IRONWOOD PHARMACEUTICALS INC
Form 10-Q
August 08, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from to

Commission file number: 001-34620

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(617) 621-7722

(Registrant s telephone number, including area code)

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

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

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

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

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

As of August 1, 2016, there were 129,933,366 shares of Class A common stock outstanding and 15,385,236 shares of Class B common stock outstanding.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

These forward-looking statements include, among other things, statements about:

- the demand and market potential for our products in the countries where they are approved for marketing, as well as the revenues therefrom;

- the timing, investment and associated activities involved in commercializing LINZESS by us and Allergan plc in the U.S. and ZURAMPIC by us 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, obtaining regulatory approval for, 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 our products;

- the ability of our partners and third-party manufacturers to manufacture and distribute sufficient amounts of linaclotide and lesinurad active pharmaceutical ingredient, drug product and finished goods, as applicable, on a commercial scale;

- our expectations regarding U.S. and foreign regulatory requirements for our products and our product candidates, including our post-approval development and regulatory requirements;

- the ability of our product candidates to meet existing or future regulatory standards;

- the safety profile and related adverse events of our products and our product candidates;

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

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

- our and our partners ability to perform our respective obligations under our collaboration, license and other agreements, and our ability to achieve milestone and other payments under such agreements;

- 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, including expectations relating to the completion of, or the realization of the expected benefits from, such transactions;

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

- our ability to repay our outstanding indebtedness when due, or redeem or repurchase all or a portion of such debt, as well as the potential benefits of the note hedge transactions described herein;

- inventory levels and write downs, or asset impairments, and the drivers thereof, and inventory purchase commitments;

- our expectations regarding amortization of intangible assets;

- 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;

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- 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.

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. ZURAMPIC® is a trademark of AstraZeneca AB. Any other trademarks referred to in this Quarterly Report on Form 10-Q are the property of their respective owners. All rights reserved.

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2016

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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)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 277,332	$ 261,287
Available-for-sale securities	48,041	178,107
Accounts receivable	1,272	2,884
Related party accounts receivable, net	51,875	51,634
Prepaid expenses and other current assets	7,622	6,293
Total current assets	386,142	500,205
Restricted cash	8,247	8,747
Property and equipment, net	17,939	21,075
Convertible note hedges	99,478	86,466
Intangible assets, net	185,935	
Goodwill	649	
Other assets	1,818	2,628
Total assets	$ 700,208	$ 619,121
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and related party accounts payable, net	$ 8,999	$ 8,589
Accrued research and development costs	6,653	4,245
Accrued expenses and other current liabilities	20,598	23,301
Current portion of capital lease obligations	2,451	2,631
Current portion of deferred rent	7,923	5,544
Current portion of deferred revenue	8,519	7,191
Current portion of PhaRMA notes payable	35,259	24,964
Current portion of contingent consideration	597	
Total current liabilities	90,999	76,465
Capital lease obligations, net of current portion	198	306
Deferred rent, net of current portion	4,409	6,395
Deferred revenue, net of current portion		1,798
Contingent consideration, net of current portion	87,052	
Note hedge warrants	86,838	75,328
Convertible senior notes	227,273	220,620
PhaRMA notes payable, net of current portion	111,938	132,964

Other liabilities		10,120		10,120
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 129,778,212 and 127,371,478 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively		130		127
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 15,394,327 and 15,870,356 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively		15		16
Additional paid-in capital		1,226,311		1,205,183
Accumulated deficit		(1,145,114)		(1,110,115)
Accumulated other comprehensive income (loss)		39		(86)
Total stockholders equity		81,381		95,125
Total liabilities and stockholders equity	$	700,208	$	619,121

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Collaborative arrangements revenue	$ 54,350	$ 27,744	$ 120,392	$ 56,676
Cost and expenses:				
Cost of revenue, excluding amortization of acquired intangible asset				12
Write-down of inventory to net realizable value and loss on non-cancellable purchase commitments		8,150		8,150
Research and development	31,682	28,648	63,524	55,289
Selling, general and administrative	36,918	32,955	73,086	63,301
Amortization of acquired intangible asset	1,065		1,065	
Total cost and expenses	69,665	69,753	137,675	126,752
Loss from operations	(15,315)	(42,009)	(17,283)	(70,076)
Other (expense) income:				
Interest expense	(9,827)	(5,874)	(19,734)	(11,094)
Interest and investment income	295	71	516	136
Gain (loss) on derivatives	3,145	(208)	1,502	(208)
Other expense, net	(6,387)	(6,011)	(17,716)	(11,166)
Net loss	$ (21,702)	$ (48,020)	$ (34,999)	$ (81,242)
Net loss per share - basic and diluted	$ (0.15)	$ (0.34)	$ (0.24)	$ (0.57)
Weighted average number of common shares used in net loss per share basic and diluted:	144,642	142,098	144,118	141,690

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 June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Net loss	$ (21,702)	$ (48,020)	$ (34,999)	$ (81,242)
Other comprehensive income:				
Unrealized gains on available-for-sale securities	10	19	125	41
Total other comprehensive income	10	19	125	41
Comprehensive loss	$ (21,692)	$ (48,001)	$ (34,874)	$ (81,201)

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)

