IRONWOOD PHARMACEUTICALS INC
Form 10-Q
April 23, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

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 April 09, 2013, there were 82,286,938 shares of Class A common stock outstanding and 26,479,272 shares of Class B common stock outstanding.

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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 market potential for LINZESS (linaclotide) in the U.S. and Constella® (linaclotide) in the E.U.;

- the timing, investment and associated activities involved in commercializing linaclotide by us and Forest Laboratories, Inc. in the U.S. and by our partners in other countries in the world;

- the timing and execution of the launch of Constella in the E.U.;

- the ability of our partners and third party manufacturers to manufacture and distribute sufficient amounts of linaclotide on a commercial scale;

- our expectations regarding U.S. and foreign regulatory requirements, including our post-approval, nonclinical and clinical post-marketing plan with the FDA to understand linaclotide s efficacy and safety in pediatric patients;

- 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;

- the safety profile and related adverse events of linaclotide;

- 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 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;

- our 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;

- trends and challenges in our potential markets;

- our ability to attract and motivate key personnel; and

- other factors discussed elsewhere in this Quarterly Report on Form 10-Q.

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

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

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2013

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PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(unaudited)

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 105,302	$ 136,700
Available-for-sale securities	136,727	31,528
Accounts receivable	12	457
Related party accounts receivable, net	36	1,030
Inventory	19,704	6,699
Prepaid expenses and other current assets	13,853	8,026
Total current assets	275,634	184,440
Restricted cash	8,147	7,647
Property and equipment, net	36,100	37,537
Other assets	5,212	283
Total assets	$ 325,093	$ 229,907
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,303	$ 14,217
Related party accounts payable, net	26,441	7,509
Accrued research and development costs	6,184	5,664
Accrued expenses	20,464	21,171
Current portion of capital lease obligations	242	261
Current portion of deferred rent	2,749	2,735
Current portion of deferred revenue	3,299	3,381
Total current liabilities	62,682	54,938
Capital lease obligations, net of current portion	254	308
Deferred rent, net of current portion	10,907	11,593
Deferred revenue, net of current portion	17,217	18,024
Notes payable	174,601	
Other liabilities	909	992
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding at March 31, 2013 and December 31, 2012		
Class A common stock, $0.001 par value, 500,000,000 shares authorized and 82,236,205 and 78,253,074 shares issued and outstanding at March 31, 2013 and December 31, 2012,	82	78

respectively				
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 26,479,272 and 29,512,253 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively		27		30
Additional paid-in capital		657,320		648,955
Accumulated deficit		(598,918)		(505,016)
Accumulated other comprehensive income		12		5
Total stockholders equity		58,523		144,052
Total liabilities and stockholders equity	$	325,093	$	229,907

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Collaborative arrangements revenue	$ 3,255	$ 12,248
Cost and expenses:		
Cost of revenue	1,231	
Research and development	32,753	29,510
Selling, general and administrative	33,374	16,319
Collaboration expense	24,730	2,055
Total cost and expenses	92,088	47,884
Loss from operations	(88,833)	(35,636)
Other income (expense):		
Interest expense	(5,121)	(14)
Interest and investment income	52	49
Other income (expense), net	(5,069)	35
Net loss	$ (93,902)	$ (35,601)
Net loss per share - basic and diluted	$ (0.87)	$ (0.34)
Weighted average number of common shares used in net loss per share basic and diluted:	108,072,643	103,751,060

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands, except share and per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Net loss	$ (93,902)	$ (35,601)
Other comprehensive income (loss):		
Unrealized gains (losses) on available-for-sale securities	7	(3)
Total other comprehensive income (loss)	7	(3)
Comprehensive loss	$ (93,895)	$ (35,604)

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (93,902)	$ (35,601)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,788	2,680
Loss on disposal of property and equipment		1
Share-based compensation expense	5,275	3,721
Accretion of discount/premium on investment securities	387	309
Non-cash interest expense	453	
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	1,439	543
Restricted cash	(500)	
Prepaid expenses and other current assets	(3,911)	(1,149)
Inventory	(13,005)	
Other assets	20	14
Accounts payable and accrued expenses	8,897	(2,227)
Accrued research and development costs	520	948
Deferred revenue	(889)	(12,138)
Deferred rent	(672)	(163)
Other liabilities	(83)	
Net cash used in operating activities	(93,183)	(43,062)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(118,869)	(23,339)
Sales and maturities of available-for-sale securities	13,290	29,265
Purchases of property and equipment	(2,936)	(4,642)
Proceeds from sale of property and equipment		4
Net cash provided by (used in) investing activities	(108,515)	1,288
Cash flows from financing activities:		
Proceeds from issuance of common stock		85,228
Proceeds from issuance of notes payable	175,000	
Costs associated with issuance of notes payable	(7,717)	
Proceeds from exercise of stock options and employee stock purchase plan	3,090	945
Payments on capital leases	(73)	(69)
Net cash provided by financing activities	170,300	86,104
Net increase (decrease) in cash and cash equivalents	(31,398)	44,330
Cash and cash equivalents, beginning of period	136,700	87,282
Cash and cash equivalents, end of period	$ 105,302	$ 131,612

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

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Overview

Ironwood Pharmaceuticals, Inc. (the Company) is an entrepreneurial pharmaceutical company focused on the discovery, development and commercialization of medicines that improve patients lives.

