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, 2015

OR

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

For the transition period from to

Commission file number: 001-34620

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**04-3404176** (I.R.S. Employer Identification Number)
301 Binney Street **Cambridge, Massachusetts** (Address of Principal Executive Offices)	**02142** (Zip Code)

(617) 621-7722

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of April 30, 2015, there were 125,941,466 shares of Class A common stock outstanding and 16,154,812 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 staten 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 demand and market potential for linaclotide in the United States, or the U.S. (LINZESS®), in the European Union, or the E.U. (CONSTELLA®), and in other countries where it is approved for marketing;

- the timing, investment and associated activities involved in commercializing LINZESS by us and Actavis plc in the U.S.;

- the timing and execution of the launches and commercialization of CONSTELLA in the E.U.;

- the timing, investment and associated activities involved in developing, launching, and commercializing linaclotide by us and our partners worldwide;

- our ability and the ability of our partners to secure and maintain adequate reimbursement for linaclotide;

- 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 for linaclotide and our product candidates, including our post-approval, nonclinical and clinical post-marketing plan with the Food and Drug Administration, or the FDA;

- 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 and our product candidates;

- the therapeutic benefits and effectiveness of linaclotide and our product candidates and the potential indications and market opportunities therefor;

- our ability to obtain and maintain intellectual property protection for linaclotide and our product candidates and the strength thereof;

- the ability of our partners to perform their obligations under our collaboration and license agreements with them;

- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;

- the in-licensing or acquisition of externally discovered businesses, products or technologies;

- our expectations as to future financial performance, expense levels, payments, tax obligations, capital raising and liquidity sources, and real estate needs, as well as the timing thereof;

- 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 healthcare 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.

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

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

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2015

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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, 2015		December 31, 2014	
ASSETS				
Current assets:				
Cash and cash equivalents	$	63,692	$	74,297
Available-for-sale securities		152,173		174,037
Accounts receivable		862		10
Related party accounts receivable, net		32,987		25,829
Inventory		4,950		4,954
Prepaid expenses and other current assets		9,212		10,603
Total current assets		263,876		289,730
Restricted cash		8,147		8,147
Property and equipment, net		27,477		29,826
Other assets		6,028		5,810
Total assets	$	305,528	$	333,513
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable and related party accounts payable, net	$	5,227	$	9,762
Accrued research and development costs		9,270		3,574
Accrued expenses		18,735		22,612
Current portion of capital lease obligations		1,177		1,152
Current portion of deferred rent		5,006		4,992
Current portion of deferred revenue		7,191		7,191
Current portion of notes payable		13,207		11,258
Total current liabilities		59,813		60,541
Capital lease obligations, net of current portion		2,268		2,571
Deferred rent, net of current portion		9,935		10,522
Deferred revenue, net of current portion		7,191		8,989
Notes payable, net of current portion		158,159		162,338
Commitments and contingencies				
Stockholders equity:				
Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding				
Class A common stock, $0.001 par value, 500,000,000 shares authorized and 125,908,933 and 124,915,658 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively		126		125

Class B common stock, $0.001 par value, 100,000,000 shares authorized and 16,154,812 and 15,907,272 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively		16		16
Additional paid-in capital		1,068,685		1,055,876
Accumulated deficit		(1,000,668)		(967,446)
Accumulated other comprehensive income (loss)		3		(19)
Total stockholders equity		68,162		88,552
Total liabilities and stockholders equity	$	305,528	$	333,513

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 per share amounts)

(unaudited)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Collaborative arrangements revenue	$ 28,932	$ 14,605
Cost and expenses:		
Cost of revenue	12	1,924
Research and development	26,641	27,144
Selling, general and administrative	30,346	29,924
Total cost and expenses	56,999	58,992
Loss from operations	(28,067)	(44,387)
Other (expense) income:		
Interest expense	(5,220)	(5,283)
Interest and investment income	65	44
Other expense, net	(5,155)	(5,239)
Net loss	$ (33,222)	$ (49,626)
Net loss per share - basic and diluted	$ (0.24)	$ (0.38)
Weighted average number of common shares used in net loss per share basic and diluted:	141,278	129,745

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)

(unaudited)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Net loss	$ (33,222)	$ (49,626)
Other comprehensive income (loss):		
Unrealized gains (losses) on available-for-sale securities	22	(14)
Total other comprehensive income (loss)	22	(14)
Comprehensive loss	$ (33,200)	$ (49,640)

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, 2015	Three Months Ended March 31, 2014
Cash flows from operating activities:		
Net loss	$ (33,222)	$ (49,626)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,891	3,179
Share-based compensation expense	5,426	6,074
Accretion of discount/premium on investment securities	161	136
Non-cash interest expense	370	386
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	(8,010)	(7,124)
Prepaid expenses and other current assets	483	938
Inventory	4	(1,264)
Other assets	(222)	(5)
Accounts payable, related party accounts payable and accrued expenses	(6,990)	(8,042)
Accrued research and development costs	5,696	(1,649)
Deferred revenue	(1,798)	(215)
Deferred rent	(573)	(682)
Net cash used in operating activities	(35,784)	(57,894)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(72,281)	(79,696)
Sales and maturities of available-for-sale securities	94,006	74,518
Purchases of property and equipment	(1,987)	(1,294)
Proceeds from sale of property and equipment	23	
Net cash provided by (used in) investing activities	19,761	(6,472)
Cash flows from financing activities:		
Proceeds from issuance of common stock		190,428
Proceeds from exercise of stock options and employee stock purchase plan	7,946	3,852
Payments on capital leases	(278)	(275)
Principal payments on debt	(2,250)	
Net cash provided by financing activities	5,418	194,005
Net (decrease) increase in cash and cash equivalents	(10,605)	129,639
Cash and cash equivalents, beginning of period	74,297	75,490
Cash and cash equivalents, end of period	$ 63,692	$ 205,129

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

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 creating medicines that make a difference for patients, building value to earn the continued support of its fellow shareholders, and empowering its team to passionately pursue excellence. The Company s core strategy is to establish a leading gastrointestinal (GI) therapeutics company, leveraging its development and commercial capabilities in addressing GI disorders as well as its pharmacologic expertise in guanylate cyclase (GC) pathways.

The Company has one marketed product, linaclotide, which is available in the United States (U.S.) and Mexico under the trademarked name LINZESS® and is available in certain European countries and Canada under the trademarked name CONSTELLA®. Linaclotide is also being developed and commercialized in other parts of the world by certain of the Company s partners.

In August 2012, the U.S. 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). The Company and Actavis plc (Actavis) began commercializing LINZESS in the U.S. in 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 to date, only drug approved in the European Union (E.U.) for IBS-C. The Company s European partner, Almirall, S.A. (Almirall), began commercializing CONSTELLA in Europe in the second quarter of 2013. Currently, CONSTELLA is commercially available in certain European countries, including the United Kingdom, Italy and Spain. In May 2014, Almirall suspended commercialization of CONSTELLA in Germany following an inability to reach agreement with the German National Association of Statutory Health Insurance Funds on a reimbursement price that reflects the innovation and value of CONSTELLA. Almirall is assessing all possibilities to facilitate continued access to CONSTELLA for appropriate patients in Germany.

In December 2013 and February 2014, linaclotide was approved in Canada and Mexico, respectively, as a treatment for adult women and men suffering from IBS-C or CIC. Actavis has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and, through a sublicense from Actavis, Almirall has exclusive rights to commercialize linaclotide in Mexico as LINZESS. In May 2014, Actavis began commercializing CONSTELLA in Canada and in June 2014, Almirall began commercializing LINZESS in Mexico.

Astellas Pharma Inc. (Astellas), the Company s partner in Japan, is developing linaclotide for the treatment of patients with IBS-C and chronic constipation in its territory. In October 2014, Astellas initiated a double-blind, placebo-controlled Phase III 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 in China, Hong Kong and Macau, with AstraZeneca having primary responsibility for the local operational execution. In the third quarter of 2013, the Company and AstraZeneca initiated a double-blind, placebo-controlled Phase III clinical trial of linaclotide in adult 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.

The Company and Actavis are also exploring development opportunities to enhance the clinical profile of LINZESS by seeking to expand its utility in its indicated populations, as well as studying linaclotide in additional indications and populations and in new formulations to assess its potential to treat various GI conditions. In November 2014, as part of this strategy, the Company and Actavis initiated a Phase III clinical trial in the U.S. evaluating a 72 mcg dose of linaclotide in adult patients with CIC to provide a broader range of treatment options to physicians and adult CIC patients. In addition to linaclotide-based opportunities, the Company is advancing multiple GI development programs as well as further leveraging the pharmacological expertise in GC pathways that it established through the development of linaclotide, a guanylate cyclase type-C agonist, to advance a second GC program targeting soluble guanylate cyclase (sGC). sGC is a validated mechanism with the potential for broad therapeutic utility and multiple opportunities for product development in cardiovascular disease and other indications.