	Six Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (34,999)	$ (81,242)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,320	6,043
Amortization of acquired intangible asset	1,065	
Share-based compensation expense	14,903	12,329
Change in fair value of note hedge warrants	11,510	(1,393)
Change in fair value of convertible note hedges	(13,012)	1,601
Write-down of inventory to net realizable value and loss on non-cancellable purchase commitments		8,150
Loss on facility subleases	3,480	
Accretion of discount/premium on investment securities	457	298
Non-cash interest expense	7,221	1,170
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	1,371	(1,210)
Restricted cash	500	
Prepaid expenses and other current assets	(1,265)	2,676
Other assets	810	(458)
Accounts payable, related party accounts payable and accrued expenses	(2,314)	(5,978)
Accrued research and development costs	2,408	1,956
Deferred revenue	(470)	(3,596)
Deferred rent	(3,087)	(1,684)
Net cash used in operating activities	(6,102)	(61,338)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(52,629)	(202,091)
Sales and maturities of available-for-sale securities	182,363	139,006
Purchases of property and equipment	(1,623)	(2,840)
Payment for acquisition of lesinurad license	(100,000)	
Proceeds from sale of property and equipment		27
Net cash provided by (used in) investing activities	28,111	(65,898)
Cash flows from financing activities:		
Proceeds from issuance of convertible senior notes		335,699
Proceeds from issuance of note hedge warrants		70,849
Purchase of convertible note hedges		(91,915)
Costs associated with issuance of convertible senior notes		(10,930)
Proceeds from exercise of stock options and employee stock purchase plan	6,163	10,941
Payments on capital leases	(828)	(561)
Principal payments on PhaRMA notes	(11,299)	(4,694)
Net cash (used in) provided by financing activities	(5,964)	309,389
Net increase in cash and cash equivalents	16,045	182,153
Cash and cash equivalents, beginning of period	261,287	74,297
Cash and cash equivalents, end of period	$ 277,332	$ 256,450

Supplemental cash flow disclosure:		
Non-cash investing activities		
Contingent consideration	$	87,649

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

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Overview

Ironwood Pharmaceuticals, Inc. (the Company) is a commercial biotechnology company leveraging its proven development and commercial capabilities as it seeks to bring multiple medicines to patients. The Company is advancing innovative product opportunities in areas of large unmet need, including irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), hyperuricemia associated with uncontrolled gout, refractory gastroesophageal reflux disease (rGERD), and vascular and fibrotic diseases.

The Company s first commercial product, linaclotide, is available to adult men and women suffering from IBS-C or CIC in the United States (U.S.) under the trademarked name LINZESS®, and is available to adult men and women suffering from IBS-C in certain European countries under the trademarked name CONSTELLA®. The Company and its U.S. partner Allergan plc (together with its affiliates, Allergan) began commercializing LINZESS in the U.S. in December 2012. Under the Company s collaboration with Allergan for North America, total net sales of LINZESS in the U.S., as recorded by Allergan, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between the Company and Allergan. The Company s former European partner, Almirall, S.A. (Almirall), began commercializing CONSTELLA in Europe for the symptomatic treatment of moderate to severe IBS-C in adults in the second quarter of 2013. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan, and the Company and Allergan entered into an amendment to the European license agreement (Note 4). Currently, CONSTELLA is commercially available in certain European countries, including the United Kingdom, Italy and Spain.

Within the Company s IBS-C/CIC franchise, the Company and Allergan are exploring development opportunities to enhance the clinical profile of LINZESS by seeking to expand its utility within IBS-C and CIC, as well as studying linaclotide in additional indications and populations to assess its potential to treat various gastrointestinal (GI) conditions. The Company and Allergan are also developing linaclotide colonic release, a targeted oral delivery formulation of linaclotide designed to potentially improve abdominal pain relief in adult IBS-C patients. The Company is also exploring linaclotide colonic release for use in additional GI disorders where lower abdominal pain is a predominant symptom such as IBS-mixed, ulcerative colitis and diverticulitis, among others. Linaclotide is also being developed and commercialized in other parts of the world by the Company s partners.

In December 2013 and February 2014, linaclotide was approved in Canada and Mexico, respectively, as a treatment for adult men and women suffering from IBS-C or CIC. Allergan has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS. In May 2014, CONSTELLA became commercially available in Canada and in June 2014, LINZESS became commercially available

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 November 2015, the Company and Astellas reported positive top-line data from Astellas Phase III clinical trial of linaclotide in adult patients with IBS-C for Japan and in February 2016, Astellas filed a new drug application (NDA) seeking approval of linaclotide for the treatment of adults with IBS-C in Japan with the Japanese Ministry of Health, Labor and Welfare. In October 2012, the Company entered into a collaboration agreement with AstraZeneca AB (together with its affiliates, 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 December 2015, the Company and AstraZeneca filed for approval with the China Food and Drug Administration to market linaclotide in China. The Company continues to assess alternatives to bring linaclotide to IBS-C and CIC sufferers in the parts of the world outside of its partnered territories.

In June 2016, the Company closed a transaction with AstraZeneca pursuant to which the Company received an exclusive license to develop, manufacture, and commercialize products containing lesinurad as an active ingredient, including ZURAMPIC®, in the U.S. Lesinurad 200mg tablets were approved as ZURAMPIC by the U.S. Food and Drug Administration (FDA) in December 2015 for use in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with uncontrolled gout. The Company is also developing a fixed-dose combination product (FDC Product) of lesinurad and allopurinol, an XOI, which is included under the license agreement.

The Company is advancing its rGERD franchise through the development of IW-3718, a gastric retentive formulation of a bile acid sequestrant.