The Company s lead product, linaclotide, is being 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. The Company and its collaboration partner, Forest Laboratories, Inc. (Forest) began commercial sale of LINZESS in December 2012.

In November 2012, the European Commission granted marketing authorization to linaclotide (Constella®) for the symptomatic treatment of moderate to severe IBS-C in adults. Constella is the first and only drug approved in the E.U. for IBS-C. The Company s European partner, Almirall, S.A. (Almirall), will market Constella in Europe (including the Commonwealth of Independent States and Turkey).

Astellas Pharma Inc. (Astellas), the Company s partner for Japan, is developing linaclotide for the treatment of patients with IBS-C in its territory. In October 2012, Astellas initiated in Japan a double-blind, placebo controlled, dose-ranging Phase II clinical trial of linaclotide in adult patients with IBS-C.

In October 2012, the Company entered into a collaboration agreement with AstraZeneca AB (AstraZeneca) to co-develop and co-commercialize linaclotide for IBS-C in China, Hong Kong and Macau. In January 2013, China s State Food and Drug Administration approved the Clinical Trial Application (CTA) submitted by the Company for a Phase III trial of linaclotide in patients with IBS-C.

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 conjunction with its partners, the Company is also exploring development opportunities to strengthen the clinical profile of LINZESS within its indicated population and to expand the product label for additional patient populations and indications, as well as exploring the potential for linaclotide-based combination products. As part of this strategy, the Company and Forest initiated a Phase IIIb clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CIC.

In addition to exploring further linaclotide development opportunities, the Company s research and development team has generated a pipeline of early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, central nervous system disorders, allergic conditions and cardiovascular disease.

Basis of Presentation

The accompanying condensed consolidated financial statements and the related disclosures are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). Certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2013.

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 normal recurring adjustments considered necessary for a fair presentation of the Company s financial position as of March 31, 2013, results of its operations for the three months ended March 31, 2013 and 2012 and its cash flows for the three months ended March 31, 2013 and 2012. The results of operations for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period. Certain prior-period amounts were reclassified to conform to the current year s presentation.

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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 condensed consolidated financial statements requires the Company s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues, 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.

Summary of Significant Accounting Policies

The Company s significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, in the 2012 Annual Report on Form 10-K.

New Accounting Pronouncements

For a discussion of recent accounting pronouncements please refer to Note 2, Summary of Significant Accounting Policies, in the 2012 Annual Report on Form 10-K. The Company did not adopt any new accounting pronouncements during the three months ended March 31, 2013 that had a material effect on the Company s condensed consolidated financial statements.

2. Net Loss Per Share

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

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

	Three Months Ended March 31,	
	2013	2012
Options to purchase common stock	20,838,549	18,631,592
Shares subject to repurchase	67,500	140,000
	20,906,049	18,771,592

The number of shares issuable under the Company s employee stock purchase plan that were excluded from the calculation of diluted weighted average shares outstanding because their effects would be anti-dilutive was insignificant.

3. Collaboration and License Agreements

Forest Laboratories, Inc.

In September 2007, the Company entered into a collaboration agreement with Forest to 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. In September 2012, Forest sublicensed the commercialization rights in Mexico to Almirall.

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

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research and development activities provided by the Company, the Company recorded the up-front license fee as collaborative arrangements 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. At March 31, 2013, $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 development milestone. 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 collaborative arrangements revenue on a straight-line basis over the period of the Company s continuing involvement through September 30, 2012. In July 2009, the Company achieved the development milestone triggering the equity investment and reclassified the forward purchase contract as a reduction to convertible preferred stock. On September 1, 2009, the Company issued 2,083,333 shares of convertible preferred stock to Forest (Note 10).

The Company achieved all six 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 collaborative arrangements revenue through September 2012. In October 2011, the Company achieved two development milestones upon the FDA s acceptance of the linaclotide New Drug Application (NDA) for both IBS-C and CIC and received milestone payments of $20.0 million from Forest. In August 2012, the Company achieved two additional development milestones upon the FDA s approval of the linaclotide NDA for both IBS-C and CIC and received milestone payments of $85.0 million from Forest in September 2012, accordingly. In accordance with ASU 2010-17, adopted in January 2011, these four development milestones were recognized as collaborative arrangements revenue in their entirety upon achievement. The remaining milestone payment received from Forest upon the achievement of sales targets will be recognized as collaborative arrangements revenue as earned.

The Company recognized collaborative arrangements revenue from the Forest collaboration agreement totaling $0 and $5.5 million during the three months ended March 31, 2013 and 2012, respectively.

As a result of the development cost-sharing arrangements under the collaboration, the Company recognized approximately $3.0 million in incremental research and development costs and offset approximately $0.8 million against research and development expense during the three months ended March 31, 2013 and March 31, 2012, respectively, to reflect its obligation under the collaboration to bear half of the development cost incurred by both parties.

The Company receives 50% of the net profits and bears 50% of the net losses from the commercial sale of LINZESS in the U.S., provided, however, that if either party provides fewer calls on physicians 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 and recorded by Forest and include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions.

The Company and Forest began commercial sale of LINZESS in December 2012. The following table presents the amounts recorded by the Company for commercial efforts related to LINZESS in the three months ended March 31, 2013 and 2012 (in thousands):

	Three Months Ended March 31,	
	2013	2012
Collaboration expense	$ 24,730	2,055
Selling and marketing costs incurred by Ironwood (1)	8,539	1,182
Ironwood s share of net loss	$ 33,269	$ 3,237

(1) Includes only selling and marketing costs attributable to the cost-sharing arrangement with Forest.

