class A common stock through a follow-on public offering and raised a total of approximately $85.2 million in net proceeds (Note 10).

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying condensed consolidated financial statements and the related disclosures as of September 30, 2012 and for the three and nine months ended September 30, 2012 and 2011 are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP) and the applicable rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company s management evaluates its estimates, including those related to revenue recognition, available-for-sale securities, inventory valuation and related reserves, 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 $33.0 million and $77.2 million at September 30, 2012 and December 31, 2011, respectively.

Available-for-Sale Securities

The Company classifies all short-term investments with a remaining maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for the amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest and investment income. Realized gains and losses, interest, dividends, 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. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no other-than-temporary impairments for the three and nine months ended September 30, 2012 and 2011.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out basis.

The Company evaluates inventory levels quarterly and any inventory that has a cost basis in excess of its expected net realizable value, inventory that becomes obsolete, inventory in excess of expected sales requirements or inventory that fails to meet commercial sale specifications is written down with a corresponding charge to cost of revenues in the period that the impairment is first identified.

The Company capitalizes inventories manufactured in preparation for initiating sales of a product candidate when the related product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate s safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, the Company evaluates risks associated with manufacturing the product candidate and the remaining shelf life of the inventories.

Costs associated with developmental products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

Concentrations of Suppliers

The Company relies on third-party manufacturers and its collaboration partners to manufacture the linaclotide active pharmaceutical ingredient (API) and final linaclotide drug product. Currently, there are two third-party manufacturers approved for the production of the linaclotide API in three facilities. The Company s collaboration partners, except AstraZeneca in China, (Forest, Almirall and Astellas) are responsible for drug product manufacturing of linaclotide into finished product for their respective territories. The Company also has an agreement with another independent third party to provide drug product manufacturing of linaclotide for its unpartnered territories and to potentially provide a second source of drug product manufacturing of linaclotide for its partnered territories. The Company and AstraZeneca also continue to explore manufacturing alternatives for China. If any of the Company s suppliers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require

up to several months, during which time the Company s production could be delayed. Such delays could have a material adverse effect on the Company s business, financial position and results of operations.

Concentrations of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, restricted cash, available-for-sale securities and accounts receivable. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company s available-for-sale investments primarily consist of U.S. Treasury securities and certain U.S. government sponsored securities and potentially subject the Company to concentrations of credit risk. The Company has adopted an investment policy which limits the amounts the Company may invest in any one type of investment, and requires all investments held by the Company to be at least 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 or payable, to or from Forest and Almirall are presented as related party transactions on the condensed consolidated balance sheets as both entities own common stock of the Company.

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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

	Accounts Receivable		Revenue			
			Three Months Ended September 30,		Nine Months Ended September 30,	
Collaborative Partner:	September 30, 2012	December 31, 2011	2012	2011	2012	2011
Forest	%	86%	93%	45%	82%	49%
Almirall	7%	2%	6%	48%	16%	43%
Astellas	93%	11%	1%	7%	2%	8%

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

Revenue Recognition

The Company s revenue is generated through collaborative research and development and licensing agreements. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, including participation on a joint development committee, and (iii) the manufacture of 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 first GC-C agonist. 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. Additionally, the Company will receive 50% of the net profits or bear 50% of the net losses from the sale of LINZESS in the U.S, expected to begin in December 2012.

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 September 30, 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. In October 2012, the Company also entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China (Note 13).

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.

Table of Contents

Ironwood Pharmaceuticals, 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. Quarterly, the Company reassesses its period of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. During the three and nine months ended September 30, 2012, the Company s estimates regarding the period of performance under its collaborative research and development and licensing agreements did not change; however, they have changed in the past and may change in the future. In the event that a license were to be terminated, the Company would recognize as revenue any portion of the up-front fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

Up-front payments on a license are deferred if the relevant facts and circumstances dictate that the license does not have standalone value to the partner. Factors considered in this determination include the research capabilities of the partner and the availability of peptide research expertise in the general marketplace. In addition, the Company considers whether the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, and whether the value of the license is dependent on the undelivered items and whether there are other vendors that can provide the undelivered item.

Milestones

At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity s performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company 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.

Other

The Company produces development materials and API for certain of its collaborators. 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. As it related to development materials and API produced for Almirall and Astellas, the Company is reimbursed at a contracted rate. Such reimbursements are considered as part of revenue generated by Almirall and Astellas license agreements and presented as collaborative arrangements revenue. Any development materials and API currently produced for Forest are recognized in accordance with the cost-sharing provisions of the Forest collaboration agreement.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The Company receives cost-sharing payments for research and development and general and administrative expenses 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 the payments will result in collaborative revenues or an offset to research and development or general and administrative 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. Through September 30, 2012, the Company did not enter into any material agreements or material modifications to existing agreements that would be accounted for pursuant to this updated guidance. However, in October 2012, the Company entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China (Note 13). This new agreement will be accounted for in accordance with ASU 2009-13.

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 with Forest in which it shares research and development expenses. 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 Forest, the Company records the payments by Forest for their share of the development effort as a reduction of research and development expense.

Share-Based Compensation

The Company s stock-based compensation programs grant awards which have included stock awards, restricted stock, and stock options. Share-based compensation is recognized as an expense in the financial statements based on the grant date fair value. 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.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The Company records the expense for stock option grants subject to performance-based milestone vesting using the accelerated attribution method 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 Income (Loss) Per Share

The Company calculates basic net income (loss) per common share and diluted net loss per common share by dividing the net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income per common share is computed by dividing net income by the diluted number of shares outstanding during the period. Except where the result would be antidilutive to net income, diluted net income per share is computed assuming the exercise of common stock options and the vesting of restricted stock (using the treasury stock method), as well as their related income tax effects. The Company allocates undistributed earnings between the classes on a one-to-one basis when computing net income (loss) per share. As a result, basic and diluted net income (loss) per Class A and Class B shares are equivalent.

Income Taxes

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

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has considered the Company s history of operating losses and concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. Accordingly, the deferred tax assets have been fully reserved at September 30, 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 September 30, 2012 or December 31, 2011.

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.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

New Accounting Pronouncements

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

Recently Adopted Accounting Standards

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

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and IFRS as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for public companies for fiscal years, and interim periods within those years, beginning after December 15, 2011 and should be applied retrospectively. In December 2011, the FASB issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12) which defers the effective date of the provisions of ASU 2011-05 pertaining to the presentation of reclassification adjustments out of accumulated other comprehensive income. All other requirements in ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-12 is effective for public companies for fiscal years, and interim periods within those years, beginning after

December 15, 2011. On January 1, 2012, the Company adopted ASU 2011-05 and ASU 2011-12 on a retrospective basis. The Company has elected to present all nonowner changes in stockholders equity in a single continuous statement of comprehensive income (loss). The adoption did not have a material impact on the Company s consolidated financial position or results of operations since these standards impact presentation only.

3. Net Loss Per Share

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss)	$ 47,635	$ (20,633)	$ (28,769)	$ (57,878)
Shares used in calculating basic net income (loss) per common share	107,266,823	100,174,100	106,036,522	99,699,545
Effect of dilutive securities:				
Options to purchase common stock	6,996,544			
Restricted stock	73,960			
Shares used in calculating diluted net income (loss) per common share	114,337,327	100,174,100	106,036,522	99,699,545

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Options to purchase common stock	9,044,014	15,861,198	18,821,908	15,861,198
Shares subject to repurchase		181,807	100,458	181,807
	9,044,014	16,043,005	18,922,366	16,043,005

The number of shares issuable under the Company s employee stock purchase plan that were excluded from the calculation of diluted net income (loss) per share because their effects were anti-dilutive was insignificant.

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 for the treatment of IBS-C, CIC 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 future net profits or losses from the development and sale of linaclotide in the U.S. The Company will also receive royalties in the mid-teens based on net sales in Canada and Mexico. Forest is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs. The Company retained the rights to develop and commercialize linaclotide outside of North America. Forest made non-refundable, up-front payments totaling $70.0 million to the Company in order to obtain rights to linaclotide in North America. Because the license to jointly develop and commercialize linaclotide did not have a standalone value without research and development activities provided by the Company, the Company recorded the up-front license fee as collaboration revenue on a straight-line basis through September 30, 2012, the period over which linaclotide was jointly developed under the collaboration. The collaboration agreement also includes contingent milestone payments, as well as a contingent equity investment, based on the achievement of specific development and commercial milestones. These payments, including the up-front license fee, could total up to $330.0 million if certain development and sales milestones are achieved for linaclotide. At September 30, 2012, $205.0 million in license fees and development milestone payments had been received by the Company, as well as a $25.0 million equity investment in the Company s capital stock. 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 was recognized as revenue on a straight-line basis over the period of the Company s continuing involvement. At September 30, 2012, the incremental deferred revenue was fully amortized. In July 2009, the Company achieved the clinical milestone triggering the equity investment and reclassified the forward purchase contract as a reduction to convertible preferred stock. The Company issued the 2,083,333 shares to Forest on September 1, 2009.