Within the Company s vascular and fibrotic franchise, it is leveraging its pharmacological expertise in guanylate cyclase pathways gained through the discovery and development of linaclotide to advance development programs targeting soluble guanylate cyclase (sGC). sGC is a validated mechanism with the potential for broad therapeutic utility and multiple opportunities for product development in vascular and fibrotic diseases, as well as other therapeutic areas. The Company is progressing two sGC development

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candidates, IW-1973 and IW-1701, which have distinct pharmacologic profiles that the Company believes may be differentiating and enable opportunities in multiple indications.

In April 2016, the Company announced the discontinuation of development of IW-9179 for gastroparesis, as top-line data from its exploratory Phase IIa clinical study indicated that IW-9179 did not meaningfully reduce the severity of symptoms in patients with diabetic gastroparesis. In July 2016, as part of its continued assessment and prioritization of resources, the Company discontinued assessing the potential of IW-9179 for the treatment of functional dyspepsia and is no longer advancing this program.

In March 2015, the Company and Exact Sciences Corp. (Exact Sciences) entered into an agreement to co-promote Cologuard®, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer, and in August 2015, the Company and Allergan entered into an agreement for the co-promotion of VIBERZI (eluxadoline) in the U.S., Allergan s treatment for adults suffering from IBS with diarrhea (IBS-D).

These agreements are more fully described in Note 3, *Business Combinations,* and Note 4, *Collaboration, License and Co-Promotion Agreements,* to these condensed consolidated financial statements.

In June 2015, the Company issued approximately $335.7 million in aggregate principal amount of 2.25% Convertible Senior Notes due 2022 (the 2022 Notes). The Company received net proceeds of approximately $324.0 million from the sale of the 2022 Notes, after deducting fees and expenses of approximately $11.7 million (Note 10).

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. Additionally, certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission on February 19, 2016 (the 2015 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 June 30, 2016, and the results of its operations for the three and six months ended June 30, 2016 and 2015 and its cash flows for the six months ended June 30, 2016 and 2015. The results of operations for the three and six months ended June 30, 2016 and 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. generally accepted accounting principles requires the Company s management to make estimates and judgments that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the amounts of revenues and expenses during the reported periods. On an ongoing basis, the Company s management evaluates its estimates, judgments and methodologies. Significant estimates and assumptions in the condensed consolidated financial statements include those related to revenue recognition, available-for-sale securities, inventory valuation, and related reserves; impairment of long-lived assets; initial valuation procedures for the issuance of convertible notes; fair value of derivatives; balance sheet classification of notes payable and convertible notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; goodwill; contingent consideration; acquired intangible assets; 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 materially from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

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Summary of Significant Accounting Policies

The Company s significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, in the 2015 Annual Report on Form 10-K. During the three months ended June 30, 2016, the Company adopted the following additional significant accounting policies:

Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination by assessing whether or not the Company has acquired inputs and processes that have the ability to create outputs. If determined to be a business combination, the Company accounts for business acquisitions under the acquisition method of accounting as indicated in the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) Topic 805, Business Combinations , (ASC 805) which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company s business acquisitions includes future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in the condensed consolidated statements of operations.

Finite and Indefinite-Lived Intangible Assets

The Company records the fair value of purchased intangible assets with definite useful lives as of the transaction date of a business combination. Purchased intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives. The Company evaluates the finite-lived intangible assets for impairment whenever events or changes in circumstances indicate the reduction in the fair value below their respective carrying amounts. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. In addition, the Company would also reassess the remaining estimated useful life of the finite-lived intangible asset.

In accordance with ASC Topic 350, Intangibles Goodwill and Other (ASC 350), during the period that an asset is considered indefinite-lived, such as in-process research and development (IPR&D), it will not be amortized. Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and costs projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing a new drug. Additionally, the projections consider the relevant market sizes and growth factors, expected

trends in technology, and the nature and expected timing of new product introductions by the Company and its competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections. Upon the acquisition of IPR&D, the Company completes an assessment of whether its acquisition constitutes the purchase of a single asset or a group of assets. Multiple factors are considered in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance and the rationale for entering into the transaction. Indefinite-lived assets are maintained on the Company s condensed consolidated balance sheet until either the project underlying it is completed or the asset becomes impaired. Indefinite-lived assets are tested for impairment on an annual basis, or whenever events or changes in circumstances indicate the reduction in the fair value of the IPR&D asset below its respective carrying amount. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. When development of an IPR&D asset is complete the associated asset would be deemed finite-lived and would then be amortized based on its respective estimated useful life at that point.

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Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but is reviewed for impairment. The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its carrying value to its implied fair value in accordance with ASC 350. Impairment may result from, among other things, deterioration in the performance of the acquired asset, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. In evaluating the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes the revenue recognition requirements in ASC 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, 2017 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. Early adoption is permitted beginning after December 15, 2016, including interim reporting periods within those years. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing* (ASU 2016-10), which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients* (ASU 2016-12), related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date as ASU 2014-09. The Company is evaluating the method of adoption and the potential impact that ASU 2014-09, ASU 2016-10 and ASU 2016-12 may have on its financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and applies to annual and interim periods thereafter. The Company does not believe that the adoption of ASU 2014-15 will have a significant impact on the Company s financial statement disclosures.