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. (U.S. GAAP). Certain information and footnote

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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 for the year ended December 31, 2014, which was filed with the Securities and Exchange Commission on February 18, 2015 (the 2014 Annual Report on Form 10-K).

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, 2015, and the results of its operations and its cash flows for the three months ended March 31, 2015 and 2014. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

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 in accordance with U.S. 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, balance sheet classification of notes payable, 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 Company s 2014 Annual Report on Form 10-K.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application. In April 2015, the FASB proposed a one year deferral of the effective date of this standard to annual periods beginning after December 15, 2017, along with an option to permit companies to early adopt the standard for annual periods beginning after December 15, 2016. The Company is currently evaluating the potential impact that ASU 2014-09 may have on its financial position and results of operations.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability rather than as a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015, but early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

For a discussion of additional recent accounting pronouncements please refer to Note 2, Summary of Significant Accounting Policies, in the Company s 2014 Annual Report on Form 10-K.

The Company did not adopt any new accounting pronouncements during the three months ended March 31, 2015 that had a material effect on the Company s condensed consolidated financial statements.

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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 (in thousands):

	Three Months Ended March 31,	
	2015	2014
Options to purchase common stock	21,090	21,876
Shares subject to repurchase	49	45
Restricted stock units	491	
	21,630	21,921

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

At March 31, 2015, the Company had collaboration agreements with Actavis and AstraZeneca, and license agreements with Almirall and Astellas. The following table provides amounts included in our consolidated statements of operations as collaborative arrangements revenue attributable to transactions from these collaborative and license arrangements (in thousands):

	Three Months Ended March 31,			
		2015		2014
Actavis plc	$	25,325	$	8,447
AstraZeneca AB		1,230		408
Almirall, S.A.		101		4,481
Astellas Pharma Inc.		2,276		1,269
Total collaborative arrangements revenue	$	28,932	$	14,605

Actavis plc

In September 2007, the Company entered into a collaboration agreement with Actavis to develop and commercialize linaclotide for the treatment of IBS-C, CIC and other GI conditions in North America. Under the terms of this collaboration agreement, the Company shares equally with Actavis all development costs as well as net profits or losses from the development and sale of linaclotide in the U.S. The Company receives royalties in the mid-teens percent based on net sales in Canada and Mexico. Actavis is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs. In September 2012, Actavis sublicensed its commercialization rights in Mexico to Almirall. Actavis 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 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, 2015, $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 $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 Actavis 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 an approximately $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 Actavis (Note 11).

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The Company achieved all six development milestones under this agreement totaling $135.0 million, which were recognized through September 2012. The remaining milestone payment that could be received from Actavis upon the achievement of sales targets will be recognized as collaborative arrangements revenue as earned.

As a result of the research and development cost-sharing provisions of the collaboration, the Company offset approximately $3.2 million and approximately $0.6 million against research and development costs during the three months ended March 31, 2015 and 2014, respectively, to reflect each Company s obligation under the collaboration to bear half of the development costs incurred. In addition, in March 2015, the Company and Actavis agreed to share certain costs relating to the manufacturing of linaclotide active pharmaceutical ingredient (API) and certain other manufacturing activities. This arrangement resulted in net amounts receivable from Actavis of approximately $4.3 million for costs incurred in prior periods, which were recorded by the Company as a reduction in research and development expenses during the three months ended March 31, 2015.

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 adjusted 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 cost of goods sold as well as selling, general and administrative expenses. Net sales are calculated and recorded by Actavis and may include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions. The Company records its share of the net profits or net losses from the sale of LINZESS on a net basis and presents the settlement payments to and from Actavis as collaboration expense or collaborative arrangements revenue, as applicable. The Company and Actavis began commercializing LINZESS in the U.S. 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, 2015 and 2014 (in thousands):

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Collaborative arrangements revenue (1) (2)	$ 25,137	$ 8,447
Selling, general and administrative costs incurred by the Company (1)	(7,688)	(7,999)
The Company s share of net profit	$ 17,449	$ 448

(1) Includes only collaborative arrangement revenue or selling, general and administrative costs attributable to the cost-sharing arrangement with Actavis.

(2) Includes a net profit share adjustment of approximately $1.2 million recorded during the quarter ended March 31, 2015, as described above.

The collaborative arrangements revenue recognized in the three months ended March 31, 2015 and 2014 primarily represents the Company s share of the net profits and net losses on the sale of LINZESS in the U.S.

In May 2014, Actavis began commercializing CONSTELLA in Canada and in June 2014, Almirall began commercializing LINZESS in Mexico. The Company records royalties on sales of CONSTELLA in Canada and LINZESS in Mexico one quarter in arrears as it does not have access to the royalty reports from its partners or the ability to estimate the royalty revenue in the period earned. The Company recognized approximately $0.2 million of royalty revenues in Canada and Mexico during the three months ended March 31, 2015.

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 GI 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 and a joint commercialization committee while the product is being commercialized.

In May 2009, the Company received an approximately $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 license agreement also included a $15.0 million 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 at approximately $6.0 million. The Company recognized the up-front license fee and the value of the contingent equity investment totaling approximately $6.0 million as collaborative arrangements revenue on a straight-line basis through September 30, 2012, the period over which linaclotide was developed under the license agreement. In November 2009, the Company achieved the development milestone triggering the equity investment and on November 13, 2009, the Company received $15.0 million from Almirall for the purchase of 681,819 shares of convertible preferred stock (Note 11).

The original license agreement also included contingent milestone payments that could total up to $40.0 million upon achievement of specific development and commercial launch milestones. In November 2010, the Company achieved a development milestone, which resulted in an approximately $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. Commercial milestone payments under the original license agreement consisted of $4.0 million due upon the first commercial launch in each of the five major E.U. countries set forth in the agreement.

In June 2013 and February 2014, the Company and Almirall amended the original license agreement. Pursuant to the terms of the amendments, (i) the commercial launch milestones were reduced to $17.0 million; (ii) new sales-based milestone payments were added to the agreement; and (iii) the escalating royalties based on sales of linaclotide were modified such that they begin in the low-twenties percent and escalate to the mid-forties percent through April 2017, and thereafter begin in the mid-twenties percent and escalate to the mid-forties percent at lower sales thresholds. In each case, these royalty payments are reduced by the transfer price paid for the API included in the product actually sold in the Almirall territory and other contractual deductions. The Company concluded that the amendments were a material modification under Accounting Standard Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13), but the modification did not have a material impact on the Company s consolidated financial statements. The commercial launch and sales-based milestones are recognized as revenue as earned. The Company records royalties on sales of CONSTELLA one quarter in arrears as it does not have access to the royalty reports from Almirall or the ability to estimate the royalty revenue in the period earned.

During the second quarter of 2013, the Company achieved two milestones under the amended Almirall license agreement, which resulted in payments of approximately $1.9 million from Almirall to the Company related to the commercial launches in two of the five major E.U. countries, the United Kingdom and Germany. The approximately $1.9 million payment represented the two $1.0 million milestones, net of foreign tax withholdings. During the first and second quarters of 2014, the Company achieved two milestones under the amended Almirall license agreement triggering payments of approximately $1.0 million each related to the commercial launches in two additional major E.U. countries, Italy and Spain. Each approximately $1.0 million payment represents the $1.0 million milestone, net of foreign tax withholdings.

The Company recognized an insignificant amount of collaborative arrangements revenue, comprised of royalty revenue, from the Almirall license agreement during the three months ended March 31, 2015. The Company recognized approximately $4.5 million in total collaborative arrangements revenue from the Almirall license agreement during the three months ended March 31, 2014, including approximately $3.4 million from the sale of API to Almirall, approximately $1.0 million in commercial launch milestones, and an insignificant amount of royalty revenue.

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 GI 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 concluded that the amendment was not 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 regulatory approval timelines for Japan. During the three months ended March 31, 2015 and 2014, the Company recognized approximately $1.3 million of revenue related to the up-front licensing fee, including approximately $0.5 million of revenue in each period attributable to the March 2013 revision to the estimated development period. At March 31, 2015, approximately $10.1 million of the up-front license fee remained deferred.

The agreement also includes three additional development milestone payments that could total up to $45.0 million, none of which the Company considers substantive. The first milestone payment consists of $15.0 million upon enrollment of the first study subject in a Phase III study for linaclotide in Japan, which was achieved in November 2014 and for which approximately $10.7 million was recognized as revenue through March 31, 2015, including approximately $0.5 million recognized during the three months ended March 31, 2015. The remaining approximately $4.3 million of this milestone payment will be recognized over the

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remaining development period. The two additional milestone payments consist of $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 percent, less the transfer price paid for the API included in the product actually sold and other contractual deductions.