Almirall, S.A.

In April 2009, the Company entered into a license agreement with Almirall to develop and commercialize linaclotide in Europe (including the Commonwealth of Independent States and Turkey) for the treatment of IBS-C, CIC and other gastrointestinal

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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 and the Company is required to participate on a joint development committee over linaclotide s development period.

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 recognized the up-front license fee as collaborative arrangements revenue on a straight-line basis through September 30, 2012, the period over which linaclotide was developed under the license agreement.

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 development and sales milestones. At March 31, 2013, $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 consist of $4.0 million due upon the first commercial launch in each of the five major European Union countries set forth in the agreement and will be recognized as earned.

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 development milestone. 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 collaborative arrangements revenue through September 2012. In November 2009, the Company achieved the development 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 (Note 10).

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. This development milestone was recognized as collaborative arrangements revenue through September 2012.

The Company recognized approximately $2.2 million and $5.9 million in total collaborative arrangements revenue from the Almirall license agreement during the three months ended March 31, 2013 and 2012, respectively, including approximately $2.2 million and $0 from the sale of active pharmaceutical ingredient (API) to Almirall.

In November 2012, Constella was approved by the European Commission for the treatment of IBS-C in adults. At March 31, 2013, Constella was not commercially available in the European territory. The Company will receive royalties which escalate based on Constella s sales volume, beginning in the mid-twenties, less the transfer price paid for the API included in the product actually sold.

Astellas Pharma Inc.

In November 2009, the Company entered into a license agreement with Astellas 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. As a result of an amendment executed in March 2013, the Company regained rights to linaclotide in South Korea, Taiwan, Thailand, the Philippines and Indonesia. The Company did not consider this amendment to be a material modification of the license agreement. Astellas continues to be responsible for all activities relating to development, regulatory approval and commercialization in Japan as well as funding any costs and the Company is required to participate on a joint development committee over linaclotide s development period.

In 2009, Astellas paid the Company a non-refundable, up-front licensing fee of $30.0 million, which is being recognized as collaborative arrangements revenue on a straight-line basis over the Company s estimate of the period over which linaclotide will be developed under the license agreement. In March 2013, the Company revised its estimate of the development period from 115 months to 85 months based on the Company s assessment of approval timelines for Japan.

The agreement also includes additional development milestone payments that could total up to $45.0 million. These milestone payments consist of $15.0 million upon initiation of a Phase III 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 royalties which escalate based on sales volume, beginning in the low-twenties, less the transfer price paid for the API included in the product actually sold.

At March 31, 2013, approximately $20.3 million of the up-front license fee remains deferred. During the three months ended March 31, 2013 and 2012, the Company recognized approximately $0.8 million and $0.9 million, respectively, in collaborative

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arrangements revenue from the Astellas license agreement, including $12,000 and $0.1 million, respectively, from the sale of API to Astellas.

AstraZeneca AB

In October 2012, the Company entered into a collaboration agreement with AstraZeneca (the AstraZeneca Collaboration Agreement) to co-develop and co-commercialize linaclotide in China, including Hong Kong and Macau (the License Territory). The collaboration provides AstraZeneca with an exclusive nontransferable license to exploit the underlying technology in the License Territory. The parties will share responsibility for continued development and commercialization of linaclotide under a joint development plan and a joint commercialization plan, respectively, with AstraZeneca having primary responsibility for the local operational execution.

The parties agreed to an Initial Development Plan (IDP) which includes the planned development of linaclotide in China, including the lead responsibility for each activity and the related FTE and external costs. The IDP indicates that AstraZeneca is responsible for a multinational Phase III clinical trial, Ironwood is responsible for nonclinical development and supplying clinical trial material and both parties are responsible for the regulatory submission process. The IDP indicates that the party specifically designated as being responsible for a particular development activity under the IDP shall implement and conduct such activities. The activities are governed by a Joint Development Committee (JDC), with equal representation from each party. The JDC is responsible for approving, by unanimous consent, the joint development plan and development budget, as well as approving protocols for clinical studies, reviewing and commenting on regulatory submissions, and providing an exchange of data information.

The AstraZeneca Collaboration Agreement will continue until there is no longer a development plan or commercialization plan in place, however, it can be terminated by AstraZeneca at any time upon 180 days prior written notice. Under certain circumstances, either party may terminate the AstraZeneca Collaboration Agreement in the event of bankruptcy or an uncured material breach of the other party. Upon certain change in control scenarios of AstraZeneca, Ironwood may elect to terminate the AstraZeneca Collaboration Agreement and may re-acquire its product rights in a lump sum payment equal to the fair market value of such product rights.

In connection with the AstraZeneca Collaboration Agreement, the Company and AstraZeneca also executed a co-promotion agreement (the Co-Promotion Agreement), pursuant to which Ironwood will utilize its existing sales force to co-promote NEXIUM® (esomeprazole magnesium), one of AstraZeneca s products, in the U.S. The Co-Promotion Agreement expires upon the earlier of May 27, 2014 or the date on which a generic version of AstraZeneca s product is first sold in the U.S. The Company may terminate the Co-Promotion Agreement on or after December 31, 2013 upon written notice to AstraZeneca.