In April 2015, the FASB issued ASU No. 2015-05, *Customer s Accounting for Fees Paid in a Cloud Computing Arrangement*, which amends ASC 350. Under this standard, if a cloud computing arrangement includes a software license, the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. The amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2015 and may be applied on either a prospective or retrospective basis. The Company adopted this standard during the three months ended March 31, 2016. The adoption of this standard did not have a material impact on the Company s financial position or results of operations.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* (ASU 2015-11). ASU 2015-11 requires entities that measure inventory using the first-in, first-out method, to do so at the lower of cost and net realizable value. The standard defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the potential impact that adoption of ASU 2015-11 may have on the Company s financial position or results of operations.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which supersedes the lease accounting requirements in ASC Topic 840, *Leases*, and most industry-specific guidance. ASU 2016-02 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a 12-month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease

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expense for operating leases and amortization and interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. In addition, ASU 2016-02 requires the use of modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating the potential impact that ASU 2016-02 may have on the Company s financial position or results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation*, which amends ASC Topic 718, *Compensation Stock Compensation* (ASU 2016-09). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The Company is evaluating the potential impact that ASU 2016-09 may have on the Company s financial position, results of operations or statement of cash flows.

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.

In June 2015, in connection with the issuance of approximately $335.7 million in aggregate principal amount of the 2022 Notes, the Company entered into convertible note hedge transactions (the Convertible Note Hedges). The Convertible Note Hedges are generally expected to reduce the potential dilution to the Company s Class A common stockholders upon a conversion of the 2022 Notes, as conversion would result in fewer shares available for purchase in the market. The Convertible Note Hedges are also designed to offset any cash payments the Company is required to make in excess of the principal amount of converted 2022 Notes in the event that the market price per share of the Company s Class A common stock, as measured under the terms of the Convertible Note Hedges, exceeds the conversion price of the 2022 Notes (Note 10). The Convertible Note Hedges are not considered for purposes of calculating the number of diluted weighted average shares outstanding, as their effect would be antidilutive.

Concurrently with entering into the Convertible Note Hedges, the Company also entered into certain warrant transactions in which it sold note hedge warrants (the Note Hedge Warrants) to the Convertible Note Hedge counterparties to acquire 20,249,665 shares of the Company s Class A common stock, subject to customary anti-dilution adjustments. The Note Hedge Warrants could have a dilutive effect on the Company s Class A common stock to the extent that the market price per share of the Class A common stock exceeds the applicable strike price of such warrants (Note 10). The Note Hedge Warrants are not considered for purposes of calculating the number of diluted weighted averages shares outstanding, as their effect would be antidilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as their effect would be anti-dilutive (in thousands):

	Six Months Ended June 30,	
	2016	2015
Options to purchase common stock	22,066	21,149
Shares subject to repurchase	192	149
Restricted stock units	1,256	492
Note hedge warrants	20,250	20,250
2022 Notes	20,250	20,250
	64,014	62,290

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

3. Business Combinations

In April 2016, the Company and AstraZeneca entered into a license agreement (the Lesinurad License Agreement) pursuant to which the Company received, upon closing the transaction in June 2016, an exclusive license to develop, manufacture and commercialize products containing lesinurad as an active ingredient, including ZURAMPIC (the Products), in the U.S. (the

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Lesinurad Transaction). Subject to the terms of the Lesinurad License Agreement, AstraZeneca will conduct certain development activities on the Company s behalf for (i) ZURAMPIC, including the post-marketing requirement activities currently required by the FDA, for which the Company will reimburse AstraZeneca up to $100.0 million over up to ten years, and (ii) the FDC Product, for which the Company will also reimburse AstraZeneca. In connection with the Lesinurad License Agreement, the Company and AstraZeneca entered into a commercial supply agreement (the Lesinurad CSA), pursuant to which the Company relies exclusively on AstraZeneca for the commercial manufacture and supply of ZURAMPIC and, if approved, the FDC Product, and a transitional services agreement (the Lesinurad TSA), pursuant to which AstraZeneca will provide certain support services, including development, regulatory and commercial services, to the Company for ZURAMPIC until such activities under the Lesinurad TSA are transferred to the Company. The Company may obtain production techniques from AstraZeneca via a manufacturing technology transfer available under the Lesinurad CSA upon provision of six-months notice. The Company is responsible for commercialization of the Products in the U.S., and any additional development of the Products for commercialization in the U.S. In addition, under the terms of the Lesinurad License Agreement, the Company will have the right of first negotiation and right of last refusal with AstraZeneca for the right to commercialize, develop and manufacture for commercialization in the U.S., products for the prevention or treatment of gout that include verinurad as at least one of its active ingredients.

The Company concluded that the Lesinurad Transaction included inputs and processes that have the ability to create outputs and accordingly accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill.

The purchase price consisted of the upfront payment to AstraZeneca of $100.0 million, which was made in June 2016, and the fair value of the contingent consideration of $87.6 million. The Company also paid approximately $1.6 million for transaction-related costs, including external consulting fees, which were expensed as incurred as selling, general and administrative expenses. Pursuant to the terms of the Lesinurad License Agreement, the Company will also pay a tiered royalty to AstraZeneca in the single-digits as a percentage of net sales of the Products in the U.S., as well as commercial and other milestones of up to $165.0 million over the duration of the agreement. The contingent consideration was valued as approximately $87.6 million, using a discounted cash flow estimate as of the acquisition date. The total fair value of consideration for the purchase was approximately $187.6 million.