During the three months ended March 31, 2015, the Company recognized approximately $2.3 million in collaborative arrangements revenue from the Astellas license agreement, including approximately $0.5 million from the sale of API to Astellas. During the three months ended March 31, 2014, the Company recognized approximately $1.3 million in collaborative arrangements revenue from the Astellas license agreement, including an insignificant amount 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, 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 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 internal and external costs. The IDP indicates that AstraZeneca is responsible for a multinational Phase III clinical trial (the Phase III Trial), the Company 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 and 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, the Company 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 the Company utilized its existing sales force to co-promote NEXIUM® (esomeprazole magnesium), one of AstraZeneca s products, in the U.S. The Co-Promotion Agreement expired in May 2014.

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 the Accounting Standards Codification (ASC) Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (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, as modified from time to time (the R&D Services),
- JDC services,
- obligation to supply clinical trial material, and
- co-promotion services for AstraZeneca s product (the Co-Promotion Deliverable).

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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 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, 2015, no contingent deliverables were provided by the Company under the AstraZeneca Agreements.

In August 2014, the Company and AstraZeneca, through the JDC, modified the IDP and development budget to include approximately $14.0 million in additional activities over the remaining development period, to be shared by the Company and AstraZeneca under the terms of the AstraZeneca Collaboration Agreement. These additional activities serve to support the continued development of linaclotide in the Licensed Territory, including the Phase III Trial. Pursuant to the terms of the modified IDP and development budget, certain of the Company s deliverables were modified, specifically the R&D Services and the obligation to supply clinical trial material. The Company determined that the 2014 modification to the IDP and development budget was a material modification under ASU No. 2009-13 to the AstraZeneca Collaboration Agreement. However, this modification did not have a material impact on the Company s consolidated financial statements as there was an insignificant amount of deferred revenue associated with the AstraZeneca Collaboration Agreement as of the date of the modification. In accordance with ASU No. 2009-13, the Company reallocated the arrangement consideration to all of the identified deliverables in the arrangement (both delivered and undelivered) based on the information available as of the date of the modification.

The total amount of the non-contingent consideration allocable to the AstraZeneca Agreements of approximately $34.0 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 the Company in the IDP or as approved by the JDC in subsequent periods, or approximately $9.0 million.

The Company allocated the Arrangement Consideration of approximately $34.0 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; (d) the stage of development of linaclotide for IBS-C and CIC and the projected timeline for regulatory approval; (e) 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 approximately $34.0 million of Arrangement Consideration, approximately $29.7 million was allocated to the License Deliverable, approximately $1.8 million to the R&D Services, approximately $0.1 million to the JDC services, approximately $0.3 million to the clinical trial material supply services, and approximately $2.1 million to the Co-Promotion Deliverable in the relative selling price model, at the time of the material modification.

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 the Company prior to the commercialization of linaclotide in the License Territory are recorded as a reduction in expense, in accordance with the Company s policy, which is consistent with the nature of the cost reimbursement. Development costs incurred by the Company that pertain to the joint development plan and subsequent amendments to the joint development plan, as approved by the JDC, are recorded as research and development expense as incurred. Payments to AstraZeneca are recorded as incremental research and development expense.

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The Company completed its obligations related to the License Deliverable upon execution of the AstraZeneca Agreements; however, the revenue recognized in the statement of operations was limited to the non-contingent portion of the License Deliverable consideration in accordance with ASC 605-25. During the three months ended March 31, 2015, and as a result of the modification to the IDP and development budget in August 2014, the Company recognized approximately $1.1 million as collaborative arrangements revenue related to this deliverable as this portion of the Arrangement Consideration was no longer contingent. During the three months ended March 31, 2014, the Company did not recognize any amounts in collaborative arrangements revenue related to the License Deliverable.

The Company also performs R&D Services and JDC services, and supplies clinical trial materials during the estimated development period. 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 $0.3 million in incremental research and development costs during the three months ended March 31, 2015, and approximately $0.4 million in incremental research and development costs during the three months ended March 31, 2014.

The amount allocated to the Co-Promotion Deliverable was recognized as collaborative arrangements revenue using the proportional performance method, which approximates recognition on a straight-line basis beginning on the date that the Company began to co-promote AstraZeneca s product, through December 31, 2013 (the earliest cancellation date). As of December 31, 2013, the Company completed its obligation related to the Co-Promotion Deliverable; however, the revenue recognized in the statement of operations was limited to the non-contingent consideration in accordance with ASC 605-25. During the three months ended March 31, 2015, the Company recognized approximately $0.1 million as collaborative arrangements revenue related to this deliverable as this portion of the Arrangement Consideration was no longer contingent. During the three months ended March 31, 2014, the Company recognized approximately $0.4 million in collaborative arrangements revenue related to this deliverable.

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.

Other Collaboration and License Agreements

The Company has other collaboration and license agreements that are not individually significant to its business. In connection with entering into these agreements, the Company made aggregate up-front payments of approximately $5.8 million, which were expensed as research and development expense. Pursuant to the terms of one agreement, the Company may be required to pay $7.5 million for development milestones, of which approximately $2.5 million had been paid as of March 31, 2015, and $18.0 million for regulatory milestones, none of which had been paid as of March 31, 2015. In addition, pursuant to the terms of another agreement, the contingent milestones could total up to $114.5 million per product to one of the Company s collaboration partners, including $21.5 million for development milestones, $58.0 million for regulatory milestones and $35.0 million for sales-based milestones. Further, under such agreements, the Company is also required to fund certain research activities and, if any product related to these collaborations is approved for marketing, to pay significant royalties on future sales. During the three months ended March 31, 2015, the Company did not incur any research and development expense associated with the Company s other collaboration and license agreements. During the three months ended March 31, 2014, the Company incurred approximately $1.0 million in research and development expense associated with the Company s other collaboration and license agreements.

In March 2015, the Company entered into an agreement to co-promote Exact Sciences Corp. s (Exact Sciences) Cologuard®, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer. Under the terms of the transaction, the Company s sales team will promote, and educate health care practitioners regarding, Cologuard, with LINZESS remaining the Company s first-position product. The Company will be compensated from the net sales of Cologuard generated from the physicians on whom it calls. Exact Sciences maintains responsibility for all other aspects of the commercialization of Cologuard outside of the co-promotion. The non-exclusive co-promotion agreement covers an initial one-year term with the opportunity for extension. This transaction did not have a significant impact on the Company s results of operations for the three months ended March 31, 2015.

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, 2015 and December 31, 2014 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

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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.

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, 2015**		**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	$	58,120	$	58,120	$		$	
Available-for-sale securities:								
U.S. Treasury securities		6,503		6,503				
U.S. government-sponsored securities		145,670				145,670		
Total	$	210,293	$	64,623	$	145,670	$	

			Fair Value Measurements at Reporting Date Using					
Description		**December 31, 2014**		**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	$	60,966	$	60,966	$		$	
Available-for-sale securities:								
U.S. Treasury securities		24,005		24,005				
U.S. government-sponsored securities		150,032				150,032		
Total	$	235,003	$	84,971	$	150,032	$	

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three months ended March 31, 2015 or 2014.

Cash equivalents, accounts receivable, related party accounts receivable, prepaid expenses and other current assets, accounts payable, related party accounts payable, accrued expenses and the current portion of capital lease obligations at March 31, 2015 and December 31, 2014 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, 2015 and December 31, 2014 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, 2015 and December 31, 2014 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2015				
U.S. Treasury securities	$ 145,668	$ 8	$ (6)	$ 145,670
U.S. government-sponsored securities	6,502	1		6,503
Total	$ 152,170	$ 9	$ (6)	$ 152,173

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	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2014				
U.S. Treasury securities	$ 150,055	$ 2	$ (25)	$ 150,032
U.S. government-sponsored securities	24,001	4		24,005
Total	$ 174,056	$ 6	$ (25)	$ 174,037

The contractual maturities of all securities held at March 31, 2015 are one year or less. There were 15 and 27 available-for-sale securities in an unrealized loss position at March 31, 2015 and December 31, 2014, 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, 2015 and December 31, 2014 was approximately $56.8 million and approximately $101.9 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, 2015.

There were no sales of available-for-sale securities during the three months ended March 31, 2015 or 2014. Gross realized gains and losses on the sales of available-for-sale securities that have been included in other (expense) income, 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 (expense) income were not 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 (expense) income is based on the specific identification method for purposes of recording realized gains and losses.