There are no refund provisions in the AstraZeneca Collaboration Agreement and the Co-Promotion Agreement (together, the AstraZeneca Agreements).

Under the terms of the AstraZeneca Collaboration Agreement, the Company received a $25.0 million non-refundable upfront payment upon execution. The Company is also eligible for $125.0 million in additional commercial milestone payments contingent on the achievement of certain sales targets. The parties will also share in the net profits and losses associated with the development and commercialization of linaclotide in the License Territory, with AstraZeneca receiving 55% of the net profits or incurring 55% of the net losses until a certain specified commercial milestone is achieved, at which time profits and losses will be shared equally thereafter.

Activities under the AstraZeneca Agreements were evaluated in accordance with ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Company identified the following deliverables in the AstraZeneca Agreements:

- an exclusive license to develop and commercialize linaclotide in the License Territory (the License Deliverable),
- research, development and regulatory services pursuant to the IDP (the R&D Services),
- JDC services,
- obligation to supply clinical trial material, and
- co-promotion services for AstraZeneca s product (the Co-Promotion Deliverable).

The License Deliverable is nontransferable and has certain sublicense restrictions. The Company determined that the License Deliverable had standalone value as a result of AstraZeneca s internal product development and commercialization capabilities, which would enable it to use the License Deliverable for its intended purposes without the involvement of the Company. The remaining deliverables were deemed to have standalone value based on their nature and all deliverables met the criteria to be accounted for as separate units of accounting under ASC 605-25. Factors considered in this determination included, among other things, whether any

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other vendors sell the items separately and if the customer could use the delivered item for its intended purpose without the receipt of the remaining deliverables.

The Company identified the supply of linaclotide drug product for commercial requirements and commercialization services as contingent deliverables because these services are contingent upon the receipt of regulatory approval to commercialize linaclotide in the License Territory, and there were no binding commitments or firm purchase orders pending for commercial supply. As these deliverables are contingent, and are not at an incremental discount, they are not evaluated as deliverables at the inception of the arrangement. These contingent deliverables will be evaluated and accounted for separately as each related contingency is resolved. As of March 31, 2013, no contingent deliverables were provided by the Company under the AstraZeneca Agreements.

The total amount of the non-contingent consideration allocable to the AstraZeneca Agreements of $26.9 million (Arrangement Consideration) includes the $25.0 million non-refundable upfront payment and 55% of the costs for clinical trial material supply services and research, development and regulatory activities allocated to Ironwood in the IDP, or $1.9 million. The Company allocated the Arrangement Consideration of $26.9 million to the non-contingent deliverables based on management s best estimate of selling price (BESP) of each deliverable using the relative selling price method as the Company did not have vendor-specific objective evidence or third-party evidence of selling price for such deliverables. The Company estimated the BESP for the License Deliverable using a multi-period excess-earnings method under the income approach which utilized cash flow projections, the key assumptions of which included the following market conditions and entity-specific factors: (a) the specific rights provided under the license to develop and commercialize linaclotide; (b) the potential indications for linaclotide pursuant to the license; (c) the likelihood linaclotide will be developed for more than one indication; (c) the stage of development of linaclotide for IBS-C and CIC and the projected timeline for regulatory approval; (d) the development risk by indication; (f) the market size by indication; (g) the expected product life of linaclotide assuming commercialization; (h) the competitive environment, and (i) the estimated development and commercialization costs of linaclotide in the License Territory. The Company utilized a discount rate of 11.5% in its analysis, representing the weighted average cost of capital derived from returns on equity for comparable companies. The Company determined its BESP for the remaining deliverables based on the nature of the services to be performed and estimates of the associated effort and cost of the services adjusted for a reasonable profit margin such that they represented estimated market rates for similar services sold on a standalone basis.

The Company concluded that a change in key assumptions used to determine BESP for each deliverable would not have a significant effect on the allocation of the Arrangement Consideration, as the estimated selling price of the License Deliverable significantly exceeds the other deliverables.

Of the $26.9 million Arrangement Consideration, $24.7 million was allocated to the License Deliverable, approximately $0.3 million to the R&D Services, approximately $28,000 to the JDC services, approximately $0.1 million to the clinical trial material supply services, and $1.8 million to the Co-Promotion Deliverable in the relative selling price model. The Company recognized all $24.7 million allocated to the License Deliverable as revenue upon the execution of the AstraZeneca Agreements as the associated unit of accounting had been delivered and there is no general right of return. At inception, the remaining $0.3 million of the Arrangement Consideration received, and allocated to the remaining deliverables based on their relative selling prices, was deferred. No additional contingent payments were received through March 31, 2013.

Because the Company shares development costs with AstraZeneca, payments from AstraZeneca with respect to both research and development and selling, general and administrative costs incurred by Ironwood prior to the commercialization of linaclotide in the License Territory are recorded as a reduction to expense, in accordance with the Company s policy, which is consistent with the nature of the cost reimbursement. Development costs incurred by Ironwood that pertain to the IDP are recorded as research and development expense as incurred.

The Company will perform the R&D Services, JDC services and supply clinical trial materials during the estimated development period of approximately 44 months. All Arrangement Consideration allocated to such services is being recognized as a reduction of research and development costs, using the proportional performance method, by which the amounts are recognized in proportion to the costs incurred. As a result of the cost-sharing arrangements under the collaboration, the Company recognized approximately $0.1 million in incremental research and development costs during the three months ended March 31, 2013. As of March 31, 2013, no clinical trial material has been delivered to AstraZeneca; therefore, no reduction of research and development expense was recorded related to this deliverable.