The Company has preliminarily valued the acquired assets and liabilities based on their estimated fair value. These estimates are subject to change as additional information becomes available. The preliminary fair values included in the balance sheet as of June 30, 2016 are based on the best estimates of the Company. The completion of the valuation of the acquired assets and liabilities may result in adjustments to the carrying value of assets and liabilities, revision to the useful life of the finite intangible asset, the determination of any residual amount that will be allocated to goodwill and the related tax effects. The related amortization of acquired finite-lived intangible asset is also subject to revision based on the final valuation. Any adjustments to the preliminary fair values will be made as such information becomes available, but no later than June 1, 2017. The following table presents the preliminary allocation of the purchase consideration for the Lesinurad Transaction as of June 2, 2016 (the Acquisition Date), including the contingent consideration (in thousands):

As of the Acquisition Date:		
Cash portion of consideration	$	100,000
Contingent consideration		87,649
Total purchase consideration	$	187,649

As of the Acquisition Date:			
Developed technology	ZURAMPIC	$	167,900
IPR&D - FDC Product			19,100
Goodwill			649
Net assets acquired		$	187,649

The fair value of the FDC Product IPR&D was determined using a probability adjusted discounted cash flow approach, including assumptions of projected revenues, operating expenses and a discount rate of 16.0% applied to the projected cash flows. The remaining cost of development for this asset is approximately $13.9 million, with an expected completion date of no earlier than 2017.

The fair value of the ZURAMPIC intangible asset was determined using a probability adjusted discounted cash flow approach, including assumptions of projected revenues, operating expenses and a discount rate of 13.5% applied to the projected cash flows. The Company considers the ZURAMPIC intangible asset acquired to be developed technology, as it was approved by the FDA for commercialization as of the Acquisition Date. The Company believes the assumptions are representative of those a market

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participant would use in estimating fair value. The ZURAMPIC intangible asset is finite lived. The amount allocated to the ZURAMPIC intangible asset will be amortized on a straight-line basis to amortization of acquired intangible assets within the Company s condensed consolidated statements of operations over its estimated useful life of 13 years, the period of estimated future cash flows. The Company believes that the straight-line method of amortization represents the pattern in which the economic benefits of the intangible asset are consumed. As of June 30, 2016, the Company recognized accumulated amortization of $1.1 million with respect to the ZURAMPIC intangible asset. The estimated future amortization of ZURAMPIC is expected to be as follows (in thousands):

		As of June 30, 2016
2016 (1)	$	6,420
2017		12,833
2018		12,833
2019		12,833
2020 and thereafter		121,916
Total	$	166,835

(1) For the six months ended December 31, 2016.

The amount allocated to the FDC Product IPR&D is considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. As of June 30, 2016, there was no impairment related to the FDC Product IPR&D or the ZURAMPIC intangible asset.

The Company allocated the excess of the purchase price over the identifiable intangible assets to goodwill. Such goodwill is not deductible for tax purposes and represents the value placed on entering new markets, expanding market share and operating synergies. As of June 30, 2016, there was no impairment of goodwill. All goodwill has been assigned to the Company s single reporting unit, which is the single operating segment human therapeutics.

These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements (Note 5).

As of June 30, 2016, the estimated fair value of the Company s contingent consideration liability did not change, compared to the Acquisition Date estimated fair value.

4. Collaboration, License and Co-Promotion Agreements

For the three and six months ended June 30, 2016, the Company had linaclotide collaboration agreements with Allergan for North America and

AstraZeneca for China, Hong Kong and Macau, as well as linaclotide license agreements with Allergan for the European territory and Astellas for Japan. The Company also had a co-promotion agreement with Exact Sciences to co-promote Cologuard in the U.S. and a co-promotion agreement with Allergan to co-promote VIBERZI in the U.S. The following table provides amounts included in the Company s condensed consolidated statements of operations as collaborative arrangements revenue attributable to transactions from these arrangements (in thousands):

	Collaborative Arrangements Revenue			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Linaclotide Agreements:				
Allergan (North America)	$ 50,036	$ 24,381	$ 100,009	$ 49,707
Allergan (Europe)	110		190	
AstraZeneca (China, Hong Kong and Macau)	164	466	294	1,696
Almirall (Europe) (1)		116	3	217
Astellas (Japan)	2,334	1,805	17,014	4,080
Co-Promotion Agreements:				
Exact Sciences (Cologuard)	1,159	976	1,878	976
Allergan (VIBERZI)	547		1,004	
Total collaborative arrangements revenue	$ 54,350	$ 27,744	$ 120,392	$ 56,676

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(1) In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan.

Linaclotide Agreements

Collaboration Agreement for North America with Allergan

In September 2007, the Company entered into a collaboration agreement with Allergan 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 Allergan all development costs as well as net profits or losses from the development and sale of linaclotide in the U.S. In addition, the Company receives royalties in the mid-teens percent based on net sales in Canada and Mexico. Allergan is solely responsible for the further development, regulatory approval and commercialization of linaclotide in Canada and Mexico and funding any costs. The collaboration agreement for North America also includes contingent milestone payments, as well as a contingent equity investment, based on the achievement of specific development and commercial milestones. As of June 30, 2016, approximately $205.0 million in license fees and all six development milestone payments had been received by the Company, as well as a $25.0 million equity investment in the Company s capital stock (Note 13). The Company can also achieve up to $100.0 million in a sales-related milestone if certain conditions are met, which will be recognized as collaborative arrangements revenue as earned.