6. Inventory

Inventory consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Raw materials	$ 4,950	$ 4,954

Inventory at March 31, 2015 and December 31, 2014 represents API that is available for commercial sale.

7. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Manufacturing equipment	$ 3,623	$ 3,623
Laboratory equipment	14,819	15,126
Computer and office equipment	5,208	5,185
Furniture and fixtures	2,093	2,093
Software	13,980	13,921
Construction in process	193	1,457
Leased vehicles	4,472	4,472
Leasehold improvements	38,563	36,928
	82,951	82,805
Less accumulated depreciation and amortization	(55,474)	(52,979)
	$ 27,477	$ 29,826

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8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Salaries and benefits	$ 12,939	$ 16,582
Professional fees	858	574
Accrued interest	839	850
Other	4,099	4,606
	$ 18,735	$ 22,612

9. 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 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. On March 15, 2014, the Company began making 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 June 15, 2024, the final legal maturity date. The Company made principal payments of approximately $3.4 million through March 31, 2015, and expects to pay approximately $13.2 million of the principal within twelve months following March 31, 2015.

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, Actavis will deposit its quarterly profit (loss) sharing payments due to the Company under the collaboration agreement, if any, into the segregated bank account. If the funds deposited by Actavis 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. 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, 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 Actavis, 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, and 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 approximately $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 approximately $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 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 additional 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 discounts as well as the accretion of the interest expense. Any such adjustments could be material to the Company s condensed consolidated financial statements.

The fair value of the notes was estimated to be approximately $180.2 million and $182.5 million as of March 31, 2015 and December 31, 2014, respectively, and was determined using Level 3 inputs, including a quoted rate.

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10. Employee Stock Benefit Plans

The Company has several share-based compensation plans under which stock options, restricted stock awards, restricted stock units (RSUs), 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, 2015 and 2014 (in thousands):

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Research and development	$ 2,054	$ 2,690
Selling, general and administrative	3,372	3,384
	$ 5,426	$ 6,074

A summary of stock option activity for the three months ended March 31, 2015 is as follows:

	Number of Shares (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2014	19,957	$ 10.07
Granted	2,542	15.61
Exercised	(1,240)	5.95
Cancelled	(169)	13.01
Outstanding at March 31, 2015	21,090	$ 10.96

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, 2015 and 2014:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Expected volatility	46.0%	46.6%
Expected term (in years)	6.0	6.1
Risk-free interest rate	1.7%	1.8%
Expected dividend yield	%	%

Beginning in the first quarter of 2015, the Company revised certain of its equity incentive programs to include RSUs, in addition to stock options, each representing the right to receive one share of the Company s Class A common stock and granted pursuant to the terms of the Company s Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan. The RSUs generally vest 25% per year on the approximate anniversary of the date of grant until fully vested, provided the employee remains continuously employed with the Company through each vesting date. Shares of the Company s Class A common stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of all RSUs is based on the market value of the Company s Class A common stock on the date of grant. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

A summary of RSU activity for the three months ended March 31, 2015 is as follows:

	Number of Shares (in thousands)		Weighted-Average Fair Value
Unvested as of December 31, 2014			
Granted (1)	493	$	15.62
Vested			
Forfeited	(2)		15.62
Unvested as of March 31, 2015	491	$	15.62

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(1) RSUs granted in the three months ended March 31, 2015 primarily represent awards made in connection with the Company s annual equity grants in March 2015.

11. Related Party Transactions

The Company has and currently obtains legal services from a law firm that is an investor in the Company. The Company paid less than $0.1 million in legal fees to this investor during the three months ended March 31, 2015 and 2014. At March 31, 2015 and December 31, 2014, the Company had less than $0.1 million of accounts payable due to this related party.

In September 2009, Actavis became a related party when the Company sold to Actavis 2,083,333 shares of the Company s convertible preferred stock. 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 Actavis 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, 2015, the Company had less than $0.1 million in related party accounts receivable associated with Almirall and approximately $33.0 million in related party accounts receivable, net of related party accounts payable, associated with Actavis. At December 31, 2014, the Company did not have any related party accounts receivable associated with Almirall and approximately $25.8 million in related party accounts receivable, net of related party accounts payable, associated with Actavis.

12. Public Offerings

In February 2014, the Company sold 15,784,325 shares of its Class A common stock through a firm commitment, underwritten public offering at a price to the public of $12.75 per share. As a result of this offering, the Company received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately $190.4 million.

13. Workforce Reduction

On January 8, 2014, the Company announced a headcount reduction of approximately 10% to align its workforce with its strategy to grow a leading GI therapeutics company. The field-based sales force and medical science liaison team were excluded from the workforce reduction.

During the three months ended March 31, 2014, the Company substantially completed the implementation of this reduction in workforce and, in accordance with ASC 420, *Exit or Disposal Cost Obligations,* recorded approximately $4.3 million of costs in research and development and selling, general and administrative expenses, including employee severance, benefits and related costs. The Company did not record any additional charges associated with this workforce reduction during the year ended December 31, 2014. All payments related to this reduction in workforce were made by the end of 2014.

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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 creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. Our core strategy is to establish a leading gastrointestinal, or GI, therapeutics company, leveraging our development and commercial capabilities in addressing GI disorders as well as our pharmacologic expertise in guanylate cyclase, or GC, pathways.

We have one marketed product, linaclotide, which is available in the United States, or U.S., and Mexico under the trademarked name LINZESS® and is available in certain European countries and Canada under the trademarked name CONSTELLA®. Linaclotide is also being developed and commercialized in other parts of the world by certain of our partners.

In August 2012, the U.S. 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. We and Actavis plc, or Actavis, began commercializing LINZESS in the U.S. in 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 to date, only drug approved in the European Union, or E.U., for IBS-C. Our European partner, Almirall, S.A., or Almirall, began commercializing CONSTELLA in Europe in the second quarter of 2013. Currently, CONSTELLA is commercially available in certain European countries, including the United Kingdom, Italy and Spain. In May 2014, Almirall suspended commercialization of CONSTELLA in Germany following an inability to reach agreement with the German National Association of Statutory Health Insurance Funds on a reimbursement price that reflects the innovation and value of CONSTELLA. Almirall is assessing all possibilities to facilitate continued access to CONSTELLA for appropriate patients in Germany.

In December 2013 and February 2014, linaclotide was approved in Canada and Mexico, respectively, as a treatment for adult women and men suffering from IBS-C or CIC. Actavis has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and, through a sublicense from Actavis, Almirall has exclusive rights to commercialize linaclotide in Mexico as LINZESS. In May 2014, Actavis began commercializing CONSTELLA in Canada and in June 2014, Almirall began commercializing LINZESS in Mexico.

Astellas Pharma Inc., or Astellas, our partner in Japan, is developing linaclotide for the treatment of patients with IBS-C and chronic constipation in its territory. In October 2014, Astellas initiated a double-blind, placebo-controlled Phase III 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 in China, Hong Kong and Macau, with AstraZeneca having primary responsibility for the local operational execution. In the third quarter of 2013, we and AstraZeneca initiated a double-blind, placebo-controlled Phase III clinical trial of linaclotide in adult 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.

We and Actavis are also exploring development opportunities to enhance the clinical profile of LINZESS by seeking to expand its utility in its indicated populations, as well as studying linaclotide in additional indications and populations and in new formulations to assess its potential to treat various GI conditions. In November 2014, as part of this strategy we and Actavis initiated a Phase III clinical trial in the U.S. evaluating a 72 mcg dose of linaclotide in adult patients with CIC to provide a broader range of treatment options to physicians and adult CIC patients. In addition to linaclotide-based opportunities, we are advancing multiple GI development programs as well as further leveraging our pharmacological expertise in GC pathways that we established through the development of linaclotide, a guanylate cyclase type-C, or GC-C, agonist, to advance a second GC program targeting soluble guanylate cyclase, or sGC. sGC is a validated mechanism with the potential for broad therapeutic utility and multiple opportunities for product development in cardiovascular disease and other indications.

To date, we have dedicated substantially all of our activities to the research, development and commercialization of linaclotide, as well as to the research and development of our other product candidates. We have incurred significant operating losses

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since our inception in 1998. As of March 31, 2015, we had an accumulated deficit of approximately $1.0 billion and we expect to continue to incur net losses for the foreseeable future.

In February 2014, we sold 15,784,325 shares of our Class A common stock through a firm commitment, underwritten public offering at a price to the public of $12.75 per share. As a result of this offering, we received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately $190.4 million. The net proceeds from this offering are being used to support the commercialization of LINZESS in the U.S. and to fund linaclotide and other development opportunities to advance our strategy to grow a leading GI company, in addition to general corporate purposes.