The amount allocated to the Co-Promotion Deliverable is being recognized as collaborative arrangements revenue using the proportional performance method, which approximates recognition on a straight-line basis beginning on the date that Ironwood began to co-promote AstraZeneca s product, through December 31, 2013 (the earliest cancellation date). During the three months ended March 31, 2013, the Company recognized approximately $0.2 million in revenue related to this deliverable.

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The Company reassesses the periods of performance for each deliverable at the end of each reporting period.

Milestone payments received from AstraZeneca upon the achievement of sales targets will be recognized as earned.

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, which was expensed 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 $114.5 million per product if all milestones are achieved. The Company will expense these payments as incurred. During the three months ended March 31, 2013 and 2012, the Company recorded approximately $0.7 million and $0.7 million, respectively, in research and development expense associated with the Protagonist agreement.

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, which was expensed 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 months ended March 31, 2013 and 2012, the Company recorded approximately $0.3 million and $3.3 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 up to $25.5 million upon the achievement of various development, regulatory and commercial milestones. The Company may also incur significant research and development costs if the related product candidate were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring. During the three months ended March 31, 2013 and 2012, the Company incurred $0 and $1.0 million in research and

development expense associated with one of the Company s other collaboration agreements.

4. Fair Value of Financial Instruments

The tables below present information about the Company s assets that are measured at fair value on a recurring basis as of March 31, 2013 and December 31, 2012 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

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information, perceived market movements, sector news and economic events. The inputs into these models may include benchmark yields, reported trades, broker-dealer quotes, issuer spreads and other relevant data.

The 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	**March 31, 2013**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash and cash equivalents:				
Money market funds	$ 82,323	$ 82,323	$	$
U.S. government-sponsored securities	15,623		15,623	
Available-for-sale securities:				
U.S. Treasury securities	21,546	21,546		
U.S. government-sponsored securities	115,181		115,181	
Total	$ 234,673	$ 103,869	$ 130,804	$

		Fair Value Measurements at Reporting Date Using		
Description	**December 31, 2012**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash and cash equivalents:				
Money market funds	$ 111,368	$ 111,368	$	$
U.S. government-sponsored securities	2,500		2,500	
Available-for-sale securities:				
U.S. Treasury securities	15,052	15,052		
U.S. government-sponsored securities	16,476		16,476	
Total	$ 145,396	$ 126,420	$ 18,976	$

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three months ended March 31, 2013 and 2012.

Cash equivalents, accounts receivable, including related party accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and the current portion of capital lease obligations at March 31, 2013 and December 31, 2012 are carried at amounts that approximate fair value due to their short-term maturities.

The non-current portion of the capital lease obligations at March 31, 2013 and December 31, 2012 approximates fair value as it bears interest at a rate approximating a market interest rate.

5. Available-for-Sale Securities

The following tables summarize the available-for-sale securities held at March 31, 2013 and December 31, 2012 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2013:				
U.S. government-sponsored securities	$ 115,169	$ 15	$ (3)	$ 115,181
U.S. Treasury securities	21,546			21,546
Total	$ 136,715	$ 15	$ (3)	$ 136,727

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2012:				
U.S. government-sponsored securities	$ 16,472	$ 5	$ (1)	$ 16,476
U.S. Treasury securities	15,051	1		15,052
Total	$ 31,523	$ 6	$ (1)	$ 31,528

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The contractual maturities of all securities held at March 31, 2013 are one year or less. There were thirteen and three investments in an unrealized loss position at March 31, 2013 and December 31, 2012, respectively, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities at March 31, 2013 and December 31, 2012 was approximately $40.1 million and $3.0 million, respectively. 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 March 31, 2013.

There were no sales of available-for-sale securities during the three months ended March 31, 2013 and 2012. Gross realized gains and losses on the sales of available-for-sale securities that have been included in other income (expense), net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income as well as gains and losses reclassified out of accumulated other comprehensive income into other income (expense) have not been material to the Company s consolidated results of operations. The cost of securities sold or the amount reclassified out of the accumulated other comprehensive income into other income (expense) is based on the specific identification method for purposes of recording realized gains and losses.

6. Inventory

Inventory consisted of the following at (in thousands):

	March 31, 2013	December 31, 2012
Raw materials	$ 19,704	$ 6,699

In the third quarter of 2012, the Company began capitalizing inventory costs for linaclotide manufactured in preparation for its launch in the U.S. and Europe. Inventory at March 31, 2013 represents API that is available for commercial sale.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2013	December 31, 2012
Salaries and benefits	$ 9,950	$ 14,594
Professional fees	1,269	1,031
Accrued interest	4,652	

Other	4,593	5,546
	$ 20,464	$ 21,171

8. Notes Payable

On January 4, 2013, the Company closed a private placement of $175.0 million in aggregate principal amount of notes due on or before June 15, 2024 (the Legal Maturity Date). The notes bear an annual interest rate of 11%, with interest payable March 15, June 15, September 15 and December 15 of each year (each a Payment Date) beginning June 15, 2013. Principal of the notes will be payable on Payment Dates from and after March 15, 2014. All outstanding principal will be paid on the Legal Maturity Date.