As a result of the research and development cost-sharing provisions of the collaboration for North America, the Company offset approximately $3.2 million and approximately $5.2 million against research and development costs during the three and six months ended June 30, 2016, respectively, and approximately $4.4 million and approximately $11.9 million during the three and six months ending June 30, 2015, respectively, to reflect the obligations of each party under the collaboration to bear half of the development costs incurred. In addition, in March 2015, the Company and Allergan agreed to share certain costs relating to the manufacturing of linaclotide active pharmaceutical ingredient (API) and certain other manufacturing activities for the North American territory. This arrangement resulted in net amounts received from Allergan 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 and Allergan began commercializing LINZESS in the U.S. in December 2012. 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 set forth in the collaboration agreement for North America. Certain of these adjustments to the share of the net profits may be reduced or eliminated in connection with the co-promotion activities under the Company s agreement with Allergan to co-promote VIBERZI in the U.S., as described below in *Co-Promotion Agreement with Allergan for VIBERZI*. Net profits or net losses consist of net sales of LINZESS to third-party customers and sublicense income in the U.S. less the cost of goods sold as well as selling, general and administrative expenses. LINZESS net sales are calculated and recorded by Allergan 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 Allergan as collaboration expense or collaborative arrangements revenue, as applicable.

The Company recognized collaborative arrangements revenue from the Allergan collaboration agreement for North America during the three and six months ended June 30, 2016 and 2015 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015		
Collaborative arrangements revenue related to sales of LINZESS in the U.S. (1) (2)	$ 48,333	$ 24,275	$ 94,980	$ 49,413
Royalty revenue	238	106	547	294
Sale of API	1,465		4,482	
Total collaborative arrangements revenue	$ 50,036	$ 24,381	$ 100,009	$ 49,707

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The collaborative arrangements revenue recognized in the three and six months ended June 30, 2016 and 2015 primarily represents the Company s share of the net profits and net losses on the sale of LINZESS in the U.S. In addition, during the three and six months ended June 30, 2016, the Company recorded collaboration revenue of approximately $1.5 million and approximately $4.5 million, respectively, related to the sale of API to Allergan under the terms of the collaboration for North America, and no such amounts were recorded during the three and six months ended June 30, 2015.

The following table presents the amounts recorded by the Company for commercial efforts related to LINZESS in the U.S. in the three and six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Collaborative arrangements revenue related to sales of LINZESS in the U.S. (1) (2)	$ 48,333	$ 24,275	$ 94,980	$ 49,413
Selling, general and administrative costs incurred by the Company (1)	(8,879)	(8,314)	(18,032)	(16,003)
The Company s share of net profit	$ 39,454	$ 15,961	$ 76,948	$ 33,410

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

(2) Certain of the unfavorable adjustments to the Company s share of the LINZESS net profits may be reduced or eliminated in connection with the co-promotion activities under the Company s agreement with Allergan to co-promote VIBERZI in the U.S., as described below in *Co-Promotion Agreement with Allergan for VIBERZI*. During the three and six months ended June 30, 2016, in connection with these co-promotion activities, the net profit share adjustments payable to Allergan under the linaclotide collaboration agreement for North America were reduced by approximately $1.4 million and $2.6 million, respectively. The Company recorded approximately $1.2 million and $2.4 million of net profit share adjustments payable to Allergan during the three and six months ended June 30, 2015, respectively, as described above.

In May 2014, CONSTELLA became commercially available in Canada and in June 2014, LINZESS became commercially available 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 partner or the ability to estimate the royalty revenue in the period earned. The Company recognized approximately $0.2 million and approximately $0.5 million of royalty revenues from Canada and Mexico during the three and six months ended June 30, 2016, respectively. The Company recognized an insignificant amount and approximately $0.3 million of royalty revenues from Canada and Mexico during the three and six months ended June 30, 2015, respectively.

License Agreement for the European Territory with Allergan (formerly with Almirall through October 2015)

In April 2009, the Company entered into a license agreement with Almirall (the European License Agreement) 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 European License Agreement, Almirall was responsible for the expenses associated with the development and commercialization of linaclotide in the European territory and the Company was required to participate on a joint development committee over linaclotide s development period and a joint commercialization committee while the product was being commercialized.

Pursuant to the terms of the European License Agreement, the Company received approximately $38.0 million, net of foreign tax withholdings, as a non-refundable up-front payment from Almirall. In November 2009, the Company achieved a development milestone triggering an equity investment and received $15.0 million from Almirall for the purchase of 681,819 shares of convertible preferred stock (Note 13). In addition, the European 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. During the years ended December 31, 2013 and 2014, the Company achieved four commercial milestones under the European License Agreement for the first commercial launch in four out of five major European Union (E.U.) countries set forth in the agreement, aggregating to $4.0 million. In connection with the achievement of these milestones, the Company received approximately $3.9 million, net of foreign tax withholdings.