On January 8, 2014, we announced a headcount reduction of approximately 10% to align our workforce with our strategy to grow a leading GI therapeutics company. As maximizing LINZESS is core to our strategy, our field-based sales force and medical science liaison teams were excluded from this reduction in workforce. During the three months ended March 31, 2014, we substantially completed the implementation of this reduction in workforce and recorded approximately $4.3 million of costs in research and development and selling, general and administrative expenses, including employee severance, benefits and related costs. We did not record any additional charges associated with this workforce reduction during the year ended December 31, 2014. All payments related to this reduction in workforce were made by the end of 2014.

In March 2015, we entered into an agreement to co-promote Exact Sciences Corp.   s, or Exact Sciences, Cologuard®, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer. Under the terms of the transaction, our sales team will promote, and educate health care practitioners regarding, Cologuard, with LINZESS remaining our first-position product. We will be compensated from the net sales of Cologuard generated from the physicians on whom we call. Exact Sciences maintains responsibility for all other aspects of the commercialization of Cologuard outside of the co-promotion. The non-exclusive co-promotion agreement covers an initial one-year term with the opportunity for extension. This transaction did not have a significant impact on our results of operations for the three months ended March 31, 2015.

Financial Overview

Revenue. Revenue to date has been generated primarily through our collaboration agreements with Actavis 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 finished drug product, active pharmaceutical ingredient, or API, or 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 finished drug product, API or development materials, payments based upon the achievement of certain milestones and royalties on product sales. Additionally, we 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 December 2012 and CONSTELLA became commercially available in certain European countries beginning in the second quarter of 2013. Linaclotide is also approved in a number of other countries.

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 of goods sold as well as selling, general and administrative expenses. Although we expect net sales to increase over time, the settlement payments between Actavis and us, resulting in collaborative arrangements revenue or collaboration expense, are subject to fluctuation based on the ratio of selling, general and administrative 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 linaclotide in the European, Canadian or Mexican markets. 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 in recent periods, it became clear to us and our partner, Almirall, that revising certain aspects of our current partnership would benefit the potential for linaclotide. Accordingly, in June 2013 and February 2014, we amended the Almirall license agreement to make the amount and timing of certain of the commercial launch milestones contingent on the reimbursement amount in such countries 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 outside of the U.S. Our cost of revenue consists of the internal and external costs of producing such API.

Research and Development Expense. Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of compensation, benefits and other employee-related expenses, research and development related facility costs, third-party contract costs relating to nonclinical study and clinical trial activities, development of manufacturing processes, regulatory registration of third-party manufacturing facilities and costs associated with linaclotide API prior to meeting our inventory capitalization policy, as well as licensing fees for our product candidates. We charge all research and development expenses to operations as incurred. Under our Actavis and AstraZeneca

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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 Actavis or AstraZeneca are recorded as incremental research and development expense.

The core of our research and development strategy is to leverage our development capabilities in addressing GI disorders as well as our pharmacologic expertise in GC pathways to develop new and innovative products.

Linaclotide. 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 and, to date, only FDA-approved GC-C agonist. Linaclotide is approved in the U.S. and in a number of E.U. and other countries. In addition, Astellas initiated a Phase III clinical trial of linaclotide in adult patients with IBS-C for Japan and we and AstraZeneca initiated a Phase III clinical trial of linaclotide in adult patients with IBS-C for China.

We and Actavis are exploring development opportunities in the U.S. to enhance the clinical profile of LINZESS by seeking to expand its utility in its indicated populations, as well as studying linaclotide in additional indications and populations and in new formulations to assess its potential to treat various GI conditions. In November 2014, as part of this strategy we and Actavis initiated a Phase III clinical trial in the U.S. evaluating a 72 mcg dose of linaclotide in adult patients with CIC, which, if approved, would provide a broader range of treatment options to physicians and adult CIC patients. These development opportunities include linaclotide colonic release, a targeted oral delivery formulation of linaclotide designed to potentially enhance lower abdominal pain relief in adult IBS-C patients, as well as providing the opportunity to investigate linaclotide as a potential treatment for multiple GI disorders with lower abdominal pain as a predominant symptom. Additionally, we and Actavis are studying linaclotide as a potential treatment of the GI dysfunction associated with opioid-induced constipation in adult patients and are working with the FDA on a plan for clinical pediatric studies with linaclotide.

Development Candidates. In addition to linaclotide-based opportunities, we are advancing multiple GI development programs. This includes IW-9179, a GC-C agonist designed to target upper GI conditions, which is being explored for the treatment of diabetic gastroparesis and functional dyspepsia. Additionally, IW-3718 is a gastric retentive formulation of a bile acid sequestrant that is being evaluated for the potential treatment of GERD symptoms in patients who have not responded adequately to treatment with a proton pump inhibitor**.** We are also leveraging our pharmacological expertise in GC pathways that we established through the development of linaclotide, a GC-C agonist, to advance a second GC program targeting sGC, which we are exploring for utility in cardiovascular disease. We have additional non-core assets in early development that we continued to advance through the first quarter of 2015, and we are currently exploring strategic options for further development of these assets.

Discovery Research. Our discovery efforts are primarily focused on identifying novel clinical candidates that draw on our proprietary and expanding expertise in GI disorders and GC.

The following table sets forth our research and development expenses related to our product pipeline for the three months ended March 31, 2015 and 2014. These expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, costs incurred to develop manufacturing processes and register manufacturing facilities with the FDA and licensing fees for our product candidates. We allocate costs related to facilities, depreciation, share-based compensation, research and development support services, laboratory supplies and certain other costs directly to programs.

	Three Months Ended March 31, 2015	2014
	(in thousands)	
Linaclotide	$ 13,464	$ 13,516
Development candidates:		
GI disorders (two compounds)(1)	3,241	3,979
sGC development candidates (two compounds)(1)	5,008	1,523
Central nervous system disorders (one compound)(1)	188	1,090
Total development candidates	8,437	6,592
Discovery research	4,740	7,036
	$ 26,641	$ 27,144

(1) Number of compounds is for the three months ended March 31, 2015 and is zero unless otherwise indicated.

Since 2004, the date we began tracking costs by program, we have incurred approximately 320.2 million of research and development expenses related to linaclotide. The expenses for linaclotide include both our portion of the research and development costs incurred by Actavis and AstraZeneca for linaclotide and invoiced to us under the cost-sharing provisions of our collaboration agreements, as well as the unreimbursed portion of research and development costs incurred by us under such cost-sharing provisions.

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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 New Drug Applications for LINZESS as a once-daily treatment for adult men and women suffering from IBS-C or CIC. In connection with the FDA approval, we are required to conduct certain nonclinical and clinical studies, including those 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 Actavis established a nonclinical and clinical post-marketing plan with the FDA to understand the efficacy and safety of LINZESS in pediatric patients. The first step in this plan was to undertake certain additional nonclinical studies, which we have completed. The FDA has concluded that the nonclinical data from these additional studies do not present a reason not to proceed with clinical studies in older pediatric patients (age 12 and above). We and Actavis are working with the FDA on a plan for clinical pediatric studies. 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, with AstraZeneca having primary responsibility for the local operational execution. We and Actavis are also exploring development opportunities to enhance the clinical profile of LINZESS by seeking to expand its utility in its indicated populations, as well as studying linaclotide in additional indications and populations and in new formulations to assess its potential to treat various GI conditions. 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, within its indicated population, in additional indications and populations or in new formulations. In addition to linaclotide-based opportunities, we are advancing multiple GI development programs as well as further leveraging our pharmacological expertise in GC pathways that we established through the development of linaclotide, a GC-C agonist, to advance a second GC program targeting sGC. sGC is a validated mechanism with the potential for broad therapeutic utility and multiple opportunities for product development in cardiovascular disease and other indications. 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 s utility will be expanded in its indicated population; if or when linaclotide will be developed in pediatrics or otherwise outside of its current markets, indications, populations or formulations; 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 that fit within our core strategy. 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.

- 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 beginning in 2012, linaclotide has been generating sales in connection with commercial launches in the U.S. and a number of E.U. and other countries.

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, the investigation of ways to enhance the clinical profile within its indicated population and the exploration of its utility in other indications and populations and in new formulations. 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, communications and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs and professional fees for accounting and legal services. As we continue to invest in the commercialization of LINZESS, we expect our selling, general and administrative expenses will be substantial for the foreseeable future. We charge all selling, general and administrative expenses to operations as incurred.

Under our AstraZeneca collaboration agreement, we are reimbursed for certain selling, general and administrative expenses and we net these reimbursements against our selling, general and administrative expenses as incurred. We include Actavis selling, general and administrative 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 Actavis as collaboration expense or collaborative arrangements revenue, respectively.