The Company has achieved all six of the development milestones under this agreement. In September 2008 and July 2009, the Company achieved development milestones which triggered $10.0 million and $20 million milestone payments, respectively. These development milestones were recognized as revenue on a straight-line basis over the period of the Company s continuing involvement, which ended in September 2012. In October 2011, the Company achieved two development milestones upon the FDA s

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

acceptance of the linaclotide NDA for both IBS-C and CIC and received milestone payments of $20.0 million from Forest. In August 2012, the Company achieved additional two development milestones upon the FDA s approval of the linaclotide NDA for both IBS-C and CIC and in September 2012 received milestone payments of $85.0 million from Forest. In accordance with ASU 2010-17, adopted in January 2011, the last four development milestones were recognized as revenue in their entirety upon achievement.

The Company recognized revenue from the Forest collaboration agreement totaling approximately $89.5 million and $100.4 million during the three and nine months ended September 30, 2012, respectively and approximately $5.4 million and $16.4 million during the three and nine months ended September 30, 2011, respectively.

Further, because the Company shares development costs equally with Forest, payments from Forest with respect to both research and development and general and administrative costs incurred by the Company are recorded as a reduction to expense, and not as revenue. As a result of the cost-sharing arrangements under the collaboration, the Company recognized approximately $0.4 million and $0.8 million in incremental research and development costs during the three and nine months ended September 30, 2012, respectively, and approximately $2.5 million and $7.5 million in incremental general and administrative expense, respectively. During the three and nine months ended September 30, 2011, as a result of the cost-sharing arrangements under the collaboration, the Company offset approximately $0.5 million and $6.7 million, respectively, against research and development expense. During the three months ended September 30, 2011, the Company recognized approximately $0.2 million in incremental general and administrative expense and during the nine months ended September 30, 2011, the Company recorded approximately $0.5 million as a reduction to general and administrative expense related to the cost-sharing arrangement.

Upon commercialization in the fourth quarter of 2012, the Company will receive 50% of the net profits or bear 50% of the net losses from the sale of LINZESS in the U.S., provided, however, that if either party provides fewer details in a particular year than it is contractually required to provide, such party s share of the net profits will be reduced as stipulated by the collaboration agreement. Net profits or net losses consist of net sales to third-party customers and sublicense income in the U.S. less the cost to manufacture LINZESS as well as distribution, selling, and marketing expenses. Net sales are calculated by Forest and include gross sales net of discounts, allowances, sales taxes, freight and insurance charges, and other applicable deductions.

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, CIC 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 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 $2.8 million of revenue in the nine months ended September 30, 2011. At September 30, 2012, the up-front license fee was fully amortized. The license agreement also includes contingent milestone payments, as well as a contingent equity investment, that could total up to $55.0 million upon achievement of specific clinical and sales milestones. At September 30, 2012, $19.0 million, net of foreign withholding taxes, in development milestone payments has already been received, as well as a $15.0 million equity investment in the Company s capital stock. Remaining 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 was recognized as revenue on a straight-line basis through September 2012. In November 2009, the Company

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

achieved the clinical milestone triggering the equity investment and reclassified the forward purchase contract as a reduction to convertible preferred stock. On November 13, 2009, the Company received $15.0 million from Almirall for the purchase of 681,819 shares of convertible preferred stock.

In November 2010, the Company achieved a development milestone under the Almirall license agreement, 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 was recognized on a straight-line basis through September 2012.

The Company recognized approximately $5.9 million and $20.2 million in total revenue from the Almirall license agreement during the three and nine months ended September 30, 2012, respectively, including approximately $13,000 and $2.5 million, respectively, from the sale of API to Almirall. The Company recognized approximately $5.9 million and $14.6 million in total revenue from the Almirall license agreement during the three and nine months ended September 30, 2011, respectively, including approximately $0.5 million during the nine months ended September 30, 2011 from the sale of API to Almirall.

Astellas Pharma Inc.

In November 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, CIC 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. The license agreement requires the Company to participate on a joint development committee over linaclotide s development period. The agreement includes additional development milestone payments, each of which the Company considers substantive, that could total up to $45.0 million. These milestone payments consist of $15.0 million upon initiation of a Phase 3 study for linaclotide in Japan, $15.0 million upon filing of the Japanese equivalent of an NDA with the relevant regulatory authority in Japan, and $15.0 million upon approval of such equivalent by the relevant regulatory authority. In addition, the Company will receive escalating royalties on linaclotide sales should Astellas receive approval to market and sell linaclotide in the Asian market. Astellas will be responsible for activities relating to regulatory approval and commercialization. The Company is recognizing the up-front license fee as revenue on a straight-line basis over 115 months, which is the Company s estimate of the period over which linaclotide will be developed under the license agreement for the Asian market. At September 30, 2012, approximately $21.9 million of the up-front license fee remains deferred. During the three and nine months ended September 30, 2012, the Company recognized approximately $1.0 million and $2.7 million respectively, in revenue from the Astellas license agreement, including approximately $0.2 million and $0.3 million, respectively, from the sale of API to Astellas. During the three and nine months ended September 30, 2011, the Company recognized approximately $0.9 million and $2.7 million, respectively, in revenue from the Astellas license agreement, including approximately $0.1 million

and $0.4 million, respectively from the sale of 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 and nine months ended September 30, 2012, the Company recorded approximately $0.7 million and $2.0 million, respectively, in research and development expense associated with the Protagonist agreement. During the three and nine months ended September 30, 2011, the Company recorded approximately $0.6 million and $4.4 million, respectively, in research and development expense, including the up-front payment, associated with the Protagonist agreement.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

Bionomics Limited

On January 4, 2012, the Company entered into a collaboration, research and license agreement with Bionomics Limited (Bionomics) in which it licensed the rights to Bionomics investigational anti-anxiety compound, BNC210, which Ironwood designates as IW-2143. 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 IW-2143 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 IW-2143 and other related compounds. The Company will expense these payments as incurred. During the three and nine months ended September 30, 2012, the Company recorded approximately $0.4 million and $4.1 million, respectively, in research and development expense, including the up-front payment, associated with the Bionomics agreement.

Other

The Company has other collaborations that are not individually significant to its business. Pursuant to the terms of those agreements, the Company may be required to pay additional amounts upon the achievement of various development, regulatory and commercial milestones which in the aggregate could be significant. The Company may also incur significant research and development costs if the related product candidate were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring. During the nine months ended September 30, 2012, the Company incurred $1.1 million in research and development expense associated with a research and development milestone under one of the Company s other collaboration agreements. During the three months ended September 30, 2012, and the three and nine months ended September 30, 2011, there were no significant milestones achieved under the Company s other collaborations.

5. Fair Value of Financial Instruments

The tables below present information about the Company s assets that are measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In

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 apply 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		
Description	**September 30, 2012**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds (included in cash and cash equivalents)	$ 32,998	$ 32,998	$	$
U.S. government-sponsored securities	67,456		67,456	
Total	$ 100,454	$ 32,998	$ 67,456	$

		Fair Value Measurements at Reporting Date Using		
Description	**December 31, 2011**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds (included in cash and cash equivalents)	$ 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 September 30, 2012 and December 31, 2011 are carried at amounts that approximate fair value due to their short-term maturities.

The non-current portion of the capital lease obligations at September 30, 2012 and December 31, 2011 approximates fair value as it bears 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 September 30, 2012 and December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2012:				
U.S. government-sponsored securities	$ 67,449	$ 12	$ (5)	$ 67,456
Total	$ 67,449	$ 12	$ (5)	$ 67,456

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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

The contractual maturities of all securities held at September 30, 2012 are one year or less. There were ten investments classified as available-for-sale securities in an unrealized loss position at September 30, 2012, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities was approximately $16.8 million. There were 12 investments classified as available-for-sale securities in an unrealized loss position at December 31, 2011, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities was approximately $35.5 million. The Company reviews its investments for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment s carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and considers whether evidence indicating the cost of the investment is recoverable outweighs evidence to the contrary. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity. The Company did not hold any securities with other-than-temporary impairment at September 30, 2012 or December 31, 2011.

The proceeds from maturities and sales of available-for-sale securities were $19.1 million and $70.5 million for the three months ended September 30, 2012 and 2011, respectively. Gross realized gains and losses on the sales of investments that have been included in other comprehensive income (loss) as well as net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income have not been material to the Company s consolidated results of operations.

7. Inventory

Inventory consisted of the following at (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	$ 965	$

In the third quarter of 2012, the Company began capitalizing inventory costs for linaclotide manufactured in preparation for its planned launch in the U.S. and Europe. Inventory at September 30, 2012 represents API that is available for commercial sale. As of September 30, 2012, the Company has not capitalized any inventory costs related to linaclotide manufactured for clinical trial use or its other drug development programs.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Salaries and benefits	$ 9,804	$ 7,525
Professional fees	1,565	820
Other	5,320	2,777
	$ 16,689	$ 11,122

9. 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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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, October 2011 and July 2012 (together the Amendments) in order to lease additional space. Pursuant to the Amendments, the Company leases an additional 96,613 rentable square feet of the 301 Binney Street building, comprised of (a) an initial phase of 35,444 rentable square feet (the Initial Phase), (b) a second phase of 21,589 rentable square feet (the Second Phase), (c) a third phase of 17,863 rentable square feet (the Third Phase) and (d) a fourth phase of 21,717 rentable square feet (the Fourth Phase). Rent for the Initial Phase commenced on July 1, 2010, rent for the Second Phase commenced on March 1, 2011, rent for the Third Phase commenced on January 1, 2012, and rent for the Fourth Phase commenced on June 1, 2012. Initial base rent for the Initial Phase is $42.00 per rentable square foot per year and the initial base rent for the Second Phase, Third Phase and Fourth Phase is $42.50 per rentable square foot per year. Base rent for the Initial Phase, Second Phase, Third Phase and Fourth Phase will increase annually by $0.50 per rentable square foot. Consistent with the Company s treatment of the lease expense associated with the initial lease agreement, lease expense associated with the Amendments, inclusive of the escalating rent payments, is recognized on a straight-line basis over the term of the lease agreement. The Amendments do not change the expiration date of the lease agreement.

The landlord has reimbursed the Company for its tenant improvements for the space occupied prior to the Amendments at a set rate per rentable square foot. Under the terms of the Amendments, the landlord has or will provide the Company with an allowance for the additional space, which consists of $55.00 per rentable square foot for tenant improvements in the Initial Phase and the Second Phase and an allowance of $40.00 per rentable square foot for the Third Phase and the Fourth Phase. As of September 30, 2012, approximately $16.6 million has been paid to the Company as reimbursement for tenant improvements under the lease agreement, including the Amendments. The reimbursement amount is recorded as deferred rent on the condensed consolidated balance sheets and is being amortized as a reduction to rent expense over the term of the lease agreement or the Amendments, as applicable.

In October 2012, the Company entered into an amendment to its 301 Binney Street building lease, pursuant to which the Company will rent 93,000 square feet of additional space in four stages. Each stage will commence no later than December 1, 2013, June 1, 2014, June 1, 2015 and June 1, 2016, respectively. The amendment also extends the term of the entire lease agreement by 24 months. The Company s operating lease obligations through January 2018 increased at least by an aggregate of $12.4 million as a result of this amendment.

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 September 30, 2012, the Company s minimum purchase requirements and other firm commitments related to supply contracts are as follows: approximately $18.1 million, $7.3 million, $9.6 million, $9.7 million, $9.7 million and $5.9 million for the years ending December 31, 2012 (remaining 3 months), 2013, 2014, 2015, 2016 and 2017, respectively.

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

Guarantees

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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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

Litigation

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

10. 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.

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 September 30, 2012 is presented below:

	Shares		Weighted-Average Grant Date Fair Value
Unvested at December 31, 2011	160,000	$	5.72
Granted		$	
Vested	(60,000)	$	5.72
Forfeited		$	
Unvested at September 30, 2012	100,000	$	5.72

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

11. Stock Option Plans

The Company has several share-based compensation plans under which stock options, restricted stock, restricted stock units, and other share-based awards are available for grant to employees, directors and consultants of the Company. At September 30, 2012 and December 31, 2011, there were 7,199,949 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 and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Expected volatility	47.1%	49.6%	49.9%	43.5%
Expected term (in years)	6.5	6.5	6.5	6.5
Risk-free interest rate	1.0%	2.2%	1. 3%	2.7%
Expected dividend yield	%	%	%	%

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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011

Employee stock options	$ 4,904	$ 2,645	$ 12,135	$ 7,888
Restricted stock awards	108	108	321	323
Non-employee stock options	8	35	53	113
ESPP	108	67	381	165
Stock awards	7	7	22	22
	$ 5,135	$ 2,862	$ 12,912	$ 8,511

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Research and development	$ 2,648	$ 1,653	$ 6,676	$ 4,456
General and administrative	2,487	1,209	6,236	4,055

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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

	Shares of Common Stock Attributable to Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2011	16,424,500	$ 6.09	6.40	$ 98,999
Granted	3,355,100	14.08		
Exercised	(652,569)	3.33		
Cancelled	(305,123)	12.33		
Outstanding at September 30, 2012	18,821,908	$ 7.51	6.39	$ 105,284
Vested or expected to vest at September 30, 2012	17,653,431	$ 7.44	6.32	$ 99,895
Exercisable at September 30, 2012(1)	9,197,858	$ 4.71	4.92	$ 75,104

(1) All stock options granted under the 1998 Amended and Restated Stock Option Plan, the Amended and Restated 2002 Stock Incentive Plan and the 2005 Plan contain provisions allowing for the early exercise of such options into restricted stock. The exercisable shares disclosed above represent those that are vested as of September 30, 2012.

The weighted-average grant date fair value per share of options granted to employees during the three and nine months ended September 30, 2012 was approximately $6.21 and $7.01, respectively, and approximately $7.86 and $6.32 during the three and nine months ended September 30, 2011, respectively. The aggregate grant-date fair value of the options granted to employees during the three and nine months ended September 30, 2012 was approximately $1.9 million and $23.5 million, respectively, and approximately $2.7 million and $17.6 million during the three and nine months ended September 30, 2011, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2012 was approximately $1.3 million and $6.6 million, respectively, and approximately $2.6 million and $15.4 million during the three and nine months ended September 30, 2011, respectively.

As of September 30, 2012, there was approximately $0.5 million and $34.7 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 1.3 years and 3.2 years, respectively. The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures.

The Company has granted to employees options to purchase shares of common stock subject to performance-based and time-accelerated milestone vesting. The vesting of the performance-based stock options occurs upon the achievement of certain performance-based milestones, and vesting of the time-accelerated stock options accelerates upon the achievement of certain performance-based milestones. During the three and nine months ended September 30, 2012, 100,000 shares and 132,500 shares vested as a result of milestone achievements, respectively, and the Company recorded related share-based compensation expense of approximately $0.7 million in both periods for these options. Additionally, as of September 30, 2012, the Company concluded that the achievement of two other milestones is probable. As a result, the Company recognized approximately $0.3 million of additional share-based compensation expense related to these performance-based and time-accelerated stock options. At September 30, 2012, the unrecognized share-based compensation related to performance-based milestone options was approximately $3.8 million. During the three and nine months ended September 30, 2011, no shares vested as a result of milestone achievement for either performance-based or time-accelerated stock options**.**

12. 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 $23,000 and $182,000 in legal fees to this investor during the three and nine months ended September 30, 2012, respectively, and approximately $29,000 and $124,000 during the three and nine months ended September 30, 2011, respectively. At September 30, 2012, the Company did not have 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

Table of Contents

Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

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 Class B common stock on a 1:1 basis upon the completion of the Company s initial public offering in February 2010. Amounts due to and due from Forest and Almirall are reflected as related party accounts payable and related party accounts receivable, respectively. These balances are reported net of any balances due to or from the related party. At September 30, 2012, the Company had approximately $13,000 in related party accounts receivable associated with Almirall and $2.1 million in related party accounts payable, net of related party accounts receivable, associated with Forest. At December 31, 2011, the Company had approximately $15,000 in related party accounts receivable associated with Almirall and approximately $0.6 million in related party accounts receivable, net of related party accounts payable associated with Forest.

13. Subsequent Events

On October 23, 2012, the Company entered into a collaboration agreement with AstraZeneca under which the companies will jointly develop and commercialize linaclotide in China. Under the terms of the agreement, AstraZeneca will make an upfront payment of $25 million to Ironwood and will share the net profits and losses associated with linaclotide in China, with AstraZeneca receiving 55% of the net profit or incurring 55% of the net loss until a certain specified milestone is achieved, moving to an equal split thereafter. The Company is also eligible for $125 million in additional commercial milestone payments, contingent on the achievement of certain sales targets in China. In addition, Ironwood s sales force will promote one of AstraZeneca s products in the U.S.

In October 2012, the Company also entered into an amendment to its 301 Binney Street building lease (Note 9).

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 dedicated to the art and science of great drugmaking. To achieve our mission, we are building a team, a culture and processes centered on creating and marketing differentiated medicines that provide clear and meaningful therapeutic benefits to patients. Our lead product, linaclotide, will be marketed in the United States, or U.S., under the trademarked name of LINZESS. On August 30, 2012, the United States Food and Drug Administration, or FDA, approved LINZESS as a once-daily treatment for adult men and women suffering from irritable bowel syndrome with constipation, or IBS-C, or chronic idiopathic constipation, or CIC. LINZESS is the first FDA-approved guanylate cyclase type-C, or GC-C, agonist, and it was shown in clinical trials to help relieve abdominal pain and constipation associated with IBS-C and improve constipation symptoms associated with CIC. We believe that LINZESS presents patients and healthcare practitioners with a unique therapy for a major medical need not yet met by existing therapies. LINZESS is being commercialized in the U.S. by us and our collaboration partner, Forest Laboratories, Inc., or Forest. We expect that LINZESS, a prescription product, will be commercially available in the U.S. in December 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. On September 21, 2012, the EMA s European Committee for Medicinal Products for Human Use, which provides non-binding recommendations for consideration by the EMA, issued a positive opinion recommending the marketing approval for linaclotide for the treatment of moderate to severe IBS-C in adults.

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

We continue to assess alternatives to bring linaclotide to IBS-C and CIC sufferers in the parts of the world outside of its partnered territories. In May 2012, we submitted a Clinical Trial Application, or CTA, to China s State Food and Drug Administration for a Phase 3 trial of linaclotide in patients with IBS-C. The CTA has been accepted for review. In October 2012, we also entered into a collaboration agreement with AstraZeneca AB, or AstraZeneca, to co-develop and co-commercialize linaclotide in China.

We continue to assess opportunities to expand the utility of linaclotide as well as the patient population who could benefit from linaclotide to ensure that we are maximizing the drug s potential value. As part of our long-term strategy, we and Forest initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CIC. In addition, we continue to explore the potential for linaclotide in other patient populations 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 a significant portion 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.

Table of Contents

We currently operate in one reportable business segment human therapeutics. Our human therapeutics segment consists of the commercialization of our lead product, linaclotide, and the development and commercialization of our product candidates.

To date, we have dedicated substantially all of our activities to the research and development of linaclotide and 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 generated net income of approximately $47.6 million in the three months ended September 30, 2012, and incurred a net loss of approximately $28.8 million in the nine months ended September 30, 2012. We incurred net losses of approximately $20.6 million and $57.9 million in the three and nine months ended September 30, 2011, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $461.2 million, and we expect to incur losses for the foreseeable future.

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

Financial Overview

Revenue. Revenue is generated primarily through our collaboration agreement with Forest, and our license agreements with Almirall and Astellas. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) the manufacture of active pharmaceutical ingredient, or API, and development materials for the collaborative partner. Payments to us may include one or more of the following: nonrefundable license fees; payments for research and development activities, payments for the manufacture of API and development materials, payments based upon the achievement of certain milestones and royalties on product sales. Additionally, we will receive 50% of the net profits or bear 50% of the net losses from the sale of LINZESS in the U.S, expected to begin in December 2012. We expect our revenue to fluctuate in the short term based on clinical and commercial milestones and based on the potential variability of demand for LINZESS upon commercial launch.

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, non-clinical 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 is linaclotide, and it represents the largest portion of our research and development expense for our product candidates. Linaclotide is the first FDA-approved GC-C agonist and is indicated for the treatment of IBS-C and CIC and is our only product, or product candidate, that has demonstrated clinical proof of concept. An NDA for LINZESS with respect to both IBS-C and CIC was approved by the FDA in August 2012.

We continue to assess opportunities to expand the utility of linaclotide as well as the patient population who could benefit from linaclotide to ensure that we are maximizing the drug s potential value. As part of our long-term strategy, we and Forest initiated a Phase 3b clinical trial to

further characterize the effect of linaclotide on abdominal symptoms in patients with CIC. In addition, we continue to explore the potential for linaclotide in other patient populations 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 and nine months ended September 30, 2012 and 2011. These expenses relate primarily to external costs associated with manufacturing, including supply chain development, non-clinical 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.

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)		(in thousands)	
Demonstrated clinical proof of concept	$ 7,150	$ 6,290	$ 24,451	$ 15,241
Early stage, pre-proof of concept	4,788	3,916	16,833	9,328
Early stage, non-clinical	2,509	3,606	7,928	10,813

Since 2004, the date we began tracking costs by program, we have incurred approximately $169.3 million of research and development expenses related to linaclotide. The expenses for linaclotide include both reimbursements to us by Forest as well as our portion of research and development costs incurred by Forest for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreement.

The lengthy process of securing regulatory 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. In August 2012, the FDA approved our NDA for LINZESS as a once-daily treatment for adult men and women suffering from IBS-C and CIC. In connection with the FDA approval, we are required to conduct certain non-clinical and clinical studies aimed at understanding: (a) whether orally administered linaclotide can be detected in breast milk, (b) the potential for antibodies to be developed to linaclotide, and if so, (c) whether antibodies specific for linaclotide could have any therapeutic or safety implications. In addition, we and Forest established a non-clinical and clinical post-marketing plan with the FDA to understand LINZESS s efficacy and safety in pediatric patients. In October 2012, we entered into a collaboration agreement with AstraZeneca under which we will jointly develop and commercialize linaclotide in China. We also are exploring the expansion of linaclotide in other parts of the world outside of our currently partnered territories, as well as the potential for linaclotide in other indications. Therefore, 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 in pediatrics, for other geographic markets or additional indications. We also continue to advance our pipeline focused on early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, CNS disorders, respiratory disease and cardiovascular disease. Given the inherent uncertainties that come with the development of pharmaceutical products, we cannot estimate with any degree of certainty how these programs will evolve, and therefore the amount of time or money that would be required to obtain regulatory approval to market them. 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 will be developed in pediatrics or for other indications or markets, 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 successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

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

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

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

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

Table of Contents

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

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

As a result of the uncertainties discussed above, we are unable to determine the duration and costs to complete current or future non-clinical and clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the data of each product candidate, the competitive landscape and ongoing assessments of such product candidate s commercial potential. As a result of the FDA s approval of our NDA in August 2012, we expect that LINZESS will begin generating sales in the fourth quarter of 2012 upon commercial launch in the U.S.

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

General and administrative expense. General and administrative expense consists primarily of compensation, benefits and other employee related expenses for personnel in our administrative, finance, legal, information technology, business development, commercial and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility and IT infrastructure costs and professional fees for accounting and legal services. We anticipate substantial increases in expenses related to developing the organization necessary to commercialize linaclotide. We charge all general and administrative expenses to operations as incurred. Under our Forest collaboration agreement, we are reimbursed for certain general and administrative expenses, and we net these reimbursements against our general and administrative expenses as incurred.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the U.S., or GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions, including those related to revenue recognition, inventory valuation and related reserves, research and development expenses and share-based compensation are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. These critical estimates and assumptions are based on our historical experience, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances and form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from our estimates under different assumptions or conditions.

During the nine months ended September 30, 2012, we adopted Accounting Standards Update, or ASU, No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04, ASU No. 2011-05, *Presentation of*

Comprehensive Income, or ASU 2011-05, and ASU 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, or ASU 2011-12, as discussed in Note 2, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no significant changes to our critical accounting policies and estimates, including as a result of the adoption of these standards, with the exception of the development of the accounting estimates and assumptions inherent in inventory valuation and related reserves. Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out basis. We evaluate inventory levels quarterly and any inventory that has a cost basis in excess of its expected net realizable value, inventory that becomes obsolete, inventory in excess of expected sales requirements or inventory that fails to meet commercial sale specifications is written down with a corresponding charge to cost of revenues in the period that the impairment is first identified. See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 29, 2012 for additional information about these critical accounting policies, as well as a description of our other significant accounting policies.

Table of Contents

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)		(in thousands)	
Collaborative arrangements revenue	$ 96,413	$ 12,218	$ 123,265	$ 33,717
Operating expenses:				
Research and development	23,453	22,905	85,201	61,869
General and administrative	25,352	10,929	66,926	30,958
Total operating expenses	48,805	33,843	152,127	92,827
Income (loss) from operations	47,608	(21,616)	(28,862)	(59,110)
Other income (expense):				
Interest expense	(14)	(16)	(41)	(49)
Interest and investment income	41	105	134	384
Other income		897		900
Other income (expense), net	27	986	93	1,235
Net income (loss) before income taxes	47,635	(20,630)	(28,769)	(57,875)
Income tax expense		3		3
Net income (loss)	$ 47,635	$ (20,633)	$ (28,769)	$ (57,878)

Three and Nine Months Ended September 30, 2012 Compared to Three and Nine Months Ended September 30, 2011

Revenue

Collaborative arrangements revenue	$ 96,413	$ 12,218	$ 84,195	689.1%	$ 123,265	$ 33,717	$ 89,548	265.6%

Collaborative Arrangements Revenue. The increase in revenue from collaborative arrangements of approximately $84.2 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily related to the Forest collaboration agreement. In August 2012, the Company achieved two milestones totaling $85.0 million under the Forest collaboration agreement due to the FDA s approval of the linaclotide NDA for both IBS-C and CIC. This increase was offset by an approximately $1.0 million decrease in the amortization of Forest s deferred revenue associated with the development phase of the collaboration as the performance period ended midway through September 2012.

The increase in revenue from collaborative arrangements of approximately $89.5 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 also was primarily related to the $85.0 million in milestone payments we earned under the Forest collaboration agreement. In June 2011, we revised our estimate of the development period associated with the Almirall license agreement which resulted in approximately $3.5 million in additional revenue recognized during the nine months ended September 2012. Additionally, during the nine months ended September 30, 2012, we recognized approximately $2.0 million more in shipments of linaclotide API to Almirall in anticipation of a potential commercial launch in

Table of Contents

Europe. These increases were offset by an approximately $1.0 million decrease in the amortization of Forest s deferred revenue associated with the development phase of the collaboration as the performance period ended midway through September 2012.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2012	2011	$	%	2012	2011	$	%
	(dollars in thousands)				(dollars in thousands)			
Operating Expenses:								
Research and development	$ 23,453	$ 22,905	$ 548	2.4%	$ 85,201	$ 61,869	$ 23,332	37.7%
General and administrative	25,352	10,929	14,423	132.0%	66,926	30,958	35,968	116.2%
Total operating expenses	$ 48,805	$ 33,834	$ 14,971	44.2%	$ 152,127	$ 92,827	$ 59,300	63.9%

Research and Development Expense. The increase in research and development expense of approximately $0.5 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily related to an increase of approximately $2.4 million in compensation, benefits, and employee related expenses associated mainly with increased headcount; an increase of approximately $1.2 million in research and development related facilities costs, including rent and amortization of leasehold improvements associated with additional space we leased in our 301 Binney Street facility; and an increase of approximately $1.0 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012; partially offset by a decrease of approximately $3.6 million due to linaclotide development, consisting of lower expenses associated with clinical trials as our Phase 3 trials were completed, decreased contract manufacturing costs associated with validation of batches of linaclotide API as we began capitalizing API in the third quarter of 2012 and decreased reimbursements from Forest, partially offset by a decrease of approximately $0.5 million in research costs related to our other pipeline candidates.

The increase in research and development expense of approximately $ 23.3 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily related to an increase of approximately $8.5 million in compensation, benefits, and employee related expenses associated mainly with increased headcount; an increase of approximately $6.3 million associated with linaclotide development, consisting of increased contract manufacturing costs associated with validation of batches of linaclotide API in anticipation of a potential commercial launch, higher collaboration expenses from Forest and decreased reimbursements from Forest, partially offset by a decrease in contract research associated with lower clinical trial expenses; an increase of approximately $3.3 million in research and development related facilities costs, including rent and amortization of leasehold improvements, associated with additional space we leased and improved in our 301 Binney Street facility; an increase of approximately $3.0 million in research costs related to our other pipeline candidates, including research and development fees, and upfront and milestone payments associated with our licensing agreements; and an increase of approximately $2.2 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012.

General and Administrative Expense. General and administrative expenses increased approximately $14.4 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily as a result of increases in our workforce expenses and infrastructure as we prepare for our anticipated commercial launch of linaclotide. These increases include approximately $5.8 million in compensation, benefits and other employee related expenses associated with increased headcount; external consulting costs of approximately $3.3 million primarily associated with developing the infrastructure to commercialize and support linaclotide; approximately $2.4 million in net commercial expenses incurred by Forest in preparation for the commercial launch of linaclotide; approximately $1.3 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012; approximately $0.8

million in corporate legal expenses; and approximately $0.7 million in general and administrative related facilities and IT infrastructure costs associated with operating our 301 Binney Street facility, including rent and amortization of leasehold improvements.

General and administrative expenses increased approximately $36.0 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily as a result of increases in our workforce expenses and infrastructure as we prepare for our anticipated commercial launch of linaclotide. These increases include approximately $12.7 million in compensation, benefits and other employee related expenses associated with increased headcount; external consulting costs of approximately $9.6 million primarily associated with developing the infrastructure to commercialize and support linaclotide; approximately $8.1 million in net commercial expenses incurred by Forest in preparation for the commercial launch of linaclotide;

Table of Contents

approximately $1.6 million in general and administrative related facilities and IT infrastructure costs associated with operating our 301 Binney Street facility, including rent and amortization of leasehold improvements; approximately $1.6 million in corporate legal and other professional service fees, and approximately $2.2 million in share-based compensation expense primarily related to our new hire grants and our annual stock option grant made in February 2012.

Other Income (Expense), Net

Other income (expense):									
Interest expense	$ (14)	$ (16)	$ 2	(12.5)%	$ (41)	$ (49)	$ 8	(16.3)%	
Interest and investment income	41	105	(64)	(61.0)%	134	384	(250)	(65.1)%	
Other income		897	(897)	(100.0)%		900	(900)	(100.0)%	
Total other income (expense), net	$ 27	$ 986	$ (959)	(97.3)%	$ 93	$ 1,235	$ (1,142)	(92.5)%	

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

Liquidity and Capital Resources

At September 30, 2012, we had approximately $193.3 million of unrestricted cash, cash equivalents and available-for-sale securities. Our cash equivalents include amounts primarily held in money market funds, stated at cost plus accrued interest, which approximates fair market value. Our available-for-sale securities include amounts held in U.S. government-sponsored securities. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to be at least A+ rated so as to primarily achieve liquidity and capital preservation.

During the nine months ended September 30, 2012, our cash balances increased approximately $38.6 million. This increase is primarily due to the approximately $85.2 million in net proceeds from our public stock offering in February 2012, $85.0 million in milestone payments from Forest upon the FDA s approval of LINZESS in August, 2012 and approximately $2.9 million in proceeds from the exercise of stock options and the issuance of shares pursuant to our employee stock purchase plan. These sources of cash were partially offset by the cash used to operate our business, as we made payments related to, among other things, research and development and general and administrative expenses as we continue to increase headcount and build infrastructure for our anticipated commercial launch of LINZESS in the U.S. and as we continue to invest in our research pipeline. We also invested approximately $10.6 million in capital expenditures and made payments of approximately $0.2 million on our capital leases.

Sources of Liquidity

We have incurred losses since our inception on January 5, 1998 and, as of September 30, 2012, had an accumulated deficit of approximately $461.2 million. We have financed our operations to date primarily through both the private sale of our preferred stock and the public sale of our common stock, including approximately $203.2 million of net proceeds from our IPO in February 2010 and approximately $85.2 million of net proceeds from our public offering in February 2012; payments received under our strategic collaborative arrangements, including milestone payments and reimbursement of certain expenses; debt financings; strategic sale of assets or businesses and interest earned on investments.

Funding Requirements

To date, we have not yet commercialized any products and have not achieved profitability. In August 2012, we received approval for LINZESS in the U.S. and expect to commence our commercial launch in the fourth quarter of 2012. Our partnership with Forest requires total net sales of LINZESS to be reduced by commercial costs incurred by each party, and such resulting net profit or net loss attributable to LINZESS will be shared equally between Forest and the Company. We cannot anticipate when proceeds generated from sales of LINZESS will enable the Company to become cash flow positive. We anticipate that we will continue to incur

Table of Contents

substantial expenses for the next several years as we further develop and launch linaclotide in the U.S and in other markets, continue to invest in our pipeline, develop the organization required to sell our product candidates and operate as a publicly traded company. In addition, we are generally required to make cash expenditures to manufacture linaclotide API in advance of selling it to our collaboration partners and collecting payments for such inventory sales, which may result in significant periodic uses of cash. We believe that our cash on hand as of September 30, 2012 will be sufficient to meet our projected operating needs at least through the next twelve months, including an increasing level of commercialization activity and expenses related to the expected launch of LINZESS in the U.S.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, including the underlying estimates regarding the costs to obtain regulatory approval and the costs to commercialize linaclotide in the U.S. and other markets, is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the Risk Factors section of this Quarterly Report on Form 10-Q. We have based our estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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

- the rate of progress and cost of our commercialization activities;
- the expenses we incur in marketing and selling LINZESS and our other product candidates;
- the revenue generated by sales of LINZESS and our other product candidates;
- the success of our third-party manufacturing activities;
- the time and costs involved in obtaining regulatory approvals for our product candidates;
- the success of our research and development efforts;
- the emergence of competing or complementary technological developments;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the terms and timing of any additional collaborative, licensing or other arrangements that we may establish; and

- the acquisition of businesses, products and technologies.

Financing Strategy

We may, from time to time, require or access additional funding through a combination of new collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all.

Contractual Commitments and Obligations

The disclosure of our contractual obligations and commitments is set forth under the heading *Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Commitments and Obligations* in our Annual Report on Form 10-K for the year ended December 31, 2011. There have been no material changes to our Contractual Obligations and Commercial Commitments table presented for the year ended December 31, 2011 other than the commitments described below.

We, and in some cases, along with our collaboration partner, Forest, have entered into multiple commercial supply agreements with contract manufacturing organizations for the purchase of a portion of the linaclotide API and drug product that was

Table of Contents

and will be used to seek regulatory approval of linaclotide in North America and the E.U., and, depending on such approval, that would be used for commercial sales in such countries. Some of the agreements contain minimum purchase commitments. As of September 30, 2012, our minimum purchase requirement across all the agreements is approximately $60.3 million and will be incurred through 2017.

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

In October 2012, we entered into an amendment to our 301 Binney Street building lease, pursuant to which we will rent 93,000 square feet of additional space in four stages. Each stage will commence no later than December 1, 2013, June 1, 2014, June 1, 2015 and June 1, 2016, respectively. The amendment also extends the term of the entire lease agreement by 24 months. Our operating lease obligations through January 2018 increased at least by an aggregate of $12.4 million as a result of this amendment.

Off-Balance Sheet Arrangements

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

New Accounting Pronouncements

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

Recently Adopted Accounting Standards

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends ASC 820, *Fair Value Measurement*, to ensure that fair value has the same meaning in GAAP and International Financial Reporting Standards (IFRS) and improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. ASU 2011-04 applies to all entities that measure assets, liabilities or instruments classified in shareholder s equity at fair value, or provide fair value disclosures for items not recorded at fair value. ASU 2011-04 results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. Consequently, ASU 2011-04 changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, ASU 2011-04 will not result in a change in the application of the requirements in ASC 820. Some of the requirements in ASU

2011-04 clarify the FASB s intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. ASU 2011-04 is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. Early application is not permitted. On January 1, 2012, we adopted ASU 2011-04 on a prospective basis. The adoption did not have a material impact on our consolidated financial position or results of operations.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and IFRS as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for public companies for fiscal years, and interim periods within those years, beginning after 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

Table of Contents

adjustments out of accumulated other comprehensive income. All other requirements in ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-12 is effective for public companies for fiscal years, and interim periods within those years, beginning after December 15, 2011. On January 1, 2012, we adopted ASU 2011-05 and ASU 2011-12 on a retrospective basis. We have elected to present all nonowner changes in stockholders equity in a single continuous statement of comprehensive income. The adoption did not have a material impact on our consolidated financial position or results of operations since these standards impact presentation only.

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

Interest Rate Risk

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

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

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

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

Foreign Currency Risk

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

Effects of Inflation

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

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

Evaluation of Disclosure Controls and Procedures

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

Table of Contents

Changes in Internal Control

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. In connection with the FDA s approval of LINZESS in August 2012, we have implemented internal controls over the inventory process. Based on that evaluation, our principal executive officer and principal financial officer concluded no changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were reasonably likely to materially affect, our internal control over financial reporting, with the exception of the development of internal controls over the inventory process.

Table of Contents

PART II OTHER INFORMATION

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

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

Risks Related to Our Business and Industry

We are highly dependent on the commercial success of LINZESS in the U.S. for the foreseeable future; we may be unable to meet expectations with respect to LINZESS sales or attain profitability and positive cash flow from operations.

On August 30, 2012, the FDA approved LINZESS (linaclotide) as a once-daily treatment for adult men and women suffering from IBS-C or CIC. LINZESS is the first FDA-approved GC-C agonist, and it was shown in clinical trials to help relieve abdominal pain and constipation associated with IBS-C and improve constipation symptoms associated with CIC. LINZESS will become commercially available for the first time in December 2012. The commercial success of LINZESS will depend on a number of factors, including:

- the effectiveness of the sales, managed markets and marketing efforts by us and our U.S. partner, Forest;
- the adoption of LINZESS by physicians, which depends on whether physicians view it as a safe and effective treatment for adult patients with IBS-C and CIC;
- our success in educating and activating IBS-C and CIC patients to enable them to more effectively communicate their symptoms and treatment history to their physicians;
- our ability to both secure adequate reimbursement for and optimize patient access to LINZESS by providing third party payors with a strong value proposition based on the existing burden of illness associated with IBS-C and CIC, and the benefits of LINZESS;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with LINZESS;

- the development or commercialization of competing products or therapies for the treatment of IBS-C or CIC, or their symptoms.

We may experience significant fluctuations in sales of LINZESS from period to period and, ultimately, we may never generate sufficient revenues from LINZESS to reach or maintain profitability or sustain our anticipated levels of operations.

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

The most common adverse reactions in IBS-C and CIC patients in the placebo-controlled trials that supported the U.S. NDA approval were diarrhea, abdominal pain, flatulence and abdominal distension, with diarrhea being the most common. Severe diarrhea was reported in 2% of the linaclotide-treated patients, and the incidence of diarrhea was similar between the IBS-C and CIC populations in these trials. If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for LINZESS or any products perceived to be similar to LINZESS, then in any of these circumstances:

- sales of LINZESS may be modest;

- regulatory approvals for linaclotide may be restricted or withdrawn;

- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;

Table of Contents

- reformulation of the product, additional non-clinical or clinical studies, changes in labeling or changes to or reapprovals of manufacturing facilities may be required;

- our reputation in the marketplace may suffer; and

- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of LINZESS, increase our expenses and impair our ability to successfully commercialize LINZESS.

Furthermore, once LINZESS is commercially available, it will be used in a wider population and in a less rigorously controlled environment than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of LINZESS is associated with serious adverse effects, undermining our commercialization efforts.

Finally, the FDA-approved label for LINZESS contains a boxed warning about its use in pediatric patients LINZESS is contraindicated in patients up to 6 years of age and physicians are cautioned to avoid use in patients 6 through 17 years of age. This warning resulted from non-clinical data from studies in young juvenile mice approximately equivalent to human pediatric patients less than 2 years of age. We and Forest have established a non-clinical and clinical post-marketing plan with the FDA. The first step in the plan is to complete additional non-clinical studies to further understand the results of the earlier neonatal mouse study and to understand the tolerability of LINZESS in older juvenile mice. Until these studies are performed, we cannot initiate pediatric studies and may be precluded from ever being able to expand the indication to pediatrics depending on the results from these studies and the view of the FDA on whether the results support studying the safety and efficacy of LINZESS in pediatrics.

We rely entirely on contract manufacturers and our collaboration partners to manufacture linaclotide. If they are unable to comply with applicable regulatory requirements, or experience manufacturing difficulties, or are unable to manufacture sufficient quantities to meet demand, our commercialization efforts may be materially harmed.

We have no internal manufacturing capabilities. Instead, we rely on a combination of contract manufacturers and our partners to manufacture linaclotide API and final linaclotide drug product. We have commercial supply agreements with independent third parties to manufacture the linaclotide API used to support all of our partnered and unpartnered territories. Each of our partners, except AstraZeneca in China (Forest, Almirall and Astellas), is responsible for drug product manufacturing of linaclotide into finished product (including bottling and packaging) for its respective territory. We also have an agreement with another independent third party to provide drug product manufacturing of linaclotide for our unpartnered territories and to potentially provide a second source of drug product manufacturing of linaclotide for our partnered territories. Among our drug product manufacturers, only Forest has manufactured linaclotide on a commercial scale, and they only recently began commercial manufacture for the U.S. market.

Each of our linaclotide API and drug product manufacturers must comply with current good manufacturing practices, or GMP, and other stringent regulatory requirements enforced by the FDA and foreign regulatory authorities in other jurisdictions. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation, which occur in addition to our quality release of linaclotide API. Manufacturers of linaclotide may be unable to comply with these GMP requirements and with other regulatory requirements. We have little control over our manufacturers or collaboration partners compliance with these regulations and standards.

Our manufacturers may experience problems with their respective manufacturing techniques and processes, including for example, quality issues, including product specification and stability failures, quality procedural deviations, improper equipment installation or operation, utility failures, contamination and natural disasters. In addition, our API manufacturers acquire the raw materials necessary to make linaclotide API from a limited number of sources. Any delay or disruption in the availability of these raw materials or a change in raw material suppliers could result in production disruptions, delays or higher costs with consequent adverse effects on us.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign

Table of Contents

regulations, and the challenges associated with complex supply chain management. Even if our manufacturers do not experience problems and commercial manufacturing is achieved, their maximum manufacturing capacities may be insufficient to meet commercial demand. Finding alternative manufacturers or adding additional manufacturers could take a significant amount of time and involve significant expense. New manufacturers would need to develop and implement the necessary production techniques and processes, which along with their facilities, would need to be inspected and approved by the regulatory authorities in each applicable territory.

If our API or drug product manufacturers fail to adhere to applicable GMP or other regulatory requirements or experience manufacturing problems, we will suffer significant consequences, including product seizures or recalls, loss of product approval, fines and sanctions, reputational damage, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs. If we experience any of these results, or if our manufacturers maximum capacities are insufficient to meet demand, we may not be able to successfully commercialize linaclotide.

We must work effectively and collaboratively with Forest to market and sell LINZESS in the U.S. in order for it to achieve its maximum commercial potential.

We are working closely with Forest to implement our joint commercialization plan for LINZESS that contemplates a commercial launch in December 2012. The commercialization plan includes an agreed upon marketing campaign that targets the physicians who see patients who could benefit from LINZESS treatment and the adult men and women who suffer from IBS-C and CIC. It also includes an integrated call plan to optimize the education of specific gastroenterologists and primary care physicians on whom our and Forest s sales representatives call upon, and the frequency by which we will meet with them.

In order to optimize LINZESS s commercial potential, we and Forest must execute upon this commercialization plan effectively and efficiently. We are working together and with the FDA s Office of Prescription Drug Promotion, or OPDP, to finalize our marketing materials that we will deploy upon commercial launch of LINZESS. We also are building a high quality, specialized and compliant national sales force to complement Forest s experienced and trained primary care sales force. In order to be effective, we and Forest must agree upon and utilize effective and compliant marketing materials, and we must properly train our sales team on the IBS-C and CIC disease states as well as how to effectively promote LINZESS in a coordinated manner.

Once LINZESS is launched, we must continually assess and modify our commercialization plan in a coordinated and integrated fashion with Forest in order to adapt to the promotional response. In addition, we must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around IBS-C, CIC and the potential for LINZESS as an appropriate therapy. Further, we and Forest must provide our sales forces with the highest quality support, guidance and oversight in order for them to continue to effectively promote LINZESS to gastroenterologists and primary care physicians. If we fail to perform these commercial functions in the highest quality manner, LINZESS will not achieve its maximum commercial potential.

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

Forest played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data, and Forest holds the NDA for LINZESS. In addition, we will co-commercialize LINZESS in the U.S. with Forest. Each of Almirall, our European partner, and Astellas, our partner in certain Asian countries, is responsible for completing the clinical programs and obtaining regulatory approval of linaclotide in its respective territory. Upon any approval, each of Almirall and Astellas is responsible for commercializing linaclotide in its respective territory, and each has agreed to use commercially reasonable efforts to do so. In October 2012, we entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China. As one of the first steps in that collaboration, AstraZeneca will lead the operational execution of a Phase 3 clinical trial to assess the efficacy and safety of linaclotide in adult patients suffering from IBS-C in China. We and our other partners are responsible for reporting adverse event information to Forest. Finally, each of our partners, other than AstraZeneca, is responsible for completing the manufacturing process of linaclotide upon production of the API, which consists of finishing and packaging linaclotide into capsules.

These functions may not be carried out effectively and efficiently if we fail to communicate and coordinate with our partners, and vice versa. Employees of our partners are not our employees, and we have limited ability to control the amount or timing of resources that they devote to linaclotide. If any of our partners fails to devote sufficient time and resources to linaclotide, or if its performance is substandard, it will delay the potential submission or approval of regulatory applications for linaclotide, as well as the

Table of Contents

manufacturing and commercialization of linaclotide in the particular territory. A material breach by any of our partners of our collaboration or license agreement with such partner, or a significant disagreement between us and a partner, could also delay the regulatory approval and commercialization of linaclotide, potentially lead to costly litigation, and could have a material adverse impact on our financial condition. Moreover, although we have non-compete restrictions in place with each of our partners, they may have relationships with other commercial entities, some of which may compete with us. If any of our partners assists our competitors, it could harm our competitive position.

If any of our partners undergoes a change in control or in management, this may adversely affect our collaborative relationship or the timeline and likelihood of successfully launching LINZESS in the U.S. or achieving regulatory approval of linaclotide in our other partnered territories.

We work jointly and collaboratively with Forest, Almirall and Astellas on many aspects of the development, manufacturing and commercialization of linaclotide. In doing so, we have established relationships with several key members of our partners management teams in functional areas such as development, quality, regulatory, operations, marketing, sales, field operations and medical science. Although we just recently entered into the collaboration with AstraZeneca for the development and commercialization of linaclotide in China, an important factor in our choosing to partner with AstraZeneca was the depth and quality of their experience in this rapidly growing pharmaceutical market. The success of our collaborations is highly dependent on the resources, efforts and skills of our partners and their key employees. As we prepare for the launch of LINZESS in the U.S. and the transition of linaclotide from development to commercialization in other parts of the world, the drug s success becomes more dependent on us maintaining highly collaborative and well aligned partnerships. If a partner undergoes a change of control or a change of management, we will need to reestablish many of these relationships, and we will need to regain alignment of our development and commercialization strategy for linaclotide. Given the inherent uncertainty and disruption that arises in a change of control, we cannot be sure that we would be able to successfully execute these courses of action. Finally, any change of control or in management may result in a reprioritization of linaclotide within such partner s portfolio, or such partner may fail to maintain the financial or other resources necessary to continue supporting its portion of the development, manufacturing or commercialization of linaclotide.

If one of our partners undergoes a change of control and the acquirer either is unable to perform such partner s obligations under its collaboration or license agreement with us or has a product that competes with linaclotide that such acquirer does not divest, we have the right to terminate the collaboration or license agreement and reacquire that partner s rights with respect to linaclotide. If we elect to exercise these rights in such circumstances, we will need to either establish the capability to develop, manufacture and commercialize linaclotide in that partnered territory on our own or we will need to establish a relationship with a new partner. In anticipation of launching LINZESS in the U.S. in December 2012, we have assembled a team of manufacturing, quality, sales, marketing, payor and pricing and field operations specialists, in addition to specialized medical scientists, who represent the functional areas necessary for a successful commercial launch of a high potential, gastrointestinal therapy in North America. If Forest was subject to a change of control that allowed us to continue LINZESS s commercialization in the U.S. on our own, and we chose to do so, we would need to enhance each of these functional aspects to replace the capabilities that Forest was previously providing to the collaboration. However, any such transition might result in a period of reduced efficiency or detailing performance by our operations and commercialization teams, which could adversely affect our ability to commercialize LINZESS and our business could be impaired.

Although many members of our global operations, commercial and medical affairs teams have strategic oversight of, and a certain level of involvement in, their functional areas globally, we do not have corresponding operational capabilities in these areas outside of North America. If Almirall, Astellas or AstraZeneca was subject to a change of control that allowed us to continue linaclotide s development or commercialization in its territory on our own, and we chose to do so rather than establishing a relationship with a new partner, we would need to build operational capabilities in the relevant territory because we currently only have strategic leadership responsibility in each of these territories. In any of these situations, the timeline and likelihood of achieving regulatory approval and, ultimately, the commercialization of linaclotide would be at risk or impaired.

Even though LINZESS has been approved by the FDA for the treatment of adults with IBS-C or CIC, it faces future post-approval development and regulatory requirements, which will present additional challenges.

On August 30, 2012, the FDA approved LINZESS as a once-daily treatment for adult men and women suffering from IBS-C or CIC. LINZESS will be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information.

Table of Contents

LINZESS is contraindicated in pediatric patients up to 6 years of age based on non-clinical data from studies in young juvenile mice approximately equivalent to human pediatric patients less than 2 years of age. Physicians are also instructed to avoid the use of LINZESS in pediatric patients 6 through 17 years of age based on this non-clinical data and the lack of clinical safety and efficacy data in pediatric patients. We and Forest have established a non-clinical and clinical post-marketing plan with the FDA to understand LINZESS s efficacy and safety in pediatric patients. The first non-clinical studies are to further understand the results of the earlier neonatal mouse study and to understand the tolerability of LINZESS in older juvenile mice. We expect these non-clinical studies to be complete in 2013. We and Forest are also working with the FDA on a plan for clinical pediatric studies, which are contingent on the outcome of the non-clinical post marketing requirements.

Finally, we and Forest have also committed to certain non-clinical and clinical studies aimed at understanding: (a) whether orally administered linaclotide can be detected in breast milk, (b) the potential for antibodies to be developed to linaclotide, and if so, (c) whether antibodies specific for linaclotide could have any therapeutic or safety implications. We expect to complete these studies over the next three to five years.

These post-approval requirements will impose burdens and costs on us. Failure to complete the required studies and meet our other post-approval commitments would lead to negative regulatory action at the FDA, which could include withdrawal of regulatory approval of LINZESS for the treatment of adults with IBS-C or CIC.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring implementation of a risk evaluation and mitigation strategy program, withdrawal of the product from the market or suspension of manufacturing. If we, LINZESS or the manufacturing facilities for LINZESS fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;

- impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products or require us to initiate a product recall.

Even though LINZESS has been approved for marketing in the U.S., we or our collaborators may never receive approval to commercialize linaclotide outside of the U.S.

We have out-licensed the European rights to develop and commercialize linaclotide to Almirall, and we have out-licensed the same rights in certain Asian countries to Astellas. We recently entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China. In the future, we may seek to commercialize linaclotide in foreign countries outside of Europe and those Asian countries with other parties or by ourselves. In order to market any products outside of the U.S., we or our partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the U.S.

Almirall submitted an MAA with the EMA in September 2011 for linaclotide for the symptomatic treatment of moderate to severe IBS-C in adult patients. In September 2012, Almirall received a positive recommendation from the Committee for Medicinal Products for Human Use, or the CHMP, for the approval of linaclotide for this indication in adult patients, and the European Medicines Agency often follows the CHMP recommendation. If approved, Almirall will market linaclotide in Europe under the brand name Constella. The time required to obtain approval in other jurisdictions, including the E.U., differs from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but

Table of Contents

a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that linaclotide may not be approved for all indications or with the label requested, which could limit the uses of linaclotide and have an adverse effect on its commercial potential or require costly post-marketing studies.

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

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

- we and our partners ability to demonstrate to the medical community, particularly general practitioners, internists and gastrointestinal specialists who may purchase or prescribe linaclotide, the clinical efficacy and safety of linaclotide as the prescription product of choice for patients who suffer from IBS-C or, in the U.S., CIC;

- the effectiveness of our and our partners sales and marketing organizations and our partners distribution networks;

- the ability of patients or providers to be adequately reimbursed for linaclotide in a timely manner from government and private payors; and

- the actual and perceived efficacy and safety profile of linaclotide, particularly if unanticipated adverse events related to linaclotide treatment arise and create safety concerns among potential patients or prescribers.

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

Our ability to commercialize LINZESS in the U.S. successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. Third-party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for LINZESS, or we may be required to sell LINZESS at an unsatisfactory price.

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

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including linaclotide, to other available therapies. Further, several European countries have implemented government measures to either freeze or reduce pricing of pharmaceutical products. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

Table of Contents

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

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

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

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

We will incur significant liability if it is determined that we are promoting any off-label use of LINZESS.

Physicians are permitted to prescribe drug products for uses that are not described in the product s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses. Accordingly, we may not promote LINZESS in the U.S. for use in any indications other than IBS-C or CIC or in any patient populations other than adult men and women. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we have put together a robust compliance program designed to ensure that all such activities are performed in a legal and compliant manner, LINZESS will be our first commercial product, so we have not yet had the opportunity to utilize the program in connection with commercialization activities.

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

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

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

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

Table of Contents

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

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

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

- the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and

- the federal Physician Payments Sunshine Act, which was passed as part of the Patient Protection and Affordable Care Act of 2010, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report payments, gifts, the provision of samples and other remuneration made to physicians and other health care professional and health care organizations.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

In preparation for the commercial launch of LINZESS, we assembled an experienced compliance team who compiled a program based on industry best practices that is designed to ensure that our commercialization of LINZESS complies with all applicable laws, regulations and industry standards. As our program has not yet been tested and the requirements in this area are constantly evolving, we cannot be certain that our program will eliminate all areas of potential exposure. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

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

The U.S. government and individual states are aggressively pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Healthcare Act, as modified by the Health Care and Education Reconciliation Act of 2010. These healthcare reform laws contain several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care plans, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain health care providers. Additional provisions of the health care reform laws that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on pharmaceuticals sold to certain Medicare Part D beneficiaries.

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

The Food and Drug Administration Amendments Act of 2007 also provides the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and

Table of Contents

compliance with risk evaluations and mitigation strategies approved by the FDA. We and Forest have established a non-clinical and clinical post-marketing plan with the FDA to understand LINZESS s efficacy and safety in pediatrics. The FDA s exercise of this authority will result in increased development-related costs following LINZESS s commercial launch for the treatment of adult men and women suffering from IBS-C or CIC, and could result in potential restrictions on the sale and/or distribution of LINZESS, even in its approved indications and patient populations.

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

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from sales of any product.

In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

- increased amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to motivate key employees of any acquired businesses.

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

Table of Contents

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

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

- obtaining regulatory approval to commence a clinical trial;

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

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

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

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

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

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

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

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

- unforeseen safety issues; or

- lack of adequate funding to continue the clinical trial.

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

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

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

We are highly dependent on the development, regulatory, commercial and financial expertise of our management, particularly Peter M. Hecht, Ph.D., our chief executive officer; Mark G. Currie, Ph.D., our senior vice president of research and development and our chief scientific officer; Michael J. Higgins, our senior vice president, chief operating officer and chief financial officer; and Thomas A. McCourt, our senior vice president, marketing and sales and chief commercial officer. If we lose any members of our management team in the future, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, the Boston area in particular is characterized by a high cost of living. As such, we could

Table of Contents

have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment efforts.

We also have scientific and clinical advisors who assist us in formulating our product development, clinical strategies and our global supply chain plans, as well as sales and marketing advisors who have assisted us in our commercialization strategy and brand plan for linaclotide. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development and commercialization of products that may compete with ours.

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

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

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

- loss of revenues; and

- the inability to commercialize our product candidates.

We currently have product liability insurance coverage for our clinical trials that is subject to industry-standard terms, conditions and exclusions. We are in the process of negotiating a potential increase to our product liability insurance coverage for the commercial sale of LINZESS, and any increased coverage will also be subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of LINZESS patients, clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Table of Contents

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

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

Risks Related to Intellectual Property

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

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

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the U.S. and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented. The United States Patent and Trademark Office, or the USPTO, recently granted a third party request for inter partes reexamination of our U.S. Patent 7,704,947, which covers a group of peptides that includes LINZESS and related molecules. We cannot be certain that the validity of this patent will be upheld until the reexamination process is completed by the USPTO. This patent is one of several issued patents and pending applications in the U.S. related to LINZESS, including a LINZESS composition of matter and methods of use patent (U.S. Patent 7,304,036) as well as additional patents and applications covering processes for making LINZESS, formulations, and dosing regimens. Although none of our other issued patents currently is subject to an ex parte patent reexamination or an inter partes, we cannot guarantee that they will not be subject to reexamination or review by the USPTO in the future. If any or all of our LINZESS-related patents were invalidated, we would still have at least five years of marketing exclusivity under the Hatch-Waxman Act from FDA approval of LINZESS. We believe that each of the patents in our LINZESS patent portfolio was rightfully issued and the portfolio gives us sufficient freedom to operate, however, if any of our present or future patents is invalidated, this could have an adverse effect on our business and financial results, particularly for the period beyond five years following marketing approval.

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Competitors may infringe our patents or may assert our patents are invalid. To counter ongoing or potential infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Litigation with generic manufacturers has become increasingly common in the biotechnology and pharmaceutical industries. In addition, in an infringement or invalidity proceeding, a court or patent administrative body may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. In January 2012, we were issued a U.S. patent that covers the use of plecanatide, another GC-C agonist being developed by Synergy Pharmaceuticals, Inc. for the treatment of IBS-C and constipation. In April 2012, we also received a notice of allowance from the European Patent Office for a European patent covering the use of plecanatide for the treatment of these disorders.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a

Table of Contents

license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments.

Risks Related to Our Finances and Capital Requirements

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

In recent years, we have focused primarily on developing linaclotide, with the goal of supporting regulatory approval for this product candidate. Although we plan to launch LINZESS in the U.S. in December 2012, we believe that it will take us some time to attain profitability and positive cash flow from operations. We have financed our operations to date primarily through the issuance of equity and our collaboration and license arrangements, and we have incurred losses in each year since our inception in 1998. We incurred net losses of approximately $28.8 million and $57.9 million in the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $461.2 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. We expect our expenses to increase in connection with our efforts to commercialize linaclotide and our research and development of our other product candidates. As a result, we expect to continue to incur significant and operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

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

Marketing and selling a primary care drug, purchasing commercial quantities of pharmaceutical products, developing product candidates and conducting clinical trials are expensive and uncertain. Circumstances, our strategic imperatives, or opportunities to create or acquire new programs could require us to, or we may choose to, seek to raise additional funds. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the costs associated with launching and commercializing LINZESS in the U.S.;
- the level of underlying demand for LINZESS by prescribers and patients in the U.S.;

- the costs of maintaining and expanding our sales, marketing and distribution capabilities;

- the rate of progress and cost of our clinical trials and other product development programs, including our post-approval non-clinical and clinical studies of LINZESS in pediatrics;

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

- the status, terms and timing of any collaboration, licensing, co-commercialization or other arrangements; and

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

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

Our quarterly and annual operating results may fluctuate significantly.

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

Table of Contents

- the costs associated with launching and commercializing LINZESS in the U.S.;

- the level of underlying demand for LINZESS in the U.S. and wholesalers buying patterns;

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

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

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

- addition or termination of clinical trials;

- regulatory developments affecting our product candidates; and

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

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

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

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation

on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company s stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. We have completed several financings since our inception which may have resulted in a change in control as defined by Section 382, or could result in a change in control in the future.

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

Because of our dual class common stock structure, the holders of our Class B common stock, who consist of our pre-IPO investors (and their affiliates), founders, directors, executives and certain of our employees, will continue to be able to control certain corporate matters listed below if any such matter is submitted to our stockholders for approval even if they come to own less than 50% of the outstanding shares of our common stock. As of September 30, 2012, the holders of our Class A common stock own approximately 71% and the holders of our Class B common stock own approximately 29% of the outstanding shares of Class A common stock and Class B common stock, combined. However, because of our dual class common stock structure these holders of our Class A common stock have approximately 20% and holders of our Class B common stock have approximately 80% of the total votes on each of the matters identified in the list below. This concentrated control of our Class B common stockholders limits the ability of the Class A common stockholders to influence those corporate matters and, as a result, we may take actions that many of our stockholders do not view as beneficial, which could adversely affect the market price of our Class A common stock.

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

- adoption of a merger or consolidation agreement involving Ironwood;

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

- a dissolution or liquidation of Ironwood; and

- every matter, if and when any individual, entity or group (as that term is used in Regulation 13D of the Securities Exchange Act of 1934, as amended, or the Exchange Act) has, or has publicly disclosed (through a press release or a filing with the SEC) an intent to have, beneficial ownership of 30% or more of the number of outstanding shares of Class A common stock and Class B common stock, combined.

Table of Contents

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

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

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

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

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

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

- the commercial performance of LINZESS in the U.S. or in Europe;
- any third-party coverage and reimbursement policies for LINZESS;
- market conditions in the pharmaceutical and biotechnology sectors;
- the upcoming federal elections and their potential impact on the structure and cost of healthcare;

- developments, litigation or public concern about the safety of our potential products;
- announcements of the introduction of new products by us or our competitors;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of others;
- actual and anticipated fluctuations in our quarterly and annual operating results;
- deviations in our operating results from the estimates of securities analysts;
- sales of additional shares of our common stock;
- additions or departures of key personnel;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price in the financial or scientific press or in online investor communities.

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

Table of Contents

Item 2. ***Unregistered Sales of Equity Securities***

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

Item 6. ***Exhibits***

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Ironwood Pharmaceuticals, Inc.

Date: November 6, 2012	By:	/s/ PETER M. HECHT Peter M. Hecht, Ph.D. Chief Executive Officer and Director *(Principal Executive Officer)*
Date: November 6, 2012	By:	/s/ MICHAEL J. HIGGINS Michael J. Higgins Senior Vice President, Chief Operating Officer and Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*

Table of Contents

EXHIBIT INDEX

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

* Filed herewith.

Furnished herewith.