In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan. Additionally, in October 2015, the Company and Allergan separately entered into an amendment to the European License Agreement relating to the development and commercialization of linaclotide in Europe. Pursuant to the terms of the amendment, (i) the remaining

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sales-based milestones payable to the Company under the European License Agreement were modified to increase the total milestone payments such that, when aggregated with the remaining commercial launch milestones, they could total up to $42.5 million, (ii) the royalties payable to the Company during the term of the European License Agreement were modified such that the royalties based on sales volume in Europe begin in the mid-single digit percent and escalate to the upper-teens percent by calendar year 2019, and (iii) Allergan assumed responsibility for the manufacturing of linaclotide API for Europe from the Company, as well as the associated costs. Furthermore, with the Company no longer responsible for the manufacturing of linaclotide API for Europe, the royalties under the European License Agreement are no longer reduced by the transfer price paid for the API included in the product actually sold by Allergan in Europe in any given period. The Company concluded that these 2015 amendments to the European License Agreement were not a modification to the linaclotide collaboration agreement with Allergan for North America.

The commercial launch and sales-based milestones under the European License Agreement are recognized as revenue as earned. The Company recognized an insignificant amount and approximately $0.2 million of royalty revenue during the three and six months ended June 30, 2016 and 2015, respectively. The Company records royalties on sales of CONSTELLA one quarter in arrears as it does not have access to the royalty reports from Allergan or the ability to estimate the royalty revenue in the period earned.

License Agreement for Japan with Astellas

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. Astellas is responsible for all activities relating to development, regulatory approval and commercialization in Japan, as well as funding the associated 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 and six months ended June 30, 2016 and 2015, the Company recognized approximately $1.3 million and approximately $2.6 million, respectively, of revenue related to the up-front licensing fee, in each period, including approximately $0.5 million and approximately $1.0 million, respectively, of revenue in each period attributable to a revision to the estimated development period in March 2013. At June 30, 2016, approximately $3.8 million of the up-front license fee remained deferred.

The agreement also includes three development milestone payments that could total up to $45.0 million, none of which the Company considers substantive. The first milestone payment, consisting of $15.0 million upon enrollment of the first study subject in a Phase III study for linaclotide in Japan, was achieved in November 2014, and approximately $13.4 million was recognized as revenue through June 30, 2016, including approximately $0.5 million and approximately $1.1 million during each of the three and six months ended June 30, 2016 and 2015, respectively. The remaining approximately $1.6 million of this milestone payment will be recognized over the remaining development period. In February 2016, Astellas filed an NDA with the Japanese Ministry of Health, Labor and Welfare seeking approval of linaclotide for the treatment of adults with IBS-C in Japan. In connection with this filing, a second milestone payment, consisting of $15.0 million, was achieved and approximately $0.5 million and $13.4 million was recognized as revenue during the three and six months ended June 30, 2016, respectively. The remaining approximately $1.6 million of this milestone payment will be recognized over the remaining development period. The third development milestone payment consists of $15.0 million upon approval of NDA by the Japanese Ministry of Health, Labor and Welfare to market linaclotide in Japan. 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 and six months ended June 30, 2016, the Company recognized approximately $2.3 million and approximately $17.0 million, respectively, in collaborative arrangements revenue from the Astellas license agreement. During the three and six months ended June 30, 2015, the Company recognized approximately $1.8 million and approximately $4.1 million, respectively, in collaborative arrangements revenue from the Astellas license agreement, including an insignificant amount and approximately $0.5 million, respectively, from the sale of API to Astellas.

Collaboration Agreement for China, Hong Kong and Macau with AstraZeneca

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

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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 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).

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 at the inception of the AstraZeneca Collaboration Agreement. 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 June 30, 2016, 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

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AstraZeneca under the terms of the AstraZeneca Collaboration Agreement. These additional activities serve to support the continued development of linaclotide in the License 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 modification did not, however, have a material impact on the Company s condensed consolidated financial statements.

The total amount of the non-contingent consideration allocable to the AstraZeneca Agreements was approximately $34.0 million (Arrangement Consideration), consisting of the $25.0 million non-refundable up-front payment and approximately $9.0 million representing 55% of the estimated 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. The Company allocated the Arrangement Consideration to the non-contingent deliverables based on management s best estimated 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. Of the total 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.

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 and six months ended June 30, 2016 the Company recognized approximately $0.2 million and approximately $0.3 million, respectively, and during the three and six months ending June 30, 2015, the Company recognized approximately $0.4 million and approximately $1.6 million, respectively, in each case, in collaborative arrangements revenue related to the License Deliverable in connection with the modification to the IDP and development budget in August 2014, as these portions of the Arrangement Consideration were no longer contingent.

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 an insignificant amount in incremental research and development costs during the three and six months ended June 30, 2016, respectively, and recognized approximately $0.4 million and approximately $0.7 million in incremental research and development costs during the three and six months ended June 30, 2015, respectively.

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 each of the three and six months ended June 30, 2016 and 2015, the Company recognized an insignificant amount as collaborative arrangements revenue related to this deliverable, as this portion of the Arrangement Consideration was no longer contingent.

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.

Co-Promotion Agreements

Co-Promotion Agreement with Exact Sciences Corp. for Cologuard

In March 2015, the Company and Exact Sciences entered into an agreement to co-promote Exact Sciences Cologuard, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer (the Exact Sciences Co-Promotion Agreement). Under the terms of the non-exclusive Exact Sciences Co-Promotion Agreement, the Company s sales team promotes and educates health care practitioners regarding Cologuard, with LINZESS remaining the Company s first-position product. Exact Sciences maintains responsibility for all other aspects of the commercialization of Cologuard outside of the co-promotion. Under the terms of the Exact Sciences Co-Promotion Agreement, the Company is compensated primarily via royalties earned on the net sales of Cologuard generated from the healthcare practitioners on whom the Company calls with such royalties being payable during the term and for up to one year following the termination of the Company s co-promotion efforts. Through June 30, 2016, the Company received approximately $3.4 million in connection with the Exact Sciences Co-Promotion Agreement. There are no refund provisions in the Exact Sciences Co-Promotion Agreement. Either party may terminate the agreement in the event of an uncured material breach by the other party, withdrawal of Cologuard from the U.S. market, restriction on the indications for Cologuard by the FDA, imposition of restrictive federal or state price controls, change of control of the other party, or bankruptcy or insolvency of the other party.