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 accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make certain estimates and assumptions that may 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. We base our estimates on our 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, 2015, 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, 2014, which was filed with the Securities and Exchange Commission, or SEC, on February 18, 2015, or the 2014 Annual Report on Form 10-K.

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 March 31,	
	2015	2014
	(in thousands)	
Collaborative arrangements revenue:	$ 28,932	$ 14,605
Cost and expenses:		
Cost of revenue	12	1,924
Research and development	26,641	27,144
Selling, general and administrative	30,346	29,924
Total cost and expenses	56,999	58,992
Other (expense) income:		
Interest expense	(5,220)	(5,283)
Interest and investment income	65	44
Other expense, net	(5,155)	(5,239)
Net loss	$ (33,222)	$ (49,626)

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Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

Revenue

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014	Change $	Change %
	(dollars in thousands)			
Collaborative arrangements revenue	$ 28,932	$ 14,605	$ 14,327	98%

Collaborative Arrangements Revenue. The increase in revenue from collaborative arrangements of approximately $14.3 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily related to an approximately $16.8 million increase in our share of the net profits from the sale of LINZESS in the U.S., and an approximately $0.8 million increase in license revenue related to our collaboration agreement with AstraZeneca recognized as a result of the modification to the initial development plan and development budget in August 2014, which was deemed to be a material modification. This increase was partially offset by an approximately $2.9 million decrease in revenue from the shipments of linaclotide API to our licensing partners outside of the U.S., and an approximately $0.4 million net decrease in revenue recognized from our linaclotide licensing partners for the achievement of milestones.

Cost and Expenses

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014	Change $	Change %
	(dollars in thousands)			
Cost and expenses:				
Cost of revenue	$ 12	$ 1,924	$ (1,912)	(99)%
Research and development	26,641	27,144	(503)	(2)%
Selling, general and administrative	30,346	29,924	422	1%
Total cost and expenses	$ 56,999	$ 58,992	$ (1,993)	(3)%

Cost of Revenue. The decrease in cost of revenue of approximately $1.9 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily related to lower sales of linaclotide API to our licensing partners outside of the U.S.

Research and Development Expense. The decrease in research and development expense of approximately $0.5 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily related to a decrease of approximately $6.8 million in net costs related to the collaboration with Actavis, including approximately $4.3 million of net amounts receivable from Actavis related to the reimbursement of certain linaclotide manufacturing costs incurred in prior periods, a decrease in costs of approximately $3.1 million related to our January 2014 workforce reduction incurred in the three months ended March 31, 2014, a decrease of approximately $0.5 million in operating costs, including information technology infrastructure costs and facility costs such as rent and amortization of leasehold improvements allocated to research and development, and a decrease of approximately $0.3 million related to the development of manufacturing processes and costs associated with linaclotide API prior to meeting our inventory capitalization policy. This decrease was partially offset by an increase of approximately $10.3 million in external costs related to the development of linaclotide, including increased costs associated with clinical trial activity.

Selling, General and Administrative Expense. Selling, general and administrative expenses increased approximately $0.4 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014, primarily as a result of an approximately $0.7 million increase in compensation, benefits and other employee-related expenses, an approximately $0.4 million increase in external consulting and other service costs primarily associated with developing and maintaining the infrastructure to support linaclotide, and an approximately $0.4 million increase in selling, general and administrative expenses related to facilities and information technology infrastructure costs associated with operating our Cambridge, Massachusetts facility, including rent and amortization of leasehold improvements. This increase was partially offset by a decrease in costs of approximately $1.2 million related to our January 2014 workforce reduction incurred in the three months ended March 31, 2014.

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Other (Expense) Income, Net

	Three Months Ended March 31, 2015	2014	Change $	%
	(dollars in thousands)			
Other (expense) income:				
Interest expense	$ (5,220)	$ (5,283)	$ 63	(1)%
Interest and investment income	65	44	21	48%
Total other expense, net	$ (5,155)	$ (5,239)	$ 84	(2)%

Interest Expense. Interest expense decreased by an insignificant amount for the three months ended March 31, 2015 compared to the three months ended March 31, 2014, mainly due to a decreased principal balance on our notes payable as a result of principal payments made thereon.

Liquidity and Capital Resources

At March 31, 2015, we had approximately $215.9 million of unrestricted cash, cash equivalents and available-for-sale securities. Our cash equivalents include amounts held in money market funds. Our available-for-sale securities include amounts held in U.S. Treasury securities and 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, with a remaining maturity when purchased of less than twelve months, so as to primarily achieve liquidity and capital preservation.

During the three months ended March 31, 2015, our balances of cash, cash equivalents and available-for-sale securities decreased approximately 32.4 million. This decrease is primarily due to the cash used to operate our business, as we made payments related to, among other things, research and development and selling, general and administrative expenses as we continued to invest in our research pipeline and support the continued commercialization of LINZESS in the U.S. We also made principal payments of approximately $2.3 million on outstanding debt, invested approximately $2.0 million in capital expenditures, and made payments of approximately $0.3 million on capital lease obligations. These cash outflows were partially offset by approximately $7.9 million in proceeds from the exercise of stock options and the issuance of shares pursuant to our employee stock purchase plan.

Sources of Liquidity

We have incurred losses since our inception in 1998 and, as of March 31, 2015, we had an accumulated deficit of approximately $1.0 billion. 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 initial public offering, or IPO, in February 2010, and approximately $413.4 million of net proceeds from our follow-on public offerings; payments received under our strategic collaborative arrangements, including upfront and milestone payments as well as reimbursement of certain expenses; debt financings, including approximately $167.3 million of net proceeds from the private placement of our notes in January 2013; and the strategic sale of assets or businesses.

Funding Requirements

In August 2012, we received regulatory approval for LINZESS in the U.S. for the treatment of IBS-C or CIC in adults and, in December 2012, commenced our commercial launch with our collaboration partner, Actavis. While we began commercializing LINZESS in the fourth quarter of 2012, our company has not achieved profitability. In November 2012, our European partner, Almirall, received approval for CONSTELLA for the treatment of IBS-C in adults, which is currently being commercialized in certain European countries by Almirall. In December 2013 and February 2014, linaclotide was approved in Canada and Mexico, respectively, as a treatment for adult women and men suffering from IBS-C or CIC. Actavis has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and, through a sublicense from Actavis, Almirall has exclusive rights to commercialize linaclotide in Mexico as LINZESS. In May 2014, Actavis began commercializing CONSTELLA in Canada and in June 2014, Almirall began commercializing LINZESS in Mexico. Our partnership with Actavis requires total net sales of LINZESS in the U.S. to be reduced by commercial costs incurred by each party, and such resulting net profit or net loss attributable to LINZESS is shared equally between us and Actavis. Additionally, we receive royalties based on sales of linaclotide in the European territory, Canada, and Mexico from our partners. We cannot anticipate when, if ever, proceeds generated from sales of LINZESS and CONSTELLA will enable us to become cash flow positive. We anticipate that we will continue to incur substantial expenses for the next several years as we further develop and commercialize linaclotide in the U.S., China and other markets, and continue to invest in our pipeline and potentially other external opportunities. 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 March 31, 2015 will be sufficient to meet our projected operating needs at least through the next twelve months.

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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., China 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 and commercialization 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 (other than in the countries where it is already approved) and our other product candidates, or to commercialize linaclotide and our other product candidates, in each case, for all of the markets, indications, populations and formulations 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 any other products;
- the revenue generated by sales of LINZESS, CONSTELLA and any other products;
- the success of our third-party manufacturing activities;
- the time and costs involved in developing, and obtaining regulatory approvals for, our product candidates;
- the success of our research and development efforts;
- the emergence of competing or complementary 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, consider 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 was reported in our 2014 Annual Report on Form 10-K. There have been no material changes from the contractual commitments and obligations previously disclosed in our 2014 Annual Report on Form 10-K in this Quarterly Report on Form 10-Q.

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

For a discussion of recent accounting pronouncements please refer to Note 2, Summary of Significant Accounting Policies, in our 2014 Annual Report on Form 10-K and Note 1, Nature of Business, in this Quarterly Report on Form 10-Q. We did not adopt

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any new accounting pronouncements during the three months ended March 31, 2015 that had a material effect on our condensed consolidated financial statements included in this report.

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 securities 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 potential instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

Our capital lease and debt obligations bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates; however, because these interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if our credit rating improves or other circumstances change.

Foreign Currency Risk

We have no significant operations outside the U.S. and we do not expect to be impacted significantly by foreign currency fluctuations.

Effects of Inflation

We do not believe that inflation and changing prices over the three months ended March 31, 2015 and 2014 had a significant impact on our results of operations.