From March 15, 2014, the Company will make quarterly payments on the notes equal to the greater of (i) 7.5% of net sales of LINZESS in the U.S. for the preceding quarter (the Synthetic Royalty Amount) and (ii) accrued and unpaid interest on the notes (the Required Interest Amount). Principal on the notes will be repaid in an amount equal to the Synthetic Royalty Amount minus the Required Interest Amount, when this is a positive number, until the principal has been paid in full. Given the principal payments on the notes are based on the Synthetic Royalty Amount, which will vary from quarter to quarter, the notes may be repaid prior to the Legal Maturity Date. The Company estimates that no principal payments will be made within twelve months following March 31, 2013, and as such, the outstanding principal balance is classified as a long term liability as of March 31,2013.

The notes are secured solely by a security interest in a segregated bank account established to receive the required quarterly payments. Up to the amount of the required quarterly payments under the notes, Forest will deposit its quarterly profit (loss) sharing

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payments due to the Company under the collaboration agreement, if any, into the segregated bank account. If the funds deposited by Forest into the segregated bank account are insufficient to make a required payment of interest or principal on a particular Payment Date, the Company is obligated to deposit such shortfall out of the Company s general funds into the segregated bank account.

The notes may be redeemed at any time prior to maturity, in whole or in part, at the option of the Company. If the applicable redemption of the notes occurs prior to January 1, 2014, the Company will pay a redemption price equal to the greater of (i) the outstanding principal balance of the notes being redeemed or (ii) the present value, discounted at the rate on U.S. Treasury obligations with a comparable maturity to the remaining expected terms of the notes being redeemed plus 1.00%, of such principal payment amounts and interest on the outstanding principal balance, plus the accrued and unpaid interest to the redemption date on the notes being redeemed. If the applicable redemption of the notes occurs on or after January 1, 2014, the Company will pay a redemption price equal to the percentage of outstanding principal balance of the notes being redeemed specified below for the period in which the redemption occurs (plus the accrued and unpaid interest to the redemption date on the notes being redeemed):

Payment Dates	**Redemption Percentage**
From and including January 1, 2014 to and including December 31, 2014	112.00%
From and including January 1, 2015 to and including December 31, 2015	105.50%
From and including January 1, 2016 to and including December 31, 2016	102.75%
From and including January 1, 2017 and thereafter	100.00%

The notes contain certain covenants related to the Company s obligations with respect to the commercialization of LINZESS and the related collaboration agreement with Forest, as well as certain customary covenants, including covenants that limit or restrict the Company s ability to incur certain liens, merge or consolidate or make dispositions of assets. The notes also specify a number of events of default (some of which are subject to applicable cure periods), including, among other things, covenant defaults, other non-payment defaults, bankruptcy and insolvency defaults. Upon the occurrence of an event of default, subject to cure periods in certain circumstances, all amounts outstanding may become immediately due and payable.

The upfront cash proceeds of $175.0 million, less a discount of $0.4 million for payment of legal fees incurred on behalf of the noteholders, were recorded as notes payable at issuance. The Company also capitalized $7.3 million of debt issuance costs, which are included in prepaid expenses and other current assets and in other assets on the Company s consolidated balance sheet. The debt issuance costs and discount are being amortized over the estimated term of the obligation using the effective interest method. The repayment provisions represent embedded derivatives that are clearly and closely related to the notes and as such do not require separate accounting treatment.

The accounting for the notes requires the Company to make certain estimates and assumptions about the future net sales of LINZESS in the U.S. LINZESS has only been marketed since December 2012 and the estimates of the magnitude and timing of LINZESS net sales are subject to significant variability due to the recent product launch and the extended time period associated with the financing transaction, and thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as the Company gains experience marketing LINZESS, which may result in future adjustments to the portion of the debt that is classified as a current liability, the amortization of debt issuance costs and discount as well as the accretion of the interest expense. Any such adjustments could be material.

The fair value of the notes was estimated to be $178.5 million as of March 31, 2013 and was determined using Level 3 inputs, including a quoted rate.

9. Employee Stock Benefit 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.

The following table summarizes share-based compensation expense reflected in the condensed consolidated statements of operations for the three months ended March 31, 2013 and 2012 (in thousands):

	Three Months Ended March 31,	
	2013	2012
Research and development	$ 2,224	$ 1,951
Selling, general and administrative	3,051	1,770
	$ 5,275	$ 3,721

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A summary of stock option activity for the three months ended March 31, 2013 is as follows:

	Number of Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2012	19,539,429	$ 7.75
Granted	2,419,570	13.08
Exercised	(941,409)	3.22
Cancelled	(179,041)	12.34
Outstanding at March 31, 2013	20,838,549	$ 8.53

The weighted-average assumptions used to estimate the fair value of the stock options using the Black-Scholes option-pricing model were as follows for the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
Expected volatility	46.25%	50.3%
Expected term (in years)	6.5	6.5
Risk-free interest rate	1.39%	1.3%
Expected dividend yield	%	%

10. Related Party Transactions

The Company has and currently obtains legal services from a law firm that is an investor in the Company. The Company paid approximately $37,000 and $152,000 in legal fees to this investor during the three months ended March 31, 2013 and 2012, respectively. At March 31, 2013 and December 31, 2012, the Company had approximately $21,000 and $23,000 of accounts payable due to this related party, respectively.