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Activities under the Exact Sciences Co-Promotion Agreement were evaluated in accordance with ASC 605-25, to determine if they represented a multiple element revenue arrangement. The Company identified the following deliverables in the Exact Sciences Co-Promotion Agreement through June 30, 2016: (i) second position sales detailing, (ii) promotional support services, and (iii) medical education services. Each of the deliverables was 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. The Company determined that the BESP for each of the three deliverables approximated the value allocated to the deliverables under the agreement. The revenue related to each deliverable is recognized as collaborative arrangements revenue in the Company s condensed consolidated statement of operations, in accordance with ASC 605-25, during the period earned. During the three and six months ended June 30, 2016, the Company recognized approximately $1.2 million and approximately $1.9 million, respectively, as collaborative arrangements revenue related to this arrangement, and approximately $1.0 million was recognized during the three and six months ended June 30, 2015.

Co-Promotion Agreement with Allergan for VIBERZI

In August 2015, the Company and Allergan entered into an agreement for the co-promotion of VIBERZI in the U.S., Allergan s treatment for adults suffering from IBS-D (the VIBERZI Co-Promotion Agreement). Under the terms of the VIBERZI Co-Promotion Agreement, the Company s clinical sales specialists are detailing VIBERZI to the approximately 25,000 health care practitioners to whom they detail LINZESS. Allergan is responsible for all costs and activities relating to the commercialization of VIBERZI outside of the co-promotion.

Under the terms of the VIBERZI Co-Promotion Agreement, the Company s promotional efforts are compensated based on the volume of calls delivered by the Company s sales force, with the terms of the agreement reducing or eliminating certain of the unfavorable adjustments to the Company s share of net profits stipulated by the linaclotide collaboration agreement with Allergan for North America, provided that the Company provides a minimum number of VIBERZI calls on physicians. The Company has the potential to achieve milestone payments of up to $10.0 million based on the net sales of VIBERZI in each of 2017 and 2018, and is also compensated via reimbursements for medical education initiatives.

The Company s promotional efforts under the non-exclusive co-promotion began when VIBERZI became commercially available in December 2015, and will continue until December 31, 2017, unless earlier terminated by either party pursuant to the provisions of the VIBERZI Co-Promotion Agreement. Either party may also terminate the VIBERZI Co-Promotion Agreement in the event of an uncured material breach by the other party, withdrawal of necessary approvals by the FDA, for convenience, or bankruptcy or insolvency of the other party. Allergan may terminate the VIBERZI Co-Promotion Agreement if the Company does not provide the minimum number of calls on physicians for VIBERZI. Activities under the VIBERZI Co-Promotion Agreement were evaluated in accordance with ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Company concluded that the VIBERZI Co-Promotion Agreement does not represent a material modification to the linaclotide collaboration agreement with Allergan for North America, as it is not material to the total arrangement consideration under the collaboration agreement, does not significantly modify the existing deliverables, and does not significantly change the term of the agreement. The Company identified the following deliverables in the VIBERZI Co-Promotion Agreement: (i) second position sales detailing of VIBERZI, and (ii) medical education services. Each of the deliverables was deemed to have standalone value based on their nature and both deliverables met the criteria to be accounted for as separate units of accounting under ASC 605-25. The Company determined the BESP for each of the deliverables approximated the value allocated to the deliverables under the agreement. As consideration is earned over the term of the agreement, the revenue will be allocated to each deliverable based on the relative selling price, using management s BESP, and recognized as collaborative arrangements revenue in the Company s condensed consolidated statement of operations, in accordance with ASC 605-25, during the quarter earned. During the three and six months ended June 30, 2016, in connection with the Company s VIBERZI co-promotion activities, the net profit share adjustments payable to Allergan under the linaclotide collaboration agreement for North America were reduced by approximately $1.4 million and approximately $2.6 million, respectively. During the three and six months ended June 30, 2016, the Company recognized approximately $0.5 million and $1.0 million, respectively, in collaboration revenue related to the VIBERZI Co-Promotion Agreement for the performance of medical education services.

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Other Collaboration and License Agreements

The Company has other collaboration and license agreements that are not individually significant to its business. 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 June 30, 2016, and $18.0 million for regulatory milestones, none of which had been paid as of June 30, 2016. 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 and six months ended June 30, 2016 and 2015, the Company did not incur any research and development expense associated with the Company s other collaboration and license agreements.

5. Fair Value of Financial Instruments

The tables below present information about the Company s assets that are measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability.

The Company s investment portfolio includes mainly 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 are 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 Company validates the prices provided by its third party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances.

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

		Fair Value Measurements at Reporting Date Using		
	June 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents:				
Money market funds	$ 274,173	$ 274,173	$	$
Available-for-sale securities:				
U.S. Treasury securities	20,037	20,037		