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

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial

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officer concluded no such changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

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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 attain profitability and positive cash flow from operations.

In August 2012, the FDA approved LINZESS as a once-daily treatment for adult men and women suffering from IBS-C or CIC. We and our partner, Actavis plc, or Actavis, began selling LINZESS in the U.S. during December 2012. The commercial success of LINZESS depends on a number of factors, including:

- the effectiveness of LINZESS as a treatment for adult patients with IBS-C or CIC;
- the size of the treatable patient population;
- the effectiveness of the sales, managed markets and marketing efforts by us and Actavis;
- 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 adult 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 and maintain adequate reimbursement for, and optimize patient access to, LINZESS by providing third party payers with a strong value proposition based on the existing burden of illness associated with IBS-C and CIC and the benefits of LINZESS;

- the effectiveness of our partners distribution networks;

- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with LINZESS; and

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

Our revenues from the commercialization of LINZESS are subject to these factors, and therefore may be unpredictable from quarter-to-quarter. Ultimately, we may never generate sufficient revenues from LINZESS to reach or maintain profitability for our company or to sustain our anticipated levels of operations.

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

The most commonly reported adverse reactions in the placebo-controlled trials that supported the approval of linaclotide in the U.S. and Europe 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 its incidence 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, if we or others detect unexpected safety signals for linaclotide or any products perceived to be similar to linaclotide, or if any of the foregoing are perceived to have occurred, then in any of these circumstances:

- sales of linaclotide may be impaired;

- 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;

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

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- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of LINZESS within its indicated populations, as well as be precluded from studying linaclotide in additional indications and populations and in new formulations;

- 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 linaclotide, increase our expenses and impair our ability to successfully commercialize linaclotide.

Furthermore, with LINZESS and CONSTELLA commercially available in certain countries and used in wider populations and in less rigorously controlled environments than in clinical studies, and as we and Actavis explore development opportunities to enhance the clinical profile of LINZESS through additional clinical trials, the number of patients treated with linaclotide within and outside of its current indications or patient populations may expand, which could result in the identification of previously unknown side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of linaclotide is associated with serious adverse effects, undermining our commercialization efforts.

In addition, the FDA-approved label for LINZESS contains a boxed warning about its use in pediatric patients. LINZESS is contraindicated in pediatric patients up to 6 years of age based on nonclinical data from studies in neonatal mice approximately equivalent to human pediatric patients less than 2 years of age. There is also a warning advising physicians to avoid the use of LINZESS in pediatric patients 6 through 17 years of age. This warning is based on data in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients of any age group. We and Actavis have established a nonclinical and clinical post-marketing plan with the FDA to understand the safety and efficacy of LINZESS in pediatric patients, which is discussed below.

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

We have no internal manufacturing or distribution capabilities. Instead, we rely on a combination of contract manufacturers and our partners to manufacture linaclotide API and final linaclotide drug product, and to distribute that drug product to third party purchasers. 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 Actavis, Almirall and Astellas is responsible for drug product and finished goods manufacturing (including bottling and packaging) for its respective territory, and distributing the finished goods to wholesalers. Among our drug product manufacturers, only Actavis and Almirall have manufactured linaclotide on a commercial scale. We have an agreement with an independent third party to serve as an additional source of drug product manufacturing of linaclotide for our partnered territories and we have worked with our partners to achieve sufficient redundancy in this component of the linaclotide supply chain. Under our collaboration with AstraZeneca, we are accountable for drug product and finished goods manufacturing for China, Hong Kong and Macau.

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 assurance 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 and distribution operations and processes, including for example, quality issues, including product specification and stability failures, 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, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our manufacturers do not experience

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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, experience delays or disruptions in the availability of raw materials or experience manufacturing or distribution 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.

If any of our partners undergoes a change in control or in management, this may adversely affect our collaborative relationship or the success of the commercialization of LINZESS in the U.S. or the continued launches and commercialization of CONSTELLA in the E.U., or the ability to achieve regulatory approval, launch and commercialize linaclotide in our other partnered territories.

We work jointly and collaboratively with each of our partners on many aspects of the development, manufacturing and commercialization of linaclotide. In doing so, we have established relationships with several key members of the management teams of our linaclotide partners in functional areas such as development, quality, regulatory, drug safety and pharmacovigilance, operations, marketing, sales, field operations and medical science. Further, the success of our collaborations is highly dependent on the resources, efforts and skills of our partners and their key employees. As we and our partners commercialize LINZESS in the U.S., continue to launch and commercialize CONSTELLA in the E.U. and develop, launch and commercialize linaclotide in other parts of the world, the drug s success becomes more dependent on us maintaining highly collaborative and well aligned partnerships. If any of our linaclotide partners undergo a change of control or in management in the future, we would need to reestablish many relationships and confirm continued alignment on our development and commercialization strategy for linaclotide. Further, in connection with any change of control or in management, there is inherent uncertainty and disruption in operations, which could result in distraction, inefficiencies, and misalignment of priorities. As a result, in the event of a change of control or in management at one of our partners, we cannot be sure that we will be able to successfully execute on our development and commercialization strategy for linaclotide in an effective and efficient manner and without disruption or reduced performance. Finally, any change of control or in management may result in a reprioritization of linaclotide within a 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 any 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. We have assembled a team of specialists in manufacturing, quality, sales, marketing, payer, pricing and field operations, and specialized medical scientists, who represent the functional areas necessary for a successful commercial launch of a high potential, GI therapy and who support the commercialization of LINZESS in the U.S. If Actavis was subject to a change of control that allowed us to further commercialize LINZESS 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 Actavis was previously providing to the collaboration. Any such transition might result in a period of reduced efficiency or performance by our operations and commercialization teams, which could adversely affect our ability to commercialize LINZESS.

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 the U.S. If

Actavis, Almirall, Astellas or AstraZeneca was subject to a change of control that allowed us to continue linaclotide s development or commercialization anywhere outside of the U.S. 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. In any of these situations, the timeline and likelihood of achieving regulatory approval and, ultimately, the commercialization of linaclotide could be negatively impacted.

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

We are working closely with Actavis to implement our joint commercialization plan for LINZESS. The commercialization plan includes an agreed upon marketing campaign that targets the physicians who see patients who could benefit from LINZESS treatment. Our marketing campaign also targets the adult men and women who suffer from IBS-C or CIC. Our commercialization

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plan also includes an integrated call plan for our sales forces to optimize the education of specific gastroenterologists and primary care physicians on whom our and Actavis   sales representatives call, and the frequency with which the representatives meet with them.

In order to optimize the commercial potential of LINZESS, we and Actavis must execute upon this commercialization plan effectively and efficiently. In addition, we and Actavis must continually assess and modify our commercialization plan in a coordinated and integrated fashion in order to adapt to the promotional response. Further, we and Actavis 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. In addition, we and Actavis 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 and Actavis fail to perform these commercial functions in the highest quality manner and in accordance with our joint commercialization plan and related agreements, LINZESS will not achieve its maximum commercial potential and we may suffer financial harm. Our efforts to further target and engage adult patients with IBS-C or CIC may not effectively increase appropriate patient awareness or patient/physician dialogue, and may not increase the revenues that we generate from LINZESS.

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

Our and Actavis   ability to commercialize LINZESS in the U.S. successfully depends in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payers. In determining whether to approve reimbursement for LINZESS and at what level, we expect that third-party payers will consider factors that include the efficacy, cost effectiveness and safety of LINZESS, as well as the availability of other treatments including generic prescription drugs and over-the-counter alternatives. Further, in order to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we may face increasing pressure to offer discounts or rebates from list prices or discounts to a greater number of third-party payers or other unfavorable pricing modifications. Obtaining and maintaining favorable reimbursement can be a time consuming and expensive process, and there is no guarantee that we or Actavis will be able to negotiate pricing terms with all third-party payers at levels that are profitable to us, or at all. Certain third-party payers also require prior authorization for, or even refuse to provide, reimbursement for LINZESS, and others may do so in the future. Our business would be materially adversely affected if we and Actavis are not able to receive approval for reimbursement of LINZESS from third-party payers on a broad, timely or satisfactory basis; if reimbursement is subject to overly restrictive prior authorization requirements; or if reimbursement is not maintained at a satisfactory level or becomes subject to prior authorization. In addition, our business could be adversely affected if private insurers, including managed care organizations, the Medicare or Medicaid programs or other reimbursing bodies or payers limit or reduce the indications for or conditions under which LINZESS may be reimbursed.

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 healthcare costs, the increasing influence of health maintenance organizations, the ongoing debates on reducing government spending and additional legislative proposals. These healthcare reform efforts or any future legislation or regulatory actions aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access or impose unfavorable pricing modifications on pharmaceutical products, could impact our and our partners ability to obtain or maintain reimbursement for linaclotide at a satisfactory level, or at all, which could materially harm our business and financial results.