In September 2009, Forest became a related party when the Company sold to Forest 2,083,333 shares of the Company s convertible preferred stock and in November 2009, Almirall became a related party when the Company sold to Almirall 681,819 shares of the Company s convertible preferred stock (Note 3). 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 March 31, 2013, the Company had approximately $36,000 in related party accounts receivable associated with Almirall and $26.4 million in related party accounts payable, net of related party accounts receivable, associated with Forest. At December 31, 2012, the Company had approximately $1.0 million in related party accounts receivable associated with Almirall and approximately $7.5 million in related party accounts payable, net of related party accounts receivable, associated with Forest.

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

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto 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 Item 1A of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are an entrepreneurial pharmaceutical company focused on the discovery, development and commercialization of medicines that improve patients lives. We have one marketed product, linaclotide, which is available in the United States, or U.S., under the trademarked name LINZESSTM and was recently approved in the European Union, or E.U, under the trademarked name Constella®. Linaclotide is also being developed in other parts of the world by certain of our partners. We are exploring development opportunities to strengthen the clinical profile of LINZESS within its indicated population and to expand the product label for additional patient populations and indications, as well as exploring the potential for linaclotide-based combination products. In addition to exploring additional development opportunities, we also have a pipeline of early development candidates and discovery research programs in multiple therapeutic areas.

In August 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 being commercialized in the U.S. by us and our collaboration partner, Forest Laboratories, Inc., or Forest. We and Forest began commercializing LINZESS in the U.S. during December 2012.

In November 2012, the European Commission granted marketing authorization to Constella for the symptomatic treatment of moderate to severe IBS-C in adults. Constella is the first and only drug approved in the E.U. for IBS-C. Our European partner, Almirall, S.A., or Almirall, will market Constella in Europe (including the Commonwealth of Independent States and Turkey).

Astellas Pharma Inc., or Astellas, our partner in Japan, is developing linaclotide for the treatment of patients with IBS-C. In October 2012, Astellas initiated a double-blind, placebo controlled, dose-ranging Phase II clinical trial of linaclotide in adult patients with IBS-C.

In October 2012, we entered into a collaboration agreement with AstraZeneca AB, or AstraZeneca, to co-develop and co-commercialize linaclotide for IBS-C in China, Hong Kong and Macau. In January 2013, China s State Food and Drug Administration approved the Clinical Trial Application, or CTA, submitted by us for a Phase III trial of linaclotide in patients with IBS-C.

We continue to assess alternatives to bring linaclotide to IBS-C and CIC sufferers in the parts of the world outside of our partnered territories.

In conjunction with our partners, we are also exploring development opportunities to strengthen the clinical profile of LINZESS within its indicated population and to expand the product label for additional patient populations and indications, as well as exploring the potential for linaclotide-based combination products. As part of this strategy, we and Forest initiated a Phase IIIb clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CIC.

In addition to exploring further linaclotide development opportunities, our research and development team has generated a pipeline of early development candidates and discovery research in multiple therapeutic areas, including gastrointestinal disease, central nervous system, or CNS, disorders, allergic conditions and cardiovascular disease.

To date, we have dedicated substantially all of our activities to the research, development and commercialization of linaclotide, our lead product and product candidate, as well as research and development of our other product candidates. We have incurred significant operating losses since our inception in 1998. As of March 31, 2013, we had an accumulated deficit of approximately $598.9 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.

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On January 4, 2013, we closed a private placement of $175.0 million in aggregate principal amount of 11% notes due on or before June 15, 2024. The notes bear an annual interest rate of 11%, with interest paid quarterly beginning June 15, 2013, and principal expected to be paid quarterly beginning June 15, 2014. As a result of the debt offering, we received aggregate net proceeds, after offering expenses, of approximately $167.3 million. We intend to use the net proceeds from this debt financing to fund our research and development efforts and to support the commercial launch of LINZESS, in addition to general corporate purposes.

Financial Overview

Revenue. Revenue to date has been generated primarily through our collaboration agreements with Forest and AstraZeneca, 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, finished drug product, and development materials for the collaborative partners. 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, finished drug product and development materials, payments based upon the achievement of certain milestones and royalties on product sales. Additionally, we will receive our share of the net profits or bear our share of the net losses from the sale of linaclotide in the U.S. and China. LINZESS launched in the U.S. in the fourth quarter of 2012 and Constella is expected to be commercially available in certain European countries in the second quarter of 2013.

We record our share of the net profits and losses from the sales of LINZESS in the U.S. on a net basis and present the settlement payments as collaborative arrangements revenue or collaboration expense, as applicable. Net profits or losses consist of net sales to third-party customers in the U.S. less the cost to manufacture LINZESS as well as selling and marketing expenses. Although we expect net sales to increase during the launch phase, the settlement payments between Forest and us, resulting in collaborative arrangements revenue or collaboration expense, are subject to fluctuation based on the ratio of selling and marketing expenses incurred by each party. In addition, our collaborative arrangements revenue may fluctuate as a result of timing and amount of license fees and clinical and commercial milestones received and recognized under our current and future strategic partnerships as well as timing and amount of royalties from the sales of Constella in the European market. One instance of this potential fluctuation relates to the challenging environment in the European pharmaceutical sector. As challenges in obtaining adequate pricing and reimbursement for pharmaceutical products in Europe have grown recently, it has become clear to us and our partner Almirall that revising certain aspects of our current partnership may benefit the potential for linaclotide. We are currently in active discussions with Almirall regarding the various financial incentives and structure of our current collaboration, and pending the results of these discussions, this could result in a rebalance of certain short term financial compensation, including the five $4-million launch milestones, in exchange for additional new sales-based incentives and a more favorable royalty structure at certain sales thresholds.

Cost of Revenue. Cost of revenue is recognized upon shipment of linaclotide API to certain of our licensing partners. Our cost of revenue consists of the costs of producing such API. We expensed most of the manufacturing costs of API as research and development expenses in the periods prior to July 1, 2012, at which date we began capitalizing linaclotide-related inventory costs as their realizability became probable. As of December 31, 2012, the previously expensed API inventory that was commercially saleable was fully utilized. We expect our cost of revenue to increase in future periods.

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, third-party contract costs relating to research, formulation, manufacturing, nonclinical study and clinical trial activities as well as licensing fees for our product candidates prior to regulatory approval. We charge all research and development expenses to operations as incurred. Under our Forest and AstraZeneca collaboration agreements, we are reimbursed for certain research and development expenses, and we net these reimbursements against our research and development expenses as incurred. Payments to Forest or AstraZeneca are recorded as incremental research and development expense.

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 guanylate cyclase type-C, or GC-C, agonist and is our only product, or product candidate, that has demonstrated clinical proof of concept. A New Drug Application, or NDA, for LINZESS with respect to both IBS-C and CIC was approved by the FDA in August 2012. In November 2012, the European Commission approved Constella for the treatment of IBS-C in adults.

We are also exploring development opportunities to strengthen the clinical profile of LINZESS within its indicated population and to expand the product label for additional patient populations and indications, and we are exploring the potential for linaclotide-based combination products. As part of this strategy, we and Forest initiated a Phase IIIb clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with CIC.

In addition to exploring further linaclotide development opportunities, 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, allergic conditions and cardiovascular disease.

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The following table sets forth our research and development expenses related to our product pipeline for the three months ended March 31, 2013 and 2012. These expenses relate primarily to external costs associated with manufacturing, including supply chain development, nonclinical studies and clinical trial costs. Costs related to facilities, depreciation, share-based compensation and research and development support services are not directly charged to programs.

	Three Months Ended March 31,	
	2013	2012
	(in thousands)	
Demonstrated clinical proof of concept	$ 10,588	$ 10,145
Early stage, pre-proof of concept	5,297	6,093
Early stage, nonclinical	2,907	3,570

Since 2004, the date we began tracking costs by program, we have incurred approximately $184.4 million of research and development expenses related to linaclotide. The expenses for linaclotide include both reimbursements to us by Forest and AstraZeneca as well as our portion of research and development costs incurred by Forest or AstraZeneca for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreements.

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 nonclinical 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 nonclinical 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, Hong Kong and Macau. 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 populations and indications and the potential for linaclotide-based combination products. 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, allergic conditions 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 when, if ever, 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 nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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

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- 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 nonclinical 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 regulatory approvals in 2012, LINZESS began generating sales in the fourth quarter of 2012 upon commercial launch in the U.S. and Constella is expected to be commercially available in the European market in the second quarter of 2013.

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 indications and other patient populations. We will also invest in our other product candidates as we advance them through nonclinical studies and clinical trials, in addition to funding full-time equivalents for research and development activities under our external collaboration and license agreements.

Selling, General and Administrative Expense. Selling, 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, sales, marketing and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs and professional fees for accounting and legal services. We anticipate substantial increases in expenses related to developing and maintaining the organization necessary to further support the commercial launch of LINZESS, including expanding our commercial and sales force teams. We charge all selling, general and administrative expenses to operations as incurred.

Under our Forest and AstraZeneca collaboration agreements, we are reimbursed for certain selling and marketing expenses and we net these reimbursements against our selling, general and administrative expenses as incurred. Beginning in the fourth quarter of 2012, we include Forest s selling and marketing cost-sharing payments in the calculation of the net profits and net losses from the sale of LINZESS in the U.S. and present the net payment to or from Forest as collaboration expense or collaborative arrangements revenue, respectively. The selling and marketing cost-sharing payment to Forest for the three months ended March 31, 2012 was reclassified to conform to the current year s presentation.

Collaboration Expense. Collaboration expense represents 50% of LINZESS net sales in the U.S. as well as cost of revenue and selling and marketing cost-sharing settlement between us and Forest. Prior to the fourth quarter of 2012, selling and marketing cost-sharing payments were presented within selling, general and administrative expenses. The cost-sharing payment to Forest for the three months ended March 31, 2012 was reclassified to conform to the current year s presentation. We expect our collaboration expense to vary in the short term due to the effects of the net profit or loss sharing arrangement under the collaboration with Forest.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our condensed 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 may affect the reported amounts of assets and liabilities, and related disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reported periods. 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. We base our estimates on historical experience, trends in the industry, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions. During the three months ended March 31, 2013, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the Securities and Exchange Commission, or SEC, on February 21, 2013.

Results of Operations

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

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	Three Months Ended March 31,	
	2013	2012
	(in thousands)	
Collaborative arrangements revenue:	$ 3,255	$ 12,248
Cost and expenses:		
Cost of revenue	1,231	
Research and development	32,753	29,510
Selling, general and administrative		