In some foreign countries, particularly Canada and the countries of Europe, the pricing and payment of prescription pharmaceuticals is subject to 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 and our partners may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including linaclotide, to other available therapies. In addition, in countries in which linaclotide is the only approved therapy for a particular indication, such as CONSTELLA as the only product approved for the symptomatic treatment of moderate to severe IBS-C in adults in Europe, there may be disagreement as to what the most comparable product is, or if there even is one. Further, several European countries have implemented government measures to either freeze or reduce pricing of pharmaceutical products. Many third-party payers and governmental authorities also consider the price for which the same product is being sold in other countries to determine their own pricing and reimbursement strategy, so if linaclotide is priced low or gets limited reimbursement in a particular country, this could result in similarly low pricing and reimbursement in other countries. 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 or reduced to unsatisfactory levels, our ability to successfully commercialize linaclotide in such country would be impacted negatively. Furthermore, if these measures prevent us or any of our partners from selling linaclotide on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of linaclotide in that country.

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If the pricing and reimbursement of CONSTELLA in the E.U. is low, our royalty revenues based on sales of linaclotide will be adversely affected.

In November 2012, the European Commission granted marketing authorization to CONSTELLA for the symptomatic treatment of moderate to severe IBS-C in adults. This approval followed the positive recommendation received from the European Committee for Medicinal Products for Human Use in September 2012. Currently, CONSTELLA is commercially available in certain European countries, including the United Kingdom, Italy and Spain. In May 2014, Almirall suspended commercialization of CONSTELLA in Germany following an inability to reach agreement with the German National Association of Statutory Health Insurance Funds on a reimbursement price that reflects the innovation and value of CONSTELLA. Almirall is assessing all possibilities to facilitate continued access to CONSTELLA for appropriate patients in Germany.

The pricing and reimbursement strategy is a key component of Almirall s commercialization plan for CONSTELLA in Europe. Reimbursement sources are different in each country, and each country may include a combination of distinct potential payers, including private insurance and governmental payers. Countries in Europe may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use. Our revenues may suffer if Almirall is unable to successfully and timely conclude reimbursement, price approval or funding processes and market CONSTELLA in key member states of the E.U., or if coverage and reimbursement for CONSTELLA is limited or reduced. If Almirall is not able to obtain coverage, pricing or reimbursement on acceptable terms or at all, or if such terms change in any countries in its territory, Almirall may not be able to, or may decide not to, sell CONSTELLA in such countries. Further, Almirall could sell CONSTELLA at a low price. Since we receive royalties on net sales of CONSTELLA in the E.U., which is correlated directly to the price at which Almirall sells CONSTELLA in the E.U., our royalty revenues globally could be limited should Almirall sell CONSTELLA at a low price or elect not to launch in a certain country within the E.U.

Because we work with partners to develop, manufacture and commercialize 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.

Actavis played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data, and Actavis holds the NDA for LINZESS. In addition, we are commercializing LINZESS in the U.S. with Actavis. Actavis is also responsible for the development, regulatory approval and commercialization of linaclotide in Canada and Mexico, which, for Mexico, it has sublicensed its commercialization rights to Almirall. Actavis is commercializing CONSTELLA in Canada and Almirall is commercializing LINZESS in Mexico. Almirall also holds the marketing authorization for CONSTELLA in the E.U. and is responsible for obtaining regulatory approval of linaclotide in the countries in its territory. Astellas, our partner in Japan, is responsible for completing the clinical programs and obtaining regulatory approval of linaclotide in its territory. Further, we are jointly overseeing the development, and will jointly oversee the commercialization, of linaclotide in China, Hong Kong and Macau through our collaboration with AstraZeneca, with AstraZeneca having primary responsibility for the local operational execution. Upon any approval, each of Almirall, Astellas and AstraZeneca is responsible for commercializing linaclotide in its respective territory, and each has agreed to use commercially reasonable efforts to do so. Each of our partners is responsible for reporting adverse event information from its territory to us. Finally, each of our partners, other than AstraZeneca, is responsible for drug product manufacturing of linaclotide and making it into finished goods (including bottling and packaging) for its respective territory. The integration of our efforts with our partners efforts is subject to the uncertainty of the markets for pharmaceutical products in each partner s respective territories, and accordingly, these relationships must evolve to meet any new challenges that arise in those regions.

These integrated functions may not be carried out effectively and efficiently if we fail to communicate and coordinate with our partners, and vice versa. Our partnering strategy imposes obligations, risks and operational requirements on us as the central node in our global network of partners. If we do not effectively communicate with each partner and ensure that the entire network is making integrated and cohesive decisions focused on the global brand for linaclotide, linaclotide will not achieve its maximum commercial potential. As the holder of the global safety database for linaclotide, we are responsible for coordinating the safety surveillance and adverse event reporting efforts worldwide. If we are unsuccessful in doing so due to poor process, execution, oversight, communication, adjudication or otherwise, then our and our partner s ability to obtain and maintain regulatory approval of linaclotide will be at risk.

We have limited ability to control the amount or timing of resources that our partners devote to linaclotide. If any of our partners fails to devote sufficient time and resources to linaclotide, or if its performance is substandard, it will delay the potential submission or approval of regulatory applications for linaclotide, as well as the manufacturing and commercialization of linaclotide in the particular 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

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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.

Even though LINZESS is 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.

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

LINZESS is contraindicated in pediatric patients up to 6 years of age based on nonclinical data from studies in neonatal mice approximately equivalent to human pediatric patients less than 2 years of age. There is also a warning advising physicians to avoid the use of LINZESS in pediatric patients 6 through 17 years of age. This warning is based on data in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients of any age group. We and Actavis have established a nonclinical and clinical post-marketing plan with the FDA to understand the safety and efficacy of LINZESS in pediatric patients. The first step in this plan was to undertake additional nonclinical studies to further understand the results of the earlier neonatal mouse study and to understand the tolerability of LINZESS in older juvenile mice. We have completed these nonclinical studies and the FDA has concluded that the nonclinical data do not present a reason not to proceed with clinical studies in older pediatric patients (age 12 and above). We and Actavis are working with the FDA on a plan for clinical pediatric studies. Our ability to conduct clinical studies in younger pediatric patients will depend, in part, on the safety and efficacy data from our clinical studies in older pediatric patients. Our ability to ever expand the indication for LINZESS to pediatrics will depend on, among other things, our successful completion of pediatric clinical studies.

We and Actavis have also committed to 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. We expect to complete these studies over the next three to five years.

These post-approval requirements 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, our partners or the manufacturing facilities for linaclotide 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 linaclotide is approved for marketing in the U.S. as LINZESS and in the E.U. as CONSTELLA, and is approved for marketing in a number of other countries, we or our collaborators may never receive approval to commercialize linaclotide in additional parts of the world.

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., the E.U. and the other countries where linaclotide is approved. Potential risks include that the regulatory authorities:

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- may not deem linaclotide safe and effective;
- may not find the data from nonclinical studies and clinical trials sufficient to support approval;
- may not approve of manufacturing processes and facilities;
- may not approve linaclotide for any or all indications or patient populations for which approval is sought;
- may require significant warnings or restrictions on use to the product label for linaclotide; or
- may change their approval policies or adopt new regulations.

If any of the foregoing were to occur, our receipt of regulatory approval in the applicable jurisdiction could be delayed or we may never receive approval at all. Further, regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. If linaclotide is not approved for all indications or patient populations or with the label requested, this would limit the uses of linaclotide and have an adverse effect on its commercial potential or require costly post-marketing studies.

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

The use of our product candidates in clinical trials and the sale of marketed products expose us to product liability claims. If we do not 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 approved products;
- impairment of our business reputation;

- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- litigation costs;
- 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 the commercial sale of linaclotide and for the clinical trials of our product candidates which is subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for expenses or losses associated with claims. 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 lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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 GI conditions.

Linaclotide competes 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 GI 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

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completing drug development for their drug candidates and obtain approval from the FDA or foreign regulatory authorities, they could limit the demand for linaclotide.

In addition, 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 or any other product.

Physicians are permitted to prescribe drug products and medical devices 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. Such 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 or medical devices 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. Similarly, we may not promote any other approved product we develop, license, co-promote or otherwise partner for any indication, population or use not described in such product s label. 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 believe we have put in place a robust compliance program, which is designed to ensure that all such activities are performed in a legal and compliant manner, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated.

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

Even though we do not (and do not expect in the future to) control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, 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 are 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 Medicare and Medicaid;

- 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 payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

